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INTERNET PHARMACIES AND THE NEED FOR A NEW FEDERALISM: PROTECTING CONSUMERS WHILE INCREASING ACCESS TO PRESCRIPTION DRUGS

Linda C. Fentiman*

I. INTRODUCTION

Today, America faces a crisis of health care access, as forty-three million Americans, or more than fourteen percent of the population, lack health insurance of any kind.¹ An even greater number of Americans lack insurance for prescription drugs, at the same time that spending on such medications accounts for an ever greater fraction of health care costs, rising from six percent to more than ten percent of personal health care spending in the last dozen years.²

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1. Robert Pear, *Health Spending Rises to 15% of Economy, A Record Level*, N.Y. TIMES, Jan. 9, 2004, at A16 [hereinafter Pear, *Health Spending Rises*]. The percentage of people without insurance has risen to 14.6% of the population, even as the proportion of people who receive health insurance through government programs, such as Medicare, Medicaid, or Child Health Plus, grows. Robert Pear, *After Decline, the Number of Uninsured Rose in 2001*, N.Y. TIMES, Sept. 30, 2002, at A22. Medicare provides coverage for hospitalization, physician office visits, some home health care services, and hospice care for Americans who are over sixty-five or suffering from end-stage renal disease. 42 U.S.C. § 1395(c) (2000); BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 842-44 (3d ed. 1997). Medicaid and Child Health Plus are partnerships between federal and state governments to provide health care to adults and children in families with very low incomes. 42 U.S.C. § 1396(v); BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 418-21, 438-39 (4th ed. 2001); see also U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE: 2001, available at <http://www.census.gov/hhes/hlthins/hlthin01/hlt01asc.html> (last visited Sept. 29, 2003) (using March 2001 data to find that fourteen percent of the population in 2000 lacked health insurance coverage for the entire year); Jeanne M. Lambrew, *Health Insurance: A Family Affair, A National Profile and State-By-State Analysis of Uninsured Parents and Their Children*, THE COMMONWEALTH FUND 1 (May 2001), available at http://www.cmuf.org/programs/insurance/lambrew_familyaffair_464.pdf (using March 2000 data).

2. Stuart H. Altman & Cindy Parks-Thomas, *Controlling Spending for Prescription Drugs*, 346 NEW ENG. J. MED. 855, 855 (2002); Pear, *Health Spending*

These rising costs are due in large part to the increased use of newer, more expensive medications. These medications have the potential to reduce overall health care spending, as prescription drugs decrease the need for hospitalization and other expensive medical interventions.³ However, many people, particularly the elderly and those suffering from chronic diseases, either cannot afford prescription drugs at all, or cannot afford the drugs that are most effective, because they are uninsured or underinsured.⁴ Although Congress finally enacted legislation providing coverage for prescription medications for Medicare recipients in December 2003,⁵

Rises, *supra* note 1. Spending on prescription drugs has increased rapidly, rising more than seventeen percent between 1999 and 2000. Robert Steinbrook, M.D., *The Prescription-Drug Problem*, 346 NEW ENG. J. MED. 790 (2002); see also Katharine Levit et al., *Inflation Spurs Health Spending in 2000: Drug Costs Once Again Constitute the Fastest-Growing Component of Health Spending, Although Hospital Spending Accounts for the Largest Share*, 21 HEALTH AFFAIRS, Jan.-Feb. 2002, at 172, 179-80 (detailing continuing rise in prescription drug costs as a percentage of overall health care spending).

3. Frank Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, NAT'L BUREAU OF ECON. RESEARCH: WORKING PAPER 8996 (June 2002), at <http://www.nber.org/papers/w8996> (finding that during a three year period, the use of a newer drug reduces non-drug expenditures significantly more than it increases drug expenditures, and that most of the cost savings comes from reductions in the expenditures for hospital and physician office visits); cf. J.D. Kleinke, *The Price of Progress: Prescription Drugs in the Health Care Market*, 20 HEALTH AFFAIRS, Sept.-Oct. 2001, at 43 (finding that the relationship between pharmaceutical use and enhanced quality of life and cost savings is a complex one, highly dependent on the particular drug involved).

4. Lichtenberg, *supra* note 3. Many managed care plans will pay only for drugs included in the plan's drug formulary. Medicaid will pay for all medically necessary drugs, and Medicare will not offer a prescription drug benefit until 2006. Drew E. Altman, *The New Medicare Prescription-Drug Legislation*, 350 NEW ENG. J. MED. 9 (2004); Robin Toner, *Security and Tax Cuts Win Bush's Protection: Brief Health-Care Remarks Draw Praise and Skepticism*, N.Y. TIMES, Jan. 30, 2002, at A23. About one third of elderly Americans presently lack any insurance "coverage for outpatient prescription drugs," while many more have inadequate coverage. Altman, *supra*; Robin Toner, *Maine at Front Line in Fight Over the High Costs of Drugs*, N.Y. TIMES, May 11, 2002, at A1 [hereinafter Toner, *Maine at Front Line*]. Older Americans are the greatest users of prescription medications. "[P]eople over 65 account for 34 percent of pharmaceutical expenditures but make up 13 percent of the population." Joy H. Lewis et al., *Compliance Among Pharmacies in California with a Prescription-Drug Discount Program for Medicare Beneficiaries*, 346 NEW ENG. J. MED. 830, 830 (2002) (citations omitted).

5. The Medicare Prescription, Drug, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, is a highly controversial, albeit bipartisan, law that provides some relief to Medicare beneficiaries (hereinafter seniors) with high prescription drug costs, but also fundamentally changes the structure of Medicare. The law creates a new Medicare prescription drug benefit, Medicare Part D, which will go into effect in 2006. *Id.* Under the law, seniors can elect Part D coverage through the purchase of a private drug insurance plan. *Id.* Seniors with low prescription drug costs will actually pay more under the new Medicare benefit, while seniors with high drug costs,

its inability or unwillingness to do so in the past⁶ led to a variety of state and private sector initiatives to address this drug gap. Some states have attempted to ameliorate the increasing burden of drug costs on their citizens through innovative drug discounting programs, but pharmaceutical manufacturers have strongly opposed them.⁷ In

particularly if they are low income, will save money. Many critics of the new law are concerned about the so-called "doughnut hole," or gap in coverage, under which a person who incurs drug expenses between \$2,250 and \$5,100 a year will receive no reimbursement for these costs. Altman, *supra* note 4, at 9; *Medicare: What You Must Know*, KIPLINGER'S MAG., Feb. 2004, at 19-20. The law is also controversial because it absolutely forbids the government to bargain with drug manufacturers for lower prices, although the private drug benefit companies may do so. Robert Pear, *Medicare Law's Costs and Benefits are Elusive*, N.Y. TIMES, Dec. 9, 2003, at A1. In addition, for the first time, Medicare will be means tested, with very high income beneficiaries required to pay a higher premium for Medicare Part B coverage, which includes doctors' visits and other outpatient health care treatments. *Medicare: What You Must Know*, *supra*. Finally, the law mandates six demonstration projects, in which Medicare will have to compete head to head with private health plans, opening the way for greater privatization of Medicare. Peter Grier, *Bush Signature Won't End Medicare Debate*, CHRISTIAN SCIENCE MONITOR, Dec. 9, 2003, at 2.

6. Congress had previously been unsuccessful in enacting a prescription drug benefit that would ensure greater access to prescription drugs for senior citizens because of a concern that this would substantially increase the costs of Medicare as well as expand a government bureaucracy. See, e.g., W.J. "BILLY" TAUZIN, ISSUES BEFORE THE COMMITTEE, HOUSE COMMITTEE ON ENERGY AND COMMERCE: DOCUMENTS RELATED TO PHARMACEUTICALS AND PRESCRIPTION DRUGS, at http://energycommerce.house.gov/issues/Pharmaceuticals_and_Prescription_Drugs.htm (last visited Nov. 6, 2003) (chronicling Committee hearings since 2001 on this topic). More than twenty bills were introduced during the 108th Congress to address the drug access problem. See <http://www.thomas.loc.gov> (last visited Nov. 6, 2003); see *infra* note 8 and accompanying text (during the summer of 2002, proposals before the Senate included expanding access to generic drugs, permitting reimportation of FDA-approved drugs from Canada, amending the Medicaid statute to explicitly authorize the states' innovative discount programs, and federal subsidies to private insurers with the goal of ensuring competition to provide drug benefits to Medicare beneficiaries). For a flavor of the varying proposals, see Helen Dewar, *Democrats Defeat Second GOP Drug Plan*, WASH. POST, July 25, 2002, at A5; Robert Pear, *Senate Begins Debate on Rival Medicare Prescription Plans*, N.Y. TIMES, July 16, 2002, at A12; Robert Pear, *Senate Kills Plan for Drug Benefits Through Medicare*, N.Y. TIMES, Aug. 1, 2002, at A1; Robert Pear, *Two Parties' Plans on Drug Costs Falter in Senate*, N.Y. TIMES, July 24, 2002, at A1.

7. To date, thirty-eight states have authorized programs to expand access to prescription drugs for senior citizens and/or low-income individuals, including those not eligible for Medicaid. NAT'L CONFERENCE OF STATE LEGISLATURES, STATE PHARMACEUTICAL ASSISTANCE PROGRAMS, at <http://www.ncsl.org/programs/health/drugaid.htm> (last visited Jan. 16, 2004). For a good overview of the variety of programs now offered, see *id.* See also Francis B. Palumbo, *The Role of the State as a Drug Purchaser*, 56 FOOD DRUG L.J. 267 (2001); ALLAN RUBIN, MAINE'S PRESCRIPTION DRUG LAW, at <http://www.therubins.com/geninfo/maine.Htm> (last modified Sept. 6, 2003). Vermont and Maine have led in the development of innovative programs that effectively require pharmaceutical companies to offer lower prices to low-income and other citizens as a condition of being approved as a participating provider in the state's

May 2003, the Supreme Court upheld the Maine Prescription Drug Assistance Program,⁸ in a decision that may presage the success of similar state efforts.

Internet pharmacies⁹ offer a partial answer to the access problem, as they hold out the promise of convenience, privacy, and perhaps economy¹⁰ for consumers who shop online for their

Medicaid program. The drug manufacturers' trade association, the Pharmaceutical Research and Manufacturers of America, has brought suit in several cases to enjoin the programs, with mixed results. Vermont's Medicaid demonstration program, which expanded coverage of the state's Medicaid discounted drug benefits to non-Medicaid beneficiaries, was struck down by the D.C. Circuit Court of Appeals as exceeding the statutory authorization of the Medicaid program. *Pharm. Research & Mfg. of Am. v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001). Maine has launched two separate initiatives, one the Healthy Maine Prescription program, a Medicaid demonstration project which expanded access to discounted drugs to individuals with household incomes of up to 300% of poverty level. *Pharm. Research & Mfrs. of Am. v. Thompson*, 191 F. Supp. 2d 48, 51 (D.D.C. 2002). The other program, the statutory "Maine Rx Program," permits all Maine residents to purchase prescription drugs from pharmacies at a discount, with the discounts effectively paid by manufacturers' rebates, such rebates being the price of the manufacturers' participating in the Maine Medicaid program. *Pharm. Research and Mfrs. of Am. v. Concannon*, 249 F.3d 66, 71 (1st Cir. 2001), *aff'd sub nom.* *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 647 (2003). Both programs have been upheld, albeit on a preliminary basis.

8. *Walsh*, 538 U.S. at 644. The Court held that the pharmaceutical manufacturers had not met their burden, necessary in a suit for preliminary injunction, of showing the probability of success on the merits of the claims that the Maine statute establishing the expanded drug assistance program was preempted by the federal Medicaid statute or that it violated the dormant commerce clause. *Id.*

9. In this article, I use the term "Internet pharmacy" to include any website that offers prescription medication via the Internet. As will be explained in detail, see *infra* Part II.A., such websites come in a variety of forms, and comply totally, partially, or not at all, with applicable state and federal law. To some extent, an Internet pharmacy is simply a more technologically advanced version of a mail order pharmacy or drug benefit plan, whose aim is to save both consumers and health insurers time and money. However, the Internet has so enhanced the ease with which pharmacies may avoid compliance with the law, that one must address Internet pharmacies as a *sui generis* phenomenon.

10. The cost of prescription medications can vary widely among Internet pharmacies, and can be higher, as well as lower, than a local pharmacy, particularly when the shipping and "consultation" costs are taken into account. Bernard S. Bloom & Ronald C. Iannaccone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 ANNALS OF INTERNAL MED. 830, 832 (1999) (finding that drugs purchased from Internet pharmacies cost an average of ten percent more than purchased from pharmacies in the Philadelphia area); *The ABCs of Drugstores*, 64 CONSUMER REPORTS 39 (Oct. 1999) (finding that prescription drugs purchased online or by mail could be up to twenty-nine percent less expensive than drugs purchased from bricks and mortar pharmacies); John Dorschner, *Online Pharmacy Rulings in Limbo—State Takes Aim at Questionnaires*, MIAMI HERALD, June 15, 2002, at 1C (citing a finding that one Internet pharmacy charges a minimum of \$100.00 per prescription and that the prices for some medications are triple those for the medication in a traditional drugstore); Sana Siwolop, *Buying Your Pills Online May Save You Money, But Who's Selling*

medications, rather than visiting the neighborhood drugstore or driving across the Canadian or Mexican border to obtain medication more cheaply.¹¹ There is a small group of Internet pharmacies, frequently off-shoots of established pharmacy chains, which function effectively and legitimately to give consumers expanded access to prescription drugs at reasonable prices.¹² At the same time, there are other Internet pharmacies that pose substantial risk to individual and public health, since their operations in the “wild west” of cyberspace¹³ are largely out of reach of federal and state regulators, for both legal and technological reasons. Thus, they can sell unproven, counterfeit, defective, or otherwise inappropriate medications to gullible and desperate consumers.

The role of Internet pharmacies in the health care economy is growing. In 1999, Americans spent approximately \$160 million on prescription drugs purchased via the Internet; by 2003 spending on Internet prescription drugs had grown to \$3.2 billion.¹⁴ By November

Them?, N.Y. TIMES, Sept. 29, 2002, §. 3 (magazine), at 10 (citing studies showing that consumers could save twenty-five percent by buying prescription drugs online but could also pay five times more); Irwin Spivak, *It's Easy for Web Drug Buyers to Get Tangled, FDA Says*, PALM BEACH POST, Jan. 24, 2000, at 1A (discussing the variable costs of buying drugs online); see also Press Release, Conn. Att'y Gen., Attorney General Releases Findings of Prescription Drug Survey: Study Shows Consumers Can Save Hundreds By Shopping Around (April 9, 2003), at <http://www.cslib.org/attygenl/press/2003/health/drugs.htm> (finding that “some of the best bargains in prescription drugs are on the Internet”).

11. Susan Coburn, *A Web Bazaar Turns Into a Pharmaceutical Free-for-All*, N.Y. TIMES, Oct. 25, 2000, at H20 (describing women who buy left-over fertility medications from women in other countries whom they contact via the Internet); Sarah Lunday, *When Purchasing Medicine in Mexico, Buyer Beware*, N.Y. TIMES, Apr. 17, 2001, at F5 (detailing the risks, as well as lower costs of buying pharmaceuticals in Mexico); April Taylor, *Seniors Find Drug Relief in Canada: Congress Will Push Again for Law to Allow Pharmacists to Import Cheaper Medications*, THE DETROIT NEWS, Aug. 19, 2001, at 1A (detailing senior citizens' trips to buy drugs in Canada because they are less than one-half the cost of the drugs in the United States).

12. Internet pharmacies that comply with all federal and state licensing and regulatory requirements are allowed to post the VIPPS emblem on their websites. For a fuller discussion of the VIPPS program, see *infra* note 23.

13. Use of frontier motifs is common in discussion of Internet pharmacies and Internet commerce generally. See, e.g., Terrence Berg, *www.wildwest.gov: The Impact of the Internet on State Power to Enforce the Law*, 2000 BYU L. REV. 1305, 1306, 1361-62; Robert T.J. Bond, *Internet Regulation—Heavy Handed or Light Touch Approach? A View from A European Union Perspective*, 27 WM. MITCHELL L. REV. 1557, 1558 (2001).

14. A January 2002 report from the Centers for Medicare and Medicaid Services estimated that the United States spent \$121.8 billion on prescription drugs in 2000. Robert Pear, *Propelled by Drug and Hospital Costs, Health Spending Surged in 2000*, N.Y. TIMES, Jan. 8, 2002, at A14; AMY TSAO, AN IFFY PROGNOSIS FOR ONLINE PHARMACIES (Nov. 25, 2003), at http://www.businessweek.com/print/technology/copntent/nov2003/tc20031125_2272_tc; see also ITAA, E-DATA E-HEALTH: JUPITER RESEARCH REPORTS ONLINE PRESCRIPTION DRUG SALES IN THE U.S. BY FOREIGN

2000, the FDA had identified about four hundred Internet pharmacies, as well as other websites where drugs were accessible with a click of a mouse, and the number is currently estimated at more than five hundred.¹⁵ Some of these Internet pharmacies have been quick to exploit public fears of vulnerability to dread diseases, including anthrax¹⁶ and SARS, and the FDA has moved to rein in the pharmacies.¹⁷

Thus, while Internet pharmacies can afford consumers convenient, private access to drugs and other health care products, they can often evade the oversight provided by the United States' complex system of pharmaceutical regulation, which relies heavily on

PHARMACIES REMAINS SMALL (May 2003), available at <http://www.itaa.org/isec/pubs/e20035-05.pdf>.

15. *Point, Click, Self-Medicare: A Review of Consumer Safeguards on Internet Pharmacy Sites: Hearing Before the House Comm. on Gov't Reform*, 108th Cong. 116 (2003) [hereinafter *Review of Consumer Safeguards*] (testimony of Carmen Catizone, Executive Director, Nat'l Ass'n of Boards of Pharmacy); *Federal News*, DOJ Official Warns Online Pharmacies To Play by Rules or Risk Prosecution, Health Law Pol'y Rep. (BNA) (Nov. 13, 2000) (citing Deputy Assistant Associate Attorney General Ethan M. Posner); United States General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69, 1, 3-4 (Oct. 2000) (providing a detailed survey of nearly two hundred Internet pharmacies, while noting that federal officials had estimated that there were 200-400 Internet pharmacies operating by July 1999). These discrepant numbers may be explained by the fact that some Internet pharmacies host multiple sites. *Id.*

16. During the anthrax scare of 2001, Internet pharmacies played a significant role in the skyrocketing sales of Cipro, Bayer A.G.'s brand name for ciprofloxacin. FDA TALK PAPER, FDA ISSUES CYBER-LETTERS TO WEB SITE SELLING UNAPPROVED FOREIGN CIPROFLOXACIN (Nov. 1, 2001), at <http://www.fdagov/bbs/topics/ANSWERS/2001/ans01115.html>. Both foreign and domestic Internet pharmacies did a brisk business, as overall sales of Cipro increased as much as 4000%. Gregory J. Wilcox, *Bioterrorism Fears Rise: Online Orders for Antibiotic Cipro Deluge Internet Firm in North Hills*, L.A. DAILY NEWS, Oct. 16, 2001, at B1. Some Internet pharmacies even solicited consumer sales of Cipro unbidden, and other pharmacies were readily discoverable through traditional Internet search engines. See Mark Brown, *Anthrax Drug Hype Spreads Like Plague: Some Online Pharmacies Capitalize on Current Scare to Make a Lot of Bucks*, CHI.-SUN TIMES, Oct. 18, 2001, at 2; Benedict Carey & Marlene Cimonis, *Response to Terror: FDA to Halt Cipro Imports in Bid to Stop Illegal Sales Over Internet*, L. A. TIMES, Oct. 20, 2001, at A3. Initially, however, the FDA did not act. When the public first rushed to buy Cipro, the heads of both the National Association of Boards of Pharmacy and the Federation of State Medical Boards voiced concern to Health and Human Services Secretary Tommy Thompson, but were told that because of a "sensitivity to states' rights[]" HHS was not going to intervene against the Internet pharmacies selling the drug. John Dorschner, *No Exam? No Doctor? No Problem! Loopholes Allow Websites to Sell Drugs to Consumer Without a Doctor's Visit*, THE MIAMI HERALD, June 23, 2002, at E1.

17. During the spring of 2003, American and Canadian regulators clamped down on more than forty websites with misleading advertising of cures or prophylactic treatment for SARS. Associated Press, *The SARS Outbreak: U.S. Orders Web Sites to Stop Promoting Bogus SARS Cures*, WALL ST. J., May 12, 2003, at B2.

federal review of drug safety and efficacy, combined with state regulation of physicians and pharmacists to ensure that patients are getting appropriate drugs for their individual conditions.¹⁸ Given the severe resource constraints presently faced by federal and state governments,¹⁹ it is easy for unscrupulous Internet pharmacies to escape detection by governmental authorities.

But, more profoundly, Internet pharmacies force us to reconsider long-held views about the appropriate role for states and federal government in health care delivery and regulation. We must examine with a fresh eye the present system of complementary federal and state authority over drug prescribing and dispensing, which is more than fifty years old. At a time when the free market health care system is under challenge on a variety of fronts, Internet pharmacies highlight the limits of voluntary self-regulation in a medium that is tailor-made for manipulation, illusion, and fraud.²⁰ The practical barriers to effective law enforcement are enormous, because finding and prosecuting Internet pharmacies is difficult, time-consuming, and expensive.²¹ These obstacles suggest that the time is ripe to rethink fundamental principles of jurisdiction (both prescriptive and adjudicative) on the state, national, and international level.

In this article I will argue that Internet pharmacies pose a significant public health problem, as they raise the classic eternal triangle of health care issues—access, quality, and financing—in a new technological context. Part II describes the phenomena of Internet pharmacies, and Part III reviews the present regulatory scheme. Part IV explains why the current legal framework is

18. That this system is not infallible is evident both by recent prosecutions of physicians who are prescribing oxycontin for pain relief, Barry Meier, *OxyContin Prescribers Face Charges in Fatal Overdoses*, N.Y. TIMES, Jan. 19, 2002, at A14, and long-standing concerns about physicians who provide medically unnecessary care to Medicaid patients. See, e.g., Clifford J. Levy, *At Adult Homes, Voiceless, Defenseless and a Source of Cash*, N.Y. TIMES, Apr. 30, 2002, at A1; Clifford J. Levy, *Doctor Admits He Did Needless Surgery on the Mentally Ill*, N.Y. TIMES, May 20, 2003, at B1; Sam Howe Verhovek, *Curbs on 'Medicaid Mills' Draws Criticism*, N.Y. TIMES, Sept. 30, 1989, at 25; Sam Howe Verhovek, *Harlem Doctor Charged with Medicaid Fraud*, N.Y. TIMES, May 31, 1991, at B2.

19. See Timothy Egan, *States, Facing Budget Shortfalls, Cut the Major and the Mundane*, N.Y. TIMES, Apr. 21, 2003, at A1.

20. See generally Bond, *supra* note 13 (discussing whether cyberspace should be regulated).

21. Berg, *supra* note 13, at 1352-59; *Drugstores on the Net: The Benefits and Risks of Online Pharmacies: Hearing Before the House Subcomm. on Oversight and Investigations of the Comm. on Commerce*, 106th Cong. 44-46 (1999), available at <http://www.ftc.gov/os/1999/07/pharmacytestimony.htm> [hereinafter *Drugstores on the Net*] (testimony of Joan Z. Bernstein, Director of the FTC Bureau of Consumer Protection) (citing the complaints of numerous state enforcement authorities); see also discussion *infra* Part IV.C.

inadequate to address the public health and safety problems posed by Internet pharmacies, focusing particularly on the jurisdictional, constitutional, and practical obstacles to effective state oversight of Internet pharmacies. Part V argues that comprehensive federal oversight of Internet prescribing and dispensing is necessary to protect individual and public health, and outlines the essential elements of such an approach.

II. INTERNET PHARMACIES

A. *How Do They Work?*

There are two major kinds of Internet pharmacies: the Internet versions of a "bricks and mortar" pharmacy; and what may be called "life-style," "midlife concerns," or "rogue" pharmacies. The first type of Internet pharmacy is simply an online version of a traditional pharmacy, such as drugstore.com, a joint venture with Rite Aid, one of the largest national pharmacy chains.²² These entities provide Internet shopping for prescription drugs, shampoo, lipstick, and vitamins, and function the same way as a traditional drugstore, where consumers purchase sundries while waiting for their prescriptions to be filled.²³ Customers deliver the prescriptions to an online pharmacist, either electronically,²⁴ via facsimile, or by mail, and the drugs, as well as other items, are sent to the consumer. Internet pharmacies thus have the potential to increase access to health care, particularly for consumers for whom transportation or communication is otherwise difficult, expensive, or painful.

The second type of Internet pharmacy is the Web equivalent of a boutique, with a kindly physician and pharmacist hovering in the

22. See, e.g., <http://www.drugstore.com> (last visited Jan. 30, 2004).

23. Some of these Internet pharmacies have been specifically endorsed by the National Association of Boards of Pharmacy (NABP) as meeting appropriate standards of pharmacist licensure, quality control, confidentiality, availability of help to consumers, and general compliance with state and federal regulatory requirements. Such pharmacies are entitled to display the Verified Internet Pharmacy Practice Sites (VIPPS) emblem. *Review of Consumer Safeguards*, *supra* note 15, at 11B; see also VERIFIED INTERNET PHARMACY PRACTICE SITES: MOST FREQUENTLY ASKED QUESTIONS, at <http://www.nabp.net/vipps/consumer/faq.asp> (last visited Sept. 24, 2003).

24. The federal electronic signature law, the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. §§ 7001-7031 (2000), makes it both legal and easier for pharmacists to receive prescriptions from physicians and other health care professionals. Of course, there may still be confusion about whether state or federal law governs a particular transaction. See THE COMM. ON UNIF. STATE LAWS, *Report on the Uniform Electronic Transaction Act, the Electronic Signatures in Global and National Commerce Act and the Electronics Signatures and Records Act*, 56 THE REC. OF THE ASS'N OF THE BAR OF THE CITY OF N.Y. 456, 457-59 (2001).

background, ready to assist “midlife” and other consumers with their pharmaceutical needs. These so-called “lifestyle” pharmacies target a specific, but large audience, selling a select group of prescription drugs with mass appeal, such as Viagra,²⁵ Prozac,²⁶ Propecia,²⁷ or Meridia,²⁸ to help aging baby boomers and others do more, feel better, have more, or have less, depending on their desires.

Many of these “lifestyle” pharmacies do not require the patient to present a prescription obtained after a physician’s examination. Rather, medications can be prescribed online via an Internet “consultation.” After a potential buyer enters the website, the person clicks through to the online “consultation” page. Although this process is designed ostensibly to ensure that no patient receives Viagra or another prescription drug in cases in which it is not medically appropriate, in many cases it appears that this online “consultation” is a charade, and that virtually anyone can purchase Viagra or another similar “lifestyle” drug online.²⁹ Some online

25. Viagra, or sildenafil, is used to treat male impotence. FDA, VIAGRA, at <http://www.fda.gov/cder/consumerinfo/druginfo/Viagra.htm> (last visited Mar. 4, 2004).

26. Prozac, or fluoxetine, is a widely used antidepressant - one of a new group of selective serotonin reuptake inhibitors (SSRIs), which came on the market in the late 1980’s. FDA, FLUOXETINE, at <http://www.fda.gov/cder/pediatric/labels/Fluoxetine.pdf> (last visited Mar. 4, 2004).

27. Propecia, or finasteride, is used to treat baldness. John Henkel, *Buying Drugs Online: It’s Convenient and Private, but Beware of Rogue Sites*, 34 FDA CONSUMER 24, 27 (Jan.-Feb. 2000), available at http://www.fda.gov/fdac/features/2000/100_online.html.

28. Meridia or sibutramine is used to assist people in losing weight. FDA, MERIDIA, at <http://www.fda.gov/cder/foi/label/2001/20632s8s11LBL.pdf> (last visited Jan. 16, 2004).

29. See Henkel, *supra* note 27. After considering the issue of Internet prescribing for several years, the American Medical Association (AMA) has concluded that while this practice is permissible under certain circumstances, physicians who prescribe solely on the basis of an Internet questionnaire are guilty of unethical and substandard practice, since the completion of an online questionnaire does not adequately protect the patient. See *infra* note 44 and accompanying text. In a June 19, 2003 policy statement, the AMA Board of Trustees declared that:

Providing a prescription solely on the basis of an online questionnaire (or online consultation) with no interpersonal interaction is insufficient. . . . [A] physician may increase his or her liability exposure by prescribing medications to individuals solely through an online interaction. Moreover, such physicians put themselves at increased risk of disciplinary action by their state boards of medicine.

AMA BD. OF TR. REP. 7-A-03, at 5 (2003). In a previous report, the Board of Trustees had expressed concern that online questionnaires frequently lacked any “mechanism to determine whether the purchaser has answered the questions accurately.” *Internet Prescribing: An Interim Report*, AMA BD. OF TR. REP. 35-A-99 (1999). The report continued:

Incorrect answers could be deliberate in order to obtain the medication or could result from a failure to understand the questions. Most web sites make

questionnaires instruct the consumer on a drug's contraindications and have the "correct" boxes pre-checked,³⁰ so that only consumers who are supremely honest or extremely stupid will fail to receive the desired medication. Other researchers have found that children,³¹ dead people, men with heart conditions, and persons taking a product containing nitrates (which are contraindicated for Viagra use),³² have all been able to obtain a prescription online.³³ Thus one may question whether anyone, let alone a licensed physician, is reviewing the online questionnaire, or if in reality, the process of prescribing is completely automated.³⁴ In this regard, it is significant

no attempt to explain the potential risks of the . . . therapy More importantly, there is very significant concern that prescriptions are being ordered without the benefit of a physical examination where a patient could be fully evaluated for . . . [the problem for which treatment is sought] in order to determine the potential underlying cause and, if necessary, the most appropriate intervention. Clearly, there essentially is no medical assessment at all, and there is no follow-up to determine whether the medication has been effective or if there are side effects.

Id. That such concern is well-founded was borne out by the reports of an investigative journalist, who testified before Congress in 1999 that he logged on to an Internet pharmacy as "Tom Cat," indicated that he weighed fifteen pounds and was six inches tall, and received Viagra after an online "consultation." *Drugstores on the Net*, *supra* note 21, at 17 (testimony of Christine Behrens, Reporter, WWMT News 3).

30. See, e.g., <http://www.net-dr.com> (last visited Sept. 23, 2003).

31. In *Kansas ex rel. Stovall v. Confimed.Com, L.L.C.*, 38 P.3d 707 (Kan. 2002), the Kansas Supreme Court reviewed a sting operation against an Internet pharmacy brought by the state Attorney General's office, and declined to find that the sale of Viagra to a sixteen year old boy was unconscionable under the UCC, given that the boy's mother was overseeing the sting transaction and it was highly unlikely that the boy would use the medication. For further discussion, see *infra* text accompanying notes 169-72.

32. A recent study has suggested that men with coronary artery disease may still use Viagra (sildenafil), provided that they do not use nitrates within seventy-two hours of taking sildenafil. Adelaide M. Arruda-Olson et al., *Cardiovascular Effects of Sildenafil During Exercise in Men With Known or Probable Coronary Artery Disease: A Randomized Crossover Trial*, 287 JAMA 719, 724 (2002).

33. See *Drugstores on the Net*, *supra* note 21, at 17 (testimony of Christine Behrens, Reporter, WWMT News 3); *Drugstores on the Net*, *supra* note 21, at 50 (testimony of Joan Z. Bernstein, Director of the Federal Trade Commission Bureau of Consumer Protection); see also *Illegal Online Pharmacies, State-Federal Cooperation to Protect Consumer: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. (2000), available at http://www.naag.org/legislation/stovall_online_pharm [hereinafter *Illegal Online Pharmacies*] (testimony of Carla J. Stovall, Attorney General of Kansas).

34. See Linda C. Fentiman, Oral Presentation at the American Society of Law, Medicine, and Ethics Annual Health Law Teachers Conference in Cleveland, Ohio (June 8-10, 2000) (on file with author) (audience comment).

that on most web sites, the consumer is charged for the consultation only if it leads to a prescription.³⁵

B. *Risks and Benefits: Access, Public Safety, and Fraud*

As this overview shows, most consumers choose Internet pharmacies because these sites provide easy access to drugs that they want. People can save time, and perhaps money, depending on where they live and what websites they visit.³⁶ They can also avoid the inconvenience and potential embarrassment of a visit to their doctor and the local pharmacy. Consumers may also be given a false sense of privacy by shopping via the Internet. While they may not be known to the Internet health care professionals involved in their prescription drug transactions, a good deal of intimate, private information may be inadvertently disclosed by consumers as they browse through various websites, through the use of technology such as “cookies” and “web bugs.”³⁷

What, then, are the objections to Internet pharmacies? First and foremost is the concern that consumers will receive substandard, unsafe, or worthless medications, because some Internet pharmacies dispense expired, subpotent, superpotent, contaminated, or counterfeit drugs.³⁸ The Food and Drug Administration views this as a particular concern for foreign Internet pharmacies, particularly

35. *Stovall*, 38 P.3d at 709; Bloom & Iannaccone, *supra* note 10, at 831; *see, e.g.*, www.kwikmed.com (last visited Sept. 23, 2003); www.net-dr.com (last visited Sept. 23, 2003). In the case of Internet pharmacies that do employ physicians to review requests for prescription medication, the physicians are paid only when they approve a prescription request.

36. *See supra* note 10 and accompanying text.

37. *See, e.g.*, Jessica J. Thill, *The Cookie Monster: From Sesame Street to Your Hard Drive*, 52 S.C. L. REV. 921 (2001) (discussing potential remedies for the increased use of “cookies” in Internet advertising); Courtenay Youngblood, *A New Millennium Dilemma: Cookie Technology, Consumers, and the Future of the Internet*, 11 DEPAUL-LCA J. ART. & ENT. L. & POL’Y 45 (2001) (discussing the “cookie crisis” and increased consumer concern about privacy on the Internet); *see also In re Pharmatrak, Inc. Privacy Litigation*, 329 F.3d 9, 23 (1st Cir. 2003) (allowing plaintiffs in a class action for a violation of the Electronic Communications Privacy Act to proceed in their suit against a computer monitoring service that conducted research on individual consumers’ use of drug company websites, and discussing, *inter alia*, the types of data that can be obtained through such research). *But see In re DoubleClick Inc. Privacy Litig.*, 154 F. Supp. 2d 497, 526-27 (S.D.N.Y. 2001) (granting motion to dismiss claim that the defendant’s use and storage of “cookie” information from plaintiffs violated federal law).

38. *E-DRUGS: Who Regulates Internet Pharmacies?: Hearing on Examining the Benefits and Risks of Pharmaceutical Sales Over the Internet, Focusing on Public Health Implications, Law Enforcement, and Regulatory Challenges Before the Senate Comm. on Health, Educ., Labor, and Pensions*, 106th Cong. 11-14 (2000) [hereinafter *E-DRUGS*] (testimony of Jane E. Henney, M.D., Commissioner of the United States Food and Drug Administration); Carey & Cimonis, *supra* note 16, at A3.

those located in countries where there may be less rigorous supervision of the drug manufacturing and pharmacist dispensing processes.³⁹ An additional concern is that controlled substances⁴⁰ may be more readily available from foreign Internet pharmacies,⁴¹ and that the United States Customs Service and the Drug Enforcement Administration lack sufficient detection and enforcement capabilities to intercept and seize all illegally imported drugs.⁴²

A second concern is the lack of medical oversight, which is part of the traditional drug prescribing and dispensing process in the United States. Without the requirement that the prescription be written by a physician who has recently examined and talked with the patient, there is a significant risk that a patient will essentially engage in self-diagnosis and choose a drug believed necessary for treatment, without benefit of the clinical judgment and expertise that a patient relies on in the usual physician-patient encounter.⁴³ The American Medical Association and the Federation of State Medical Boards have declared that when physicians prescribe medication for patients "based solely on an electronic medical questionnaire," i.e., on a so-called Internet "consultation," this conduct falls below the acceptable standard of care and is "outside the bounds of professional conduct."⁴⁴ One need only recall the

39. *Drugstores on the Net*, *supra* note 21, at 96-98 (testimony of Janet Woodcock, Director of the Center for Drug Evaluation and Research); *see also* Carey & Cmons, *supra* note 16.

40. Controlled substances are prescription medications that have the potential for patient abuse, leading to physiological or psychological dependency, and therefore access to them is restricted. *See, e.g.*, Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. 21,181 (Apr. 27, 2001). *See* 21 C.F.R. §§ 1308.11-1308.15 (2003), for the schedules of controlled substances.

41. Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. at 21,183.

42. *Drugs in the Mail: How Can it be Stopped?: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources of the House Comm. on Gov't Reform*, 106th Cong. 37-48 (2000) [hereinafter *Drugs in the Mail*] (testimony of Kevin Dellicolli, Director Cyber Smuggling, Office of Investigations, U.S. Custom Service); *see also* Robert Pear, *Online Sales Spur Illegal Importing of Medicine to U.S.*, N.Y. TIMES, Jan. 10, 2000, at A1.

43. *E-DRUGS*, *supra* note 38, at 14 (testimony of Jane E. Henney, Commissioner of the United States Food and Drug Administration).

44. According to the Special Committee on Professional Conduct and Ethics of the Federation of State Medical Boards of the United States, Inc., the burden is on the physician to show that before prescribing medication to a patient, four essential requirements have been met:

- 1) an adequate patient evaluation, including the taking of a medical history and a physical examination;
- 2) an exchange between the patient and physician sufficient to identify the risks and benefits of alternative treatment approaches;
- 3) a subsequent treatment review to assess its therapeutic outcome; and

anthrax scare of 2001 and the run on both Internet and traditional pharmacies' supplies of Cipro to know that patient self-diagnosis and

-
- 4) [the] maintenance of a contemporaneous medical record . . . readily available to patients and their other health care professionals.

CONDUCT AND ETHICS REPORT OF THE SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS OF THE FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC., *available at* http://www.fsmb.org/policy%20white%20papers/conduct_56_ethics (last visited Sept. 24, 2003) (original policy adopted April 2000) [hereinafter SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS].

The AMA has also concluded that while Internet prescribing "can reduce errors that occur from failure to understand written and verbal (e.g. telephone) prescriptions," such prescribing must stringently be limited to circumstances which will ensure that a valid doctor-patient relationship exists. *Guidance for Physicians on Internet Prescribing*, AMA BD. OF TR. REP. 7-A-03, (2003). The AMA has declared that: "Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components." The physician shall:

- [1] obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
- [2] have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
- [3] as appropriate, follow-up [sic] with the patient to assess the therapeutic outcome;
- [4] maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and
- [5] include the electronic prescription information as part of the patient medical record.

Id. at 2.

The AMA has also imposed several additional requirements to protect patients and to ensure compliance with applicable state and federal law:

Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside [unless the patient has visited the physician in the state in which that physician is licensed to practice medicine].

....

Physicians who prescribe via the Internet should transmit prescriptions over a secure network (i.e., provisions for password protection, encrypted electronic prescriptions, or other reliable authentication techniques [e.g., AMA Internet ID]) in order to protect patient privacy [and]

....

[P]hysicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the Web site, including (but not necessarily limited to) name, practice location (address and contact information), all states in which licensure is held, and financial interests in any products prescribed. Posting of actual physicians' license numbers (e.g., the Drug Enforcement Administration [DEA] number) is unnecessary.

Id. at 3-4.

self-prescription⁴⁵ can pose a significant threat to both individual and public health.⁴⁶

A third concern is fraud, either because the Internet pharmacy never ships the drug that the consumer purchased or because it is counterfeit, adulterated, ineffective, or super-potent.⁴⁷ One defendant has already been convicted of wire fraud for selling a phony HIV home testing kit on the Internet.⁴⁸ It appears to be only a matter of time before prosecutors and innovative plaintiffs' lawyers will bring suits against Internet pharmacies and their principals, alleging fraud, including wire⁴⁹ and mail⁵⁰ fraud, and, therefore, RICO violations.⁵¹

III. THE CURRENT REGULATORY FRAMEWORK

The present American framework for pharmaceutical safety allocates responsibility for ensuring that a drug is safe, effective, and appropriate for a particular patient among a large group of federal and state agencies, as well as individual health care professionals.⁵² The federal government oversees and regulates drug safety, efficacy, labeling,⁵³ and advertising,⁵⁴ as well as the importation of pharmaceutical products and medical devices.⁵⁵ A multitude of

45. See Carey & Cimon, *supra* note 16, at A3.

46. Brown, *supra* note 16; Melody Petersen, *With Anthrax Fears, Bayer Is to Lift Antibiotic Output*, N.Y. Times, Oct. 11, 2001, at C2.

47. *E-DRUGS*, *supra* note 38, at 14. In July 2003, the Food and Drug Administration established a Counterfeit Drug Task Force to address the growing problem of counterfeit medications. FDA'S COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (last visited Sept. 16, 2003).

48. Paula Kurtzweil, *Investigators' Reports: Internet Sales of Bogus HIV Test Kits Result in First-of-Kind Wire Fraud Conviction*, FDA CONSUMER MAG., July-Aug. 1999, available at <http://www.fda.gov/oc/buyonline/fdacir.html>.

49. Wire fraud is governed by 18 U.S.C. § 1343 (2000).

50. Mail fraud is governed by 18 U.S.C. § 1341.

51. The Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961-1968, permits both criminal prosecutions, § 1963, and civil actions, which authorize recovery for treble damages and attorney's fees, § 1964(c).

52. Another important aspect of ensuring drug safety is, of course, the tort system. However, the potential role of that system is largely beyond the scope of this article.

53. Drug safety, efficacy, and labeling are within the purview of the United States Food and Drug Administration, pursuant to the Food Drug and Cosmetic Act, 21 U.S.C. §§ 351, 352(a)-(c), (e)(1), (e)(3), (e)(4), (f)-(j), (n)-(r), and 355(a)(1)-(4), (b)-(d), (e), (j)(4) (2000).

54. The FDA and the Federal Trade Commission (FTC) have overlapping jurisdiction over drug advertising, dependent on whether the drug is available via prescription or over-the-counter. See *infra* notes 102-05 and accompanying text.

55. Different agencies have differing responsibilities. For example, oversight of drug importation is allocated among the FDA, the Drug Enforcement Administration

federal agencies are involved, including: the Food and Drug Administration (FDA); the Federal Trade Commission (FTC); the Drug Enforcement Administration (DEA); the Customs Service; and the Postal Service. This federal system is supplemented and supported by the actions of state governments, which: license and discipline physicians, nurse practitioners, and other drug prescribers;⁵⁶ license and discipline the pharmacies and pharmacists who dispense these medications;⁵⁷ and enforce general consumer protection laws,⁵⁸ as well as laws directed specifically at Internet pharmacies.⁵⁹ This regulatory system depends heavily on the expertise and integrity of individual clinicians. To the extent that these professionals are either absent from, or corruptly involved in, the Internet pharmacy prescribing and dispensing process, American consumers are vulnerable to injuries, abuse, and rip-offs.

A. Federal Oversight

1. Food and Drug Administration

The federal Food and Drug Administration is the lead agency responsible for protecting consumers from unsafe or ineffective drugs.⁶⁰ The FDA determines the safety and efficacy of all drugs and medical devices marketed in the United States,⁶¹ approving them only after lengthy clinical testing and review,⁶² on condition that they are dispensed by a licensed pharmacist, pursuant to a prescription

(DEA), an agency within the Department of Justice, and the United States Customs Service, under the Department of Homeland Security.

56. See, e.g., TEX. OCC. CODE ANN. § 157.054 (Vernon 2003) (authorizing physician assistants and nurse practitioners to prescribe under the supervision of a physician).

57. See, e.g., ARK. CODE ANN. § 17-92-302 (Michie 2002) (declaring that only licensed pharmacists and pharmacy students serving internships may dispense prescription medications); CAL. HEALTH & SAFETY CODE § 11026 (West 2003) (authorizing physicians and pharmacists to dispense a prescription).

58. See, e.g., *New Jersey: State Files Consumer Fraud Charges Against Eight Internet Pharmacies*, Health Care Pol'y Rep. (BNA), at 578 (Apr. 10, 2000) (detailing actions brought against unlicensed Internet pharmacies under New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 to -2.13, for failing to disclose to consumers that the pharmacies "were not licensed to dispense prescription drugs or controlled dangerous substances or to practice medicine in New Jersey").

59. See discussion *infra* Part III.B.

60. The FDA's jurisdiction extends to prescription drugs and over-the-counter medications, as well as medical devices.

61. See 21 U.S.C. § 355 (2000).

62. See *id.*; see also Harold Edgar & David J. Rothman, *New Rules for New Drugs: The Challenge of AIDS to the Regulatory Process*, 68 MILLBANK Q. 111, 112-14 (1990).

written by a licensed prescriber,⁶³ both of whom are regulated by the state in which they practice. A drug not dispensed in this manner is deemed "misbranded" under the Food Drug and Cosmetic Act.⁶⁴ This system is designed to ensure that prescription drugs, which carry risks as well as benefits, are only made available to patients who have been evaluated by a skilled, licensed healthcare professional, who can match a particular drug to the medical needs of the patient.⁶⁵

The physician's central role in the prescribing process has long been recognized in professional practice and by statute. Recently, both the American Medical Association and the Federation of State Medical Boards have reiterated this position, declaring in separate policy statements that a physician who prescribes medication to a patient through an Internet consultation, without a recent or current examination, is engaging in the substandard practice of medicine.⁶⁶ This means that a physician who causes injury to a patient through online prescribing, without a pre-existing relationship with that patient, is likely to be found negligent, and thus subject to a finding of medical malpractice and tort liability, as well as professional disciplinary action, including license suspension or revocation, even if no injury occurs.⁶⁷

2. The Learned Intermediary Rule

Over thirty years ago, as strict liability in tort for defective and dangerous products was emerging as a new doctrine, the division of responsibility between governmental safety regulators and individual physicians and pharmacists gave rise to the Learned Intermediary

63. 21 U.S.C. § 353(b)(1). Generic drugs, which have the same active ingredients as prescription medications whose patents have expired, are not subject to clinical testing but must meet requirements of bioequivalence under § 355(i)(8)(B).

64. *Id.* § 353(b)(4).

65. This is the basis for the Learned Intermediary Rule, discussed in the next subsection.

66. See SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS, *supra* note 44.

67. A number of states have already taken disciplinary or other actions against physicians for their online prescribing practices. Typically they have targeted out-of-state physicians, alleging that they were practicing medicine without a license by prescribing medication to in-state patients. See, e.g., *Arizona: State Settles Consumer Fraud Lawsuit Against Online Pharmacy*, *Ohio Physician*, Health Care Pol'y Rep. (BNA) (Nov. 28, 2000) [hereinafter *Arizona: State Settles Consumer Fraud*]; *Connecticut: State Attorney General Files Lawsuit Over Internet Sale of Prescription Drugs*, Health Care Pol'y Rep. (BNA) (May 18, 2001); *New Jersey: State Charges Online Pharmacies with Illegally Selling Prescriptions over Internet*, Health Care Pol'y Rep. (BNA) (Jan. 2, 2001).

Rule.⁶⁸ Under this Rule, physicians and other licensed health care professionals play a pivotal role in ensuring that patients receiving drug treatment have optimal outcomes.⁶⁹ The Learned Intermediary Rule gives a defense to pharmaceutical manufacturers who are alleged to have violated their duty to warn consumers of a drug's potential adverse effects, when the drug is prescribed by a "learned intermediary,"⁷⁰ who has been educated by the manufacturer about the risk/benefit calculus of a particular drug, and can then apply that calculus to the individual patient.⁷¹

However, the use of the Learned Intermediary Rule as an airtight defense against pharmaceutical company liability has been undermined by the recent dramatic rise in "direct to consumer" (DTC) advertising, as both academics and practicing attorneys have argued that the doctrine's premise is undercut by direct appeals to

68. This rule, which is recognized in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(b),(d) (1998), was first enunciated in *Magee v. Wyeth Laboratories, Inc.*, 29 Cal. Rptr. 322, 328-30 (Ct. App. 1963) (holding that the manufacturer was not liable for breach of warranty because of the break in causation due to the physician's failure to follow the prescribed methods for the drug's use). See also *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1967) (holding that a drug manufacturer had a duty to warn a patient's physician of a potentially severe side effect of the drug).

69. Courts have, however, recognized limited exceptions to the Learned Intermediary Rule where a physician could not evaluate the individual circumstances of the patient and thus provide appropriate warnings. See, e.g., *Hill v. Searle Labs.*, 884 F.2d 1064, 1070-71 (8th Cir. 1989) (recognizing that physicians play a limited role in a patient's birth control choice); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 130-31 (9th Cir. 1968) (holding that in the case of mass immunization efforts, individualized physician warnings to patients are not possible); see also *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68-70 (Mass. 1985) (suggesting that the Learned Intermediary Rule would not apply in the context of oral contraceptives, when manufacturers direct their marketing to the consumer and the patient is the prime mover in seeking the prescription).

70. Under the laws of many states, physicians, physician assistants, and nurse practitioners can prescribe medication to patients. See generally FURROW ET AL., *supra* note 1, at 76; see also TEX. OCC. CODE § 157.054 (authorizing physician assistants and nurse practitioners to prescribe under the supervision of a physician); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 92-93 (Tex. Ct. App. 2000) (holding that the learned intermediary rule applied to a licensed nurse practitioner). For ease of expression, rather than the perpetuation of hierarchy, the terms "physician" and "licensed prescriber" will be used to encompass all health care professionals authorized by law to prescribe medications to patients. See also *infra* note 135.

71. As the court explained in *Sterling Drug*, 370 F.2d at 85, for a prescription medication, unlike "a normal consumer item," the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. "If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided." *Id.*

patients.⁷² Such advertising was made possible by a 1997 change to the FDA's advertising rules,⁷³ which now permit pharmaceutical companies to reach potential consumers through mass-market television advertising, in which they are urged to "ask your doctor" whether a particular drug "is right for you."⁷⁴ An announced goal of the relaxed FDA rules, adopted in response to pharmaceutical industry lobbying, was to promote consumer knowledge about illnesses which were frequently under-diagnosed and under-treated, and thus "empower" consumers to initiate a dialogue with their physicians about treatment options. This new FDA "guidance" permitted drug companies to mention a drug and the illness it is intended to treat, as long as the ad mentions a drug's risks and side effects, and refers consumers to a source of additional information.⁷⁵

In practice, these guidelines have permitted a massive increase in pharmaceutical company spending on DTC advertising, which grew from just under \$600 million in 1996 to more than \$2 billion in 2000.⁷⁶ The increase in advertising dollars is a major contributor to increased spending on prescription drugs, along with a generally aging population, the expanding efficacy of drug treatment compared

72. See, e.g., *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999); Jack E. Karns, *Direct Advertising of Prescription Drugs: The Duty to Warn and the Learned Intermediary Rule*, 3 DEPAUL J. HEALTH CARE L. 273, 290 (2000) (concluding that certain advertising tactics may be unsuccessful since courts have held that direct advertising may serve as an exception to the Learned Intermediary Rule); Marilyn A. Morberg et al., *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD & DRUG L.J. 213, 220 (1998).

73. Prior to 1997, advertisement was only feasible in print media, primarily magazines, because FDA rules required pharmaceutical manufacturers to give a "brief summary" detailing a drug's benefits and side-effects. 21 U.S.C. § 352(n)(3) (2000).

74. See, e.g., NEWSWEEK, tear out insert, Mar. 4, 2002 (offering a "Free 7-Day Trial Certificate" for patients whose physicians prescribe Nexium).

75. Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (Aug. 12, 1997); *Trends & Timeliness-Direct-to-Consumer Ads: FDA Rules Create Ad Bonanza*, AMERICAN HEALTH LINE, Aug. 10, 1998.

76. While the precise amount spent on DTC advertising is open to some dispute, with estimates for 2000 ranging from \$2.0 to \$2.5 billion, all commentators agree that the increase in advertising dollars is marked, and may even rival the amount spent on advertising in medical journals. Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW. ENG. J. MED. 498, 499-500 (2002); Steven Woloshin et al., *Direct-To-Consumer Advertisements for Prescription Drugs: What are Americans Being Sold?*, 358 LANCET 1141 (Oct. 6, 2001), available at <http://search.epnet.com/direct.asp?an=52833550&db=aph> [hereinafter *DTC Ads*] ("[C]ompanies spent more on advertisements in newspapers and popular magazine than they did in medical journals."); see Melody Petersen, *Increased Spending on Drugs is Linked to More Advertising*, N.Y. TIMES, Nov. 21, 2001, at C1, C4; *For Consumers Free Samples Are a Virtual Reality*, MED. AD. NEWS, Jan. 1, 2002; *Return to Spender, Part I*, MED. AD. NEWS, June 1998.

to surgery, and the fact that many advertised drugs are used to treat chronic conditions, and are therefore prescribed for extended time periods. Such drugs are generally recent arrivals on the pharmaceutical market and, thus, are likely to be “expensive,” especially compared to generic drugs.⁷⁷ While the AMA, consumer groups, and individual physicians have criticized DTC drug advertising, its proponents claim that such advertising will encourage patients to seek help from their physicians and assist them in becoming more informed participants in health care decisionmaking.⁷⁸

Even before DTC television advertising hit its stride, in *Perez v. Wyeth Laboratories Inc.*,⁷⁹ the New Jersey Supreme Court rejected the proposition that the Learned Intermediary Rule provides pharmaceutical companies with an absolute shield against liability based upon a breach of the duty to warn. *Perez* involved Wyeth Laboratories’ alleged failure to warn patients about the potential adverse side effects of Norplant (an implanted contraceptive) and the pain and scarring that can accompany the implant’s removal. The *Perez* court found that “[d]irect advertising of drugs to consumers alters the calculus of the learned intermediary doctrine,”⁸⁰ holding that drug manufacturers who engage in such marketing will no longer be able to reflexively invoke the physician as a shield against liability. Instead, there will be a presumption that an FDA-approved warning is adequate, which may be rebutted if a plaintiff patient can show that the pharmaceutical manufacturer’s DTC advertising was so misleading or inaccurate as to obviate the warning given by a licensed prescriber based on the manufacturer’s information.⁸¹

Perez premised its decision on the dramatic changes in the American health care system over the last several decades, including the marked changes in the physician-patient relationship accomplished by managed care and DTC advertising. The court opened with the bold statement—“Our medical-legal jurisprudence is based on images of health care that no longer exist”⁸²—then proceeded to demolish the Learned Intermediary Rule’s provision of

77. Petersen, *supra* note 76, at C1.

78. For a flavor of the debate, see *DTC Ads*, *supra* note 76; Alan F. Holmer, *Direct-to-Consumer Advertising—Strengthening Our Health Care System*, 346 NEW ENG. J. MED. 526 (2002); Susan Okie, *With TV Spots, Drug Firms Aim at Patients’ Role; Strategy for Prescriptions Shifts Away from Doctors*, WASH. POST, May 22, 2000, at A1, A10; Petersen, *supra* note 76, at C1, C4; Sidney M. Wolfe, *Direct-to-Consumer Advertising—Education or Emotion Promotion?*, 346 NEW ENG. J. MED. 524 (2002).

79. 734 A.2d 1245 (N.J. 1999).

80. *Id.* at 1254.

81. *Id.* at 1254-59.

82. *Id.* at 1246.

absolute immunity from liability. The court observed that the rule is itself an exception to the general principle that defendants will be strictly liable in tort if they make dangerous products unless they warn the ultimate user of the product's risks and benefits and the ways to use it most safely.⁸³ *Perez* declared that:

when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.⁸⁴

Instead, the court held "that [although] a warning or instruction . . . [will be presumed] adequate on drug or food products if the warning has been approved or prescribed by the Food and Drug Administration,"⁸⁵ an injured plaintiff may rebut that presumption by showing reliance on inconsistent warnings from the manufacturer received from DTC advertising or other sources.⁸⁶

At present, *Perez* is the only court to rule that DTC advertising mandates a change in the analytical framework of the Learned Intermediary Rule. Some courts have declined to reach the question of the Rule's continued viability, finding it to be a matter for legislative action;⁸⁷ while others have held that the Learned Intermediary Rule still applies, notwithstanding DTC advertising, because the physician still plays a significant role in prescribing medications and educating the patient about their risks and benefits.⁸⁸

3. FDA Policy Permitting Importation for Personal Use

The physician, as wise overseer of patient health, has also been at the heart of an FDA policy permitting patients to import a limited amount of a non FDA-approved drug, as long as the patient's treating physician certifies that no FDA-approved drug is available to treat the patient, and that the physician will supervise the patient's use of the imported drug.⁸⁹ The FDA has long emphasized that this policy

83. *Id.* at 1249 (citing the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1997)); *id.* at 1256 (citing *Edwards v. Basel Pharm.*, 116 F.3d 1341, 1343 (10th Cir. 1997)).

84. *Perez*, 734 A.2d at 1247.

85. *Id.* at 1254.

86. *Id.* at 1259.

87. *See, e.g., Odgers v. Ortho Pharm. Corp.*, 358 N.W. 2d 873, 874 (Mich. 1984).

88. *In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999).

89. Edgar & Rothman, *supra* note 62, at 112-14; Susan M. King, *Legal and Risk Management Concerns Relating to the Use of Non-FDA Approved Drugs in the Practice of Psychiatry*, RX FOR RISK (Spring 1998), available at <http://www.apa->

reflects the exercise of agency discretion under narrow, carefully defined circumstances and does not create a general entitlement to import non-FDA approved drugs.⁹⁰ In pre-Internet pharmacy days, the limited exception for importation for personal use required a physician to file a formal application on behalf of the patient with the FDA, stating the reasons why the non-approved drug was necessary.⁹¹ If a personal use exemption was approved, the patient (or a family member) went abroad and brought home a three month supply of the drug, although sometimes the mails were used. Although the 2000 Medicine Equity and Drug Safety Act⁹² attempted to relax the requirements for importation somewhat, many consumers still lack easy access to affordable prescription medications.

Internet pharmacies offer an important way to avoid regulatory hurdles. By going to a foreign Internet pharmacy website,⁹³ consumers can readily order and receive medication not approved by the FDA. Some foreign Internet pharmacies have been the targets of FDA-initiated “cyberletters,” admonishing them that they are in violation of the Food, Drug, and Cosmetic Act.⁹⁴ The FDA has also worked with some foreign governments to shut down Internet pharmacies,⁹⁵ although such efforts may be of limited utility, given the ease with which a website can be set up and dismantled. Several years ago the FDA adopted a “look the other way” approach, because Internet pharmacies in Canada and other Western European countries were viewed as subject to regulatory oversight comparable

plip.com/RiskManagement/news_nonFDA drugs1.htm (citing Paul M. Hyman, *Legal Overview of FDA Authority Over Imports*, 49 FOOD & DRUG L. J. 525, 531-32 (1994)); FDA REGULATORY PROCEDURES MANUAL, COVERAGE OF PERSONAL IMPORTATIONS, available at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html (last visited Sept. 16, 2003) [hereinafter COVERAGE OF PERSONAL IMPORTATIONS].

90. See COVERAGE OF PERSONAL IMPORTATIONS, *supra* note 89; Carey & Cimon, *supra* note 16, at A3.

91. See *id.* But see PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 561-63 (2d. ed. 1991).

92. See Pub. L. No. 106-387, 114 Stat. 1549 (2000) (amending §§ 801 and 804 of the Food Drug and Cosmetic Act, codified at 21 U.S.C. §§ 381 and 384). This law has not yet been implemented, because of the FDA's concern that the law would not provide sufficient protection to consumers from harm from defective or counterfeit drugs.

93. In this context “foreign” means that the pharmacy is in some way operated outside the territorial reach of the United States, including the off-shore location of the web server or the company's place of incorporation, principal place of business, or the location of the pharmacist or pharmaceutical warehouse.

94. See, e.g., CENTER FOR DRUG EVALUATION AND RESEARCH, FDA, COMPLIANCE ACTIVITIES: “CYBER” LETTERS 2001, at <http://www.fda.gov/cder/warn/cyber/cyber2001.htm> (last visited Sept. 25, 2003).

95. Robert Pear, *U.S. and Thai Officials Attack Internet Sales of Medicine*, N.Y. TIMES, Mar. 21, 2000, at A18.

to that of the United States, and therefore a reasonable alternative for persons who cannot afford to buy drugs in this country.⁹⁶ However, in the last year, as both individuals and state and local governments seek to purchase prescription medications from Canadian Internet pharmacies because of the enormous cost savings,⁹⁷ the FDA has taken a much harder line.⁹⁸ Taken together, the data in the GAO Report, the growing reliance on Canadian imports, and the reports of high volume sales of Cipro and other drugs in the wake of the anthrax and SARS scares⁹⁹ all suggest that purchase of drugs via foreign Internet pharmacies is booming.

96. The FDA's initial, laissez-faire, approach was expressed this way by one senior FDA official:

We don't want anyone to get their prescriptions filled in a foreign country. We urge people not to import foreign drugs. That said, if people are going to go ahead and order drugs outside the U.S., they're better off getting them from Canada than from a country like Thailand or Mexico. At least Canada has drug regulations and testing systems that are comparable to ours in the U.S., which makes it a little safer. . . .

Joel Baglole, *U.S. Drug Imports Worry Canadians*, WALL. ST. J., Oct. 22, 2002, at A7. However, this approach has been criticized, not only by the American pharmaceutical industry, but by Canadian regulators as well. *Id.* In January 2003, GlaxoSmithKline, a major drug manufacturer, announced that it would stop shipping its products to Canadian pharmacies that ship these drugs to U.S. consumers in violation of American law. Karen Pallarito, *Pharmacy Board Takes Action Against Illegal Imports*, REUTERS HEALTH, April 2, 2003, available at <http://www.reutershealth.com/archive/2003/04/02/eline/links/20030402eline041.htm>. And more recently, the National Association of Boards of Pharmacy criticized the FDA's ambivalent policy, saying that it confused consumers and opened them up to fraud and defective medications. *Id.*

97. More than a dozen states, and several cities, are exploring the possibility of importing drugs through Canadian Internet pharmacies, citing a need to save money for government employees and citizens. Ceci Connolly, *Kennedy Endorses Drug Importation*, WASH. POST, Dec. 19, 2003 at A16; Kim Dixon, *Despite FDA Stance, US States Move on Canada Drugs*, REUTERS HEALTH, Jan. 9, 2004, available at <http://www.reutershealth.com/archive/2004/01/09/business/links/20040109manc001.html>. Drug prices in Canada are approximately half that of brand-name drugs in the United States. Warren Wolfe, *Drug Import Project takes Minnesota Officials to Canada*, MINNEAPOLIS STAR-TRIBUNE, Dec. 16, 2003, available at <http://www.startribune.com/stories/462/4270206.html>.

98. The FDA contends that states should not be able to import prescription medications from Canada because there is no way to guarantee that such drugs are not counterfeited, contaminated, or otherwise unsafe. William M. Welch, *FDA on Canada drugs: 'No Way'*, WASH. POST, Dec. 23, 2003, at 1A; LAURAN NEERGAARD, *FDA CHIEF VOWS ACTION ON DRUG IMPORT BAN*, available at http://news.yahoo.com/news?tmpl=story2&cid=534&u=/ap/20040110/ap_on_go_ca_st_pe (last visited Sept. 16, 2003). Critics of the FDA's position claim that the FDA is concerned only with the economic health of American drug manufacturers, and not the safety of American citizens. Connolly, *supra* note 97, at A16.

99. See *supra* notes 16-17, 38, 46-47, and accompanying text.

4. Federal Trade Commission

Internet pharmacies are also regulated by the Federal Trade Commission (FTC), which has authority under the Federal Trade Commission Act¹⁰⁰ to regulate deceptive consumer advertising.¹⁰¹ The FTC and the FDA share regulatory oversight over drugs and other health products under a 1971 interagency liaison agreement.¹⁰² The FDA has primary enforcement authority over claims made by a drug's manufacturer, packer, or distributor in the labeling and advertising of prescription drugs and labeling of over-the-counter medications. The FTC is the lead regulator in all other cases of false or misleading statements (including advertising) made in regard to foods, drugs, cosmetics, or devices offered to consumers.¹⁰³ The FTC has recently taken action against several Internet pharmacies and other health product websites, which allegedly made misleading statements about the safety and efficacy of the health products they were offering, the existence of a network of physicians to support the pharmacy, or the website's privacy policies.¹⁰⁴ In *FTC v. Rennert*, for example, the agency obtained injunctive relief against defendants who were selling prescription drugs via the Internet, falsely representing that prescription drug orders were reviewed by a network of physicians and filled by an on-site pharmacy, and then selling the consumer information obtained to third parties.¹⁰⁵ The

100. 15 U.S.C. §§ 41-58 (2000).

101. *Id.* §§ 52-55.

102. Mem. of Understanding Between FTC and the FDA, 36 Fed. Reg. 18,539 (Sept. 16, 1970) (establishing liaison officers within the two agencies for the purpose of coordinating agency action in view of concurrent, and potentially conflicting jurisdiction); see also *Drugstores on the Net*, *supra* note 21 (testimony of Joan Z. Bernstein, Director of the Bureau of Consumer Protection of the FTC).

103. Mem. of Understanding Between FTC and the FDA, 36 Fed. Reg. at 18,539.

104. *Drugstores on the Net*, *supra* note 21 (testimony of Joan Z. Bernstein, Director of the Bureau of Consumer Protection of the FTC); see also *Review of Consumer Safeguards*, *supra* note 15, at 27-41 (testimony of J. Howard Beales, Director of the Bureau of Consumer Protection of the FTC); *Enforcing the Laws on Internet Pharmaceutical Sales: Where Are the Feds?: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 23-29 (2000), available at <http://www.usdoj.gov/criminal/cybercrime/posner.htm> [hereinafter *Enforcing the Laws*] (testimony of Ethan M. Posner, Deputy Associate Attorney General at the Department of Justice) (identifying other avenues for legal action by the FTC and the DOJ such as prosecutions of Internet pharmacies that state, falsely, that a physician will review each "online consultation" form or for dispensing drugs without disclosing their known side effects); Press Release, FTC, Online Pharmacies Settle FTC Charges (July 12, 2000), at <http://www.ftc.gov/opa/2000/07/iog.htm>; Press Release, FTC, "Operation Cure All" Wages New Battle in Ongoing War Against Internet Health Fraud (June 14, 2001), at <http://www.ftc.gov/opa/2001/06/cureall.htm>.

105. See FTC, ONLINE PHARMACIES SETTLE FTC CHARGES (July 12, 2000), available at <http://www.ftc.gov/opa/2000/07/iog.htm>.

defendants agreed not to advertise or sell prescription drugs over the Internet unless they accurately identified the physicians and pharmacists involved in their operation and where they were licensed, disclosed that dispensing a prescription drug without a prescription is a violation of federal law, indicated the states from which they would accept orders for such drugs, and accurately stated their policy and practice in regard to obtaining personal consumer information and credit card billing.¹⁰⁶

The FTC has also been a key player in cooperative agency action, which has involved joint activities among federal, state, Canadian, and Mexican health and law enforcement agencies.¹⁰⁷ The FTC has launched a special intergovernmental initiative, Operation Cure. All, a consumer education and law enforcement effort, that identifies and then sanctions companies which engage in fraudulent marketing of health products on the Internet.¹⁰⁸ Operation Cure. All swung into action after the anthrax panic in the fall of 2001, conducting "a coordinated Internet 'surf,'" to find web sites making bogus claims of efficacy on behalf of products they touted as providing a defense against bioterrorism. The web sites were notified that they must immediately remove all such claims or face prosecution for violating the Federal Trade Commission Act.¹⁰⁹

5. The Drug Enforcement Administration

The Drug Enforcement Administration (DEA) is the agency of the Department of Justice responsible for enforcing federal drug laws, including the Controlled Substances Act,¹¹⁰ which prohibits the dispensing of physically and psychologically addicting drugs ("controlled substances") without a prescription.¹¹¹ In recent months, there has been a marked rise in the availability of controlled substances on the Internet, leading to great concern among law enforcement officials that Internet pharmacies and other web sites

106. Rennert, 2002-2 Trade Cas. at I and II.

107. *Review of Consumer Safeguards*, *supra* note 15, at 29-30 (testimony of J. Howard Beales, Director of the Bureau of Consumer Protection of the FTC).

108. Linda Bren, *Agencies Team Up in War Against Internet Health Fraud*, FDA CONSUMER (Sept.-Oct. 2001), available at http://www.fda.gov/fdac/features/2001/501_war.html.

109. Press Release, FTC, FTC Cracks down on Marketers of Bogus Bioterrorism Defense Products: Agency Tells Web Site Operators Get Off the Net or Face Prosecution (Nov. 19, 2001), available at <http://www.ftc/opa/2001/11/webwarn.html>.

110. 21 U.S.C. §§ 801-966 (2000).

111. Some drugs, such as heroin, marijuana, and mescaline are deemed so dangerous that they cannot be purchased even with a prescription. 21 C.F.R. § 1308 (setting forth Schedules I-V of controlled substances, arranged according to their level of danger).

may undermine the United States' strict drug control laws.¹¹² In December 2003, a federal grand jury in Virginia indicted ten defendants for selling controlled substances on the Internet, and other prosecutions have been brought as well.¹¹³ In March 2004, the Bush Administration unveiled a National Drug Control Strategy focused on the growing problem of prescription drug abuse, including the wide-spread availability of prescription drugs via the Internet.¹¹⁴ This action represents an expansion of previous DEA regulatory "guidance" to prescribers, pharmacists, other federal and state government agencies, and the general public.¹¹⁵ In the DEA's view, the Internet has worked no change in federal drug laws, and thus all controlled substances must continue to be dispensed pursuant to a valid prescription, obtained from a legitimate physician-patient encounter.¹¹⁶ The DEA asserts that individuals may not receive controlled substances from foreign pharmacies unless they register with the DEA as controlled substances importers.¹¹⁷ Finally, the Justice Department has asserted that foreign Internet pharmacies selling controlled substances to United States consumers violate the 1988 United Nations Convention Against Illicit Traffic in Narcotics and Psychotropic Substances.¹¹⁸

6. Customs Service Enforcement

Of course, while the FDA and the DEA may threaten to prosecute consumers and foreign Internet pharmacies for unlawfully importing prescription drugs and controlled substances, unless these agencies can prevent shipment of the drugs at their source or

112. Alice Dembner, *The Internet Fix: Easy Narcotics*, BOSTON GLOBE, Mar. 24, 2002, at A1.

113. Jerry Markon, *Online Drug Ring Bust in Va. Charges Ten People in Three States; Federal Probe Alleges Six Million Doses Dispensed Illegally*, WASH. POST, Dec. 4, 2003, at B5.

114. Press Release, Off. of Nat'l Drug Pol'y, U.S. Drug Prevention, Treatment, Enforcement Agencies Take on "Doctor Shoppers," "Pill Mills" (Mar. 1, 2004), at <http://www.whitehousedrugpolicy.gov/news/press04/030104.html>.

115. Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. at 21,181. The DEA also inaugurated a pilot project to test an electronic system for the transmission of controlled substances prescriptions as an alternative to the current paper system, which could permit Internet pharmacies to more readily dispense controlled substances. Notice of Intent to Conduct Performance Verification Testing of Public Key Infrastructure Enabled Controlled Substance Orders, 67 Fed. Reg. 1507 (Jan. 11, 2002).

116. See Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. at 21,181.

117. Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. at 21,184.

118. *Enforcing the Laws*, *supra* note 104, at 28 (testimony of Ethan M. Posner, Deputy Associate Attorney General at the Department of Justice).

intercept them upon arrival in the United States, foreign Internet pharmacies threaten to undercut United States laws governing legal and illegal drugs. The federal government has developed a multi-pronged strategy. First, as noted above, the FDA has sent "cyberletters," the Internet version of a cease and desist order, to offshore pharmacies selling prescription drugs and other health products to American purchasers.¹¹⁹ Second, federal Customs officials are working with foreign governments to intercept shipments from Internet pharmacies at their source, by raiding warehouses and otherwise actively preventing goods from being shipped from a foreign nation to the United States.¹²⁰ Third, the Department of Justice is working with the Group of Eight nations¹²¹ and the Council of Europe,¹²² to develop new treaties,¹²³ as well as practical law enforcement strategies, to combat cybercrime, of which Internet pharmacies are one aspect.¹²⁴ At present, enhanced enforcement at the border cannot keep pace with the vastly increased importation of drugs made possible by the Internet.¹²⁵ Most drugs from foreign Internet pharmacies are not inspected, because searches must be done by hand and there are not enough postal inspectors and

119. Press Release, FDA, FDA Launches "Cyber" Letters Against Potentially Illegal, Foreign-Based Online Drug Sites (Feb. 2, 2000), *available at* <http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html>; *see* CENTER FOR DRUG EVALUATION AND RESEARCH, FDA, COMPLIANCE ACTIVITIES: "CYBER" LETTERS 2001, *at* <http://www.fda.gov/cder/warn/cyber/cyber2001.htm> (last visited Sept. 24, 2003).

120. Pear, *supra* note 95.

121. U.S. DEPT OF STATE, INT'L INFO. PROGRAMS, THE GROUP OF SEVEN AND THE GROUP OF EIGHT, *at* <http://usinfo.state.gov/topical/econ/group8/g8what.htm> (last visited Sept. 29, 2003). The Group of Eight nations include the seven major industrial powers (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States, also known as the Group of Seven) plus Russia. *Id.*

122. COUNCIL OF EUROPE, WHAT'S WHAT?, *at* http://www.coe.int/T/E/Communication_and_Research/Contacts_with_the_public/About_Council_of_Europe/what's_what/ (last visited Sept. 29, 2003). (explaining that the Council of Europe, headquartered in Strasbourg, France, includes the "44 democratic countries of Europe").

123. The Council of Europe approved a Convention on Cybercrime in November 2001, which has been signed by a number of the member states as well as the United States. However, in order for the convention to have legal effect five signatories must ratify it, and to date no signatory has done so. The Convention has been criticized for giving inadequate attention to privacy and civil liberties concerns, enhancing government powers of surveillance, and inappropriately criminalizing many intellectual property violations. *Enforcing the Laws*, *supra* note 104, at 28-29 (testimony of Ethan M. Posner, Deputy Associate Attorney General at the Department of Justice).

124. *Id.*

125. Spivak, *supra* note 10, at 1A.

Customs officials to do this.¹²⁶ Interception of drugs depends on a triage process based on guesswork and a calculation of rough odds that a package contains contraband.¹²⁷ Of course, neither controlled substances nor illegal prescription drugs are likely to be the top priority of the Postal Service or the Customs Service in the post-September 11th anti-terrorist environment. If current trends of heavy consumer use of foreign Internet pharmacies continue, along with the growth of a gray market in prescription medication imported from Canada and Mexico and the lack of sufficient law enforcement resources to intercept foreign pharmaceutical shipments, our current system of prescription drug regulation¹²⁸ to protect the health of consumers may well break down.¹²⁹

B. State Government Oversight

1. Regulation of Physicians and Other Health Care Professionals

In this country, the states' police power to regulate the practice of medicine, nursing, and other health professions has long been recognized.¹³⁰ States have shaped the practice of medicine through

126. *Drugs in the Mail*, *supra* note 42, at 10-51 (testimony of Kevin Dellicolli, Director Cyber Smuggling, Office of Investigations, U.S. Custom Service). Even though there was a 450% increase in the number of pharmaceutical seizures in 1999 compared to 1998, there are not enough people to inspect more than a small fraction of parcels that are shipped. In addition, greater cooperation and coordination between Customs and the United States Postal Service is needed. *Id.*

127. *Id.*

128. This includes patent law and other intellectual property rules.

129. Whether that is a good thing or not depends on whether one sees the FDA oversight as beneficent parentalism at its finest, providing needed public health protection, or a threat to individual autonomy and the free market system.

130. See, e.g., *State v. Doran*, 134 N.W. 53 (S.D. 1912) (upholding South Dakota's state police power to regulate the practice of medicine even as it declared a statute requiring non-resident "itinerant physicians" to pay a licensing fee unconstitutional); BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 92 (4th ed. 2001). States regulate the practice of medicine, nursing, physician assistants, pharmacists, and other health care professions. See, e.g., ARK. CODE ANN. § 17-92-301 (Michie 2002) (requiring licensing for pharmacists); N.Y. EDUC. LAW § 6524 (McKinney 2001 & Supp. 2003) (articulating the requirements for physician licensure); N.Y. EDUC. LAW § 6541 (McKinney 2001) (enumerating the requirements for registration as a physician assistant); N.Y. EDUC. LAW § 6805 (McKinney 2001) (enumerating the requirements for licensure as a pharmacist assistant); N.Y. EDUC. LAW § 6905 (McKinney 2001) (setting forth the requirements for licensure as a registered nurse). In this article, the terms "physicians" and "medicine" will be used generally as a shorthand form to refer to all health care professionals, despite the unfortunate oversimplification and perpetuation of hierarchy that this choice entails. Many states are moving, albeit slowly, to allow other health care providers to prescribe medication, both in recognition of these professionals' skills and competence, and as the fiscal

the common law process, developing standards for quality of care through medical malpractice¹³¹ and informed consent¹³² case law, as well as through statutory enactments¹³³ and the administrative processes of physician licensing and discipline.¹³⁴ In order to prescribe medication in a particular state, the physician must be licensed in that state.¹³⁵ The current regulatory system relies on physician oversight as an essential aspect of ensuring that drugs are safely and appropriately prescribed.¹³⁶ Congress has provided that a drug will be deemed "misbranded" if it is not given to a patient pursuant to a prescription written by a licensed health care provider.¹³⁷

In order for physician oversight to be meaningful, it is essential that the physician examine the patient before prescribing medication, except in those rare cases in which a patient with a pre-existing relationship with the physician has straightforward symptoms of a malady that can be described over the phone, diagnosed, and treated with a prescription phoned in to the patient's pharmacy. This crucial role for the physician has been undercut by those Internet pharmacies that provide for an online medical consultation through a patient questionnaire. This process is highly suspect, because the "correct" answers may be pre-checked,¹³⁸ there is

constraints of managed care lead HMOs and legislators to consider less costly options for the delivery of health care services. *See, e.g.*, LA. REV. STAT. ANN. § 913(3)(a), (5) (West 2003); *see also supra* note 70 (discussing other licensed prescribers).

131. *See e.g.*, Hall v. Hilbun, 466 So. 2d 856, 869-73 (Miss. 1985) (comparing local and national standards for competent physicians).

132. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 790 (D.C. Cir. 1972) (holding that physicians must provide patients with information regarding the potential risks and benefits of proposed courses of treatment).

133. *See, e.g.*, N.Y. PUB. HEALTH LAW. § 2805-d (McKinney 2001 & Supp. 2003) (establishing the elements of a cause of action for lack of informed consent).

134. *See, e.g.*, N.Y. EDUC. LAW § 6530 (McKinney 2001 & Supp. 2003) (defining professional misconduct for health care professionals).

135. *See, e.g.*, ARK. CODE ANN. § 17-92-302 (Michie 2002). *But see* IOWA ADMIN. CODE r. 441-105.9 (2003) (permitting an out-of-state physician to prescribe drugs to Iowa residents if licensed in the state where the physician practices, apparently codifying the decision of the Iowa Supreme Court in *State v. Rasmussen*, 213 N.W.2d 661, 666 (Iowa 1973) (holding that an Iowa statute limiting prescribing authority to Iowa-licensed physicians was preempted by the Federal Controlled Substances Act of 1970, 21 U.S.C. §§ 801-971 (2000)). *Cf.* Nichols v. Bd. of Pharmacy, 657 P.2d 216 (Or. Ct. App. 1983) (rejecting the reasoning of *Rasmussen* in the course of upholding disciplinary action against a pharmacist who filled prescriptions for controlled substances written by out-of-state physicians, in violation of an Oregon statute).

136. *See supra* notes 65-91 (discussing the physician's role as clinical expert and the Learned Intermediary Rule).

137. 21 U.S.C. § 353(b)(1).

138. *See supra* note 30 and accompanying text; *see also* Felice J. Freyer, *Doctor Disciplined for Prescribing Drugs Online*, PROVIDENCE J. BULL., Nov. 3, 2001, at A-03; Press Release, Pa. Att'y Gen., AG Fisher Sues Several Online Companies, Pharmacies

no way for an online physician to verify the patient's vital signs, symptoms, and overall medical condition to ascertain if the medication which is sought should be prescribed; and, in most cases, the physician is paid only if the medication sought is prescribed.¹³⁹

In response to the concern about physicians' online prescribing, the Federation of State Medical Boards has issued a report reiterating that physicians who prescribe to a patient without taking a history, conducting a physical examination, and discussing the risks and benefits of the proposed treatment with the patient are engaging in substandard medical practice.¹⁴⁰ In addition, the report recommends that physicians maintain an accessible contemporaneous medical record of their patient encounters and review the efficacy of the treatment afterwards, to ensure that minimal professional standards are satisfied.¹⁴¹ To give teeth to these recommendations, the Federation has urged state medical boards to: 1) adopt policies that specify that prescribing without these safeguards is unprofessional conduct; 2) gather relevant information about physicians' web-based activities at the time of licensing and license renewal; and 3) require physicians to disclose sufficient identifying, licensing, and conflict of interest information on their websites to protect patients.¹⁴² More recently, the eRisk Working Group for Healthcare, a consortium of medical malpractice insurers and professional organizations, including the AMA and the Federation of State Medical Boards, has developed Guidelines to govern physician-patient interactions over the Internet, including the requirement that all "substantive patient-physician email occur solely within the context of a pre-existing [professional] relationship."¹⁴³

More than half the states have adopted at least some of these recommendations, either by statute or by medical licensing board

and Doctors Claiming Illegal Sales of Prescription Drugs (May 3, 2000), at <http://www.attorneygeneral.gov/press/release.cfm?p=42E56EFE-E948-11D3-8DEA0060972D7515> (describing pre-marked answers).

139. See *supra* note 35 and accompanying text; Oscar S. Cisneros, *A Prescription for Trouble*, WIRED NEWS, Aug. 9, 2000, at <http://www.wired.com/news/politics/0,1283,20310.html> (describing the Osteopathic Medical Board of California's disciplinary actions against Dr. James DeYarman, who prescribed Propecia to visitors to his website, Drpropecia.com, without examining them); see also *Stovall*, 38 P.3d at 707.

140. SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS, *supra* note 44.

141. *Id.*

142. *Id.*

143. P.R. Newswire, *New Guidelines Remove Risk from Doctor-Patient E-Mail* (Dec. 4, 2002) (on file with author).

decision.¹⁴⁴ Nevada, for example, has enacted a law which prohibits licensed health care professionals (either within or outside Nevada) from prescribing a drug if they have not examined the patient within the previous six months and either know or have reason to know that the prescription will be delivered to the patient via an Internet pharmacy that is not licensed in Nevada.¹⁴⁵ In addition, health care professionals who violate this statute and prescribe a Schedule I controlled substance or any other drug which causes substantial bodily harm or death to the recipient can be charged with a felony and imprisoned for three to fifteen years and be fined up to \$100,000.¹⁴⁶ California has also enacted a law that requires physicians to examine patients before prescribing any medication to be delivered via the Internet.¹⁴⁷ Texas has adopted a similar policy through the actions of the State Board of Medical Examiners.¹⁴⁸

More than twenty states have commenced disciplinary proceedings against physicians who have engaged in Internet or telephone prescribing without conducting a physical examination or otherwise forming a physician-patient relationship.¹⁴⁹ Although

144. Press Release, Quarles & Brady LLP, Health Law Update: May You Prescribe if You Have Not Physically Examined the Patient? (Oct. 2001), at http://www.quarles.com/up_heal3.asp (identifying the following states as having adopted some recommendations: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Kansas, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Texas, Virginia, Washington, and West Virginia).

145. NEV. REV. STAT. ANN. § 453.3643(1)-(2) (Michie Supp. 2001).

146. *Id.* § 453.3643(6).

147. "No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices . . . on the Internet for delivery to any person in this state, without a good faith prior examination and medical indication therefore, except as authorized by Section 2242 [enumerating certain limited exceptions]." CAL. BUS. & PROF. CODE § 2242.1 (West 2003). California has launched several disciplinary actions under this law. See Suzanne Bohan, *State Fines Physicians for Prescribing on Net*, OAKLAND TRIB., Feb. 11, 2003; see also *infra* text accompanying note 149.

148. TEX. STATE BD. OF MED. EXAMINERS: INTERNET PRESCRIBING POLICY (Dec. 8-11, 1999), available at <http://www.tsbme.state.tx.us/guidelines/ipp.htm>; see also Mary Ann Roser, *Long-Distance Doctor Under Texas Scrutiny*, AUSTIN AM.-STATESMAN, June 5, 2001, at A1 (reporting on the first administrative challenge to the policy that found that it was unprofessional for a doctor "to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship," which does not include a relationship established over the phone or on the Internet) (quoting State Board Official).

149. See, e.g., In the Matter of Daniel Lee Thompson, M.D. (Sept. 11, 2000), available at <http://www5.state.oh.us/med/formala/35049547.pdf> (enter of order following an Ohio doctor's voluntary surrender of his license to practice medicine for failure to meet with his Internet patients before prescribing pharmaceuticals); Freyer, *supra* note 138, at 52; Tyler Chin, *Rx Surveillance: Watch Out for Prescribing Over the*

initially many regulators trod lightly, resolving the proceedings if the physician agreed to stop prescribing to Internet "patients,"¹⁵⁰ the trend is toward stricter enforcement once legislation is enacted that makes clear the state's policy. The California Medical Board recently made headlines when it permanently revoked the license of a California physician who had written more than 11,000 prescriptions for patients via the Internet without ever examining them, and levied a fine of \$48 million against six out-of-state physicians, who together issued nearly 2,000 prescriptions to Internet pharmacy consumers.¹⁵¹

In other cases, states have enforced long-standing laws requiring physicians to be licensed in that state in order to prescribe medications for patients residing there.¹⁵² In practice, such prosecutions are extremely difficult and resource-intensive, as each state must track down the out-of-state physician who is prescribing on the Internet, and then initiate disciplinary proceedings and seek injunctive relief prohibiting such conduct in the future, working with its own medical licensing board as well as the board of the physician's home state.

2. Regulation of Pharmacists and Pharmacies

Like physicians, pharmacists and pharmacies must be licensed by the state in which they are physically located in order to dispense

Internet, AMEDNEWS.COM, Oct. 22-29, 2001, at http://www.ama-assn.org/sci-pubs/amnews/pick_011tesa1022.htm (discussing California's efforts to prevent physicians from prescribing via the internet without examining their patients); *Minnesota Physician Reprimanded for Online Prescribing*, at <http://www.ihealthbeat.org> (last visited Sept. 16, 2003) (describing the actions of the North Carolina Medical Board and the Minnesota Pharmacy Board taken against a Minnesota physician accused of online prescribing).

150. See, e.g., *Doctor Avoids Suspension If Rules Met*, MORNING STAR, Jan. 18, 2002, at Local/State 3B; Douglas E. Beeman, *Doctor Ordered Not To Practice for Now*, PRESS ENTERPRISE, May 3, 2002, at B07.

151. Bohan, *supra* note 147, at 55.

152. See U.S. GEN. ACCT. OFF., REPORT TO THE SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, COMM. ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES, PRESCRIPTION DRUGS: STATE MONITORING PROGRAMS PROVIDE USEFUL TOOL TO REDUCE DIVERSION (May 2002), at <http://www.gao.gov/new.items/d02634.pdf>. However, at least one state, Iowa, has declared, long before the advent of Internet pharmacies, that out-of-state physicians may prescribe to Iowa residents, and Iowa pharmacists may fill these prescriptions, as a necessary aspect of federalism and comity with the Federal Controlled Substances Act. See *supra* note 135; see also AMA BD. OF TR. REP. 7-A-03, *supra* note 44 (recognizing that many states permit pharmacists to fill prescriptions written by out-of-state physicians for patients who were examined by those physicians when the patient visited their offices in the state where they are licensed); accord MICH. COMP. LAWS § 333.17751(2) (2003) (authorizing Michigan pharmacists to fill prescriptions of out-of-state physicians under certain limited circumstances).

medication.¹⁵³ Recently, in response to widespread publicity concerning the increased use of Internet pharmacies, states have adopted a variety of regulatory schemes directed at Internet pharmacies, in order to enhance public protection by expanding government oversight. A few states have enacted new statutes, some have taken enforcement actions pursuant to existing statutes, while others have adopted new policies via regulation or pharmacy board action.

Several states have adopted stringent new statutes. California forbids pharmacists and Internet pharmacies from dispensing drugs unless they are filling prescriptions that are the product of "a good faith prior [medical] examination," effectively establishing a duty to inquire about the nature of the physician-patient relationship that led to the prescription.¹⁵⁴ The California statute provides that:

No person . . . shall dispense . . . dangerous drugs or devices . . . on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person . . . either *knew or reasonably should have known* that the prescription was not issued pursuant to a good faith prior examination.¹⁵⁵

This choice of a negligence (should have known) standard for pharmacist discipline is very expansive, and makes it much easier for prosecutors and/or state licensing boards to succeed in reining in Internet pharmacies.¹⁵⁶ Nevada has also taken a stringent approach, making it illegal for a person who is not a Nevada-licensed pharmacist to dispense drugs via the Internet.¹⁵⁷

Other states have enacted statutes that require Internet pharmacies to register with that state and make appropriate on-line disclosures, but defer to the board of pharmacy in the state where the Internet pharmacy is licensed before taking enforcement action. Illinois, New Hampshire, and New York have statutes of this type, which demand that all Internet pharmacies dispensing medication to their residents: 1) be licensed in some state; 2) disclose all relevant licensing information on their websites, as well as the identity and addresses of corporate officers; 3) maintain adequate records of the

153. See, e.g., ARK. CODE ANN. § 17-92-301 (Michie 2002) (governing the licensing of pharmacists); see also MICH. COMP. LAWS § 333.17751(2) (2001) (authorizing Michigan pharmacists to fill prescriptions of out-of-state physicians under certain limited circumstances).

154. CAL. BUS. & PROF. CODE § 4067 (2001).

155. *Id.* (emphasis added); see also MASS. REGS. CODE tit. 247, § 901 (2003); NEV. REV. STAT. ANN. 453.3638 (Michie Supp. 2001); W. VA. CODE § 30-5-3 (2002).

156. See *infra* notes 162-66 and accompanying text (describing actions taken by Texas and California authorities).

157. NEV. REV. STAT. ANN. 453.3643 (Michie Supp. 2001).

drugs dispensed; and 4) provide a minimum of forty hours a week of toll-free telephone service to consumers.¹⁵⁸ If these requirements are met, these three states will defer initially to the regulatory authority of the Internet pharmacy's home state and will only undertake disciplinary action or other prosecution if the home state fails to act.

More than forty states have enacted statutes that require out-of-state pharmacies, including Internet pharmacies, to receive a permit from the state board of pharmacy.¹⁵⁹ At least one state, South Carolina, requires each out-of-state pharmacy to designate an in-state registered agent for service of process, providing that South Carolina's secretary of state shall be designated as the default service recipient if the pharmacy fails to designate an agent.¹⁶⁰

Still other states have dealt with Internet pharmacies through board of pharmacy action, such as the adoption of policies that prohibit the dispensing of medication without a prescription obtained from a legitimate physician-patient encounter. However, like statutes, the promulgation of new policies can be politically complicated, cumbersome, and time-consuming.¹⁶¹

An increasing number of states have brought disciplinary action against individual pharmacists and Internet pharmacies who have dispensed drugs, particularly controlled substances, without any prescription, or have dispensed pursuant to a prescription which the pharmacist either knew or *should have known* was not the result of a proper physician-patient encounter.¹⁶² The California Board of Pharmacy made headlines in May 2002 when it invoked its new statutory authority¹⁶³ to impose an \$88.7 million dollar fine against a Los Angeles pharmacy and two of its pharmacists for filling

158. ILL. COMP. STAT. § 85/16a (2001); N. H. REV. STAT. ANN. § 318:37 (Supp. 2002); N.Y. COMP CODES R. & REGS. tit. 8, § 63.6 (2003).

159. See, e.g., KY. REV. STAT. ANN. § 315.0351 (Michie 2001) (requiring out of state pharmacies to register with Kentucky authorities, and have records of all prescriptions readily available); see also, *supra* note 143-44.

160. S.C. CODE ANN. § 40-43-83(B) (2001). This mechanism for establishing jurisdiction over an out-of-state pharmacy might raise due process concerns, discussed *infra* Part IV.A.

161. See, e.g., *Texas: State Board Bars Pharmacists from Filling Internet-Based or Telephoned Prescriptions*, Health Care Pol'y Rep. (BNA) (June 13, 2001); Bob LaMendola, *Plan Would Curb Online Drug Sales*, FLORIDA SUN-SENTINEL, June 12, 2002, at 1B; Dorschner, *supra* note 10, at 1C (describing the slow progress of Florida's Board of Pharmacy in adopting a new rule).

162. CAL. BUS. & PROF. CODE § 4067 (2003). The Texas Board of Medicine has adopted a similar policy, which declares that it is unprofessional conduct for a doctor "to initially prescribe any dangerous drugs or controlled substances without establishing a proper physician-patient relationship," which does not include a relationship established over the phone or on the Internet. Roser, *supra* note 148, at A1.

163. CAL. BUS. & PROF. CODE § 4067.

prescriptions which the Board said the pharmacists should have known were not written pursuant to a legitimate physician-patient encounter.¹⁶⁴ The Texas Board of Pharmacy invoked a similar theory in initiating disciplinary proceedings against a San Antonio pharmacy and one of its pharmacists for filling prescriptions from a physician who did not physically examine the patients for whom he prescribed. The Texas Board asserted that the large quantity of prescriptions written by this physician should have alerted the pharmacy that something was amiss.¹⁶⁵ Interestingly, the same pharmacy had been the subject of a successful civil suit brought by the Missouri Attorney General three years earlier, which resulted in an injunction against the pharmacy dispensing to customers in Missouri.¹⁶⁶ This incident demonstrates the extraordinary resilience of Internet pharmacies, whose operations can be “shut down” in one state while they continue to do business in other jurisdictions.

3. Civil Actions

In addition to assisting in disciplinary actions brought against physicians and pharmacists involved in Internet prescribing and dispensing, several state attorneys general have initiated civil suits, in some cases using state consumer protection statutes in a creative manner. In settlement of these cases, Attorneys General of Arizona, Missouri, New Jersey, Pennsylvania, and Texas have obtained consent decrees that enjoin doctors and pharmacists (typically from out-of-state) from advertising, prescribing and/or dispensing medications to in-state consumers, unless the physicians or pharmacists are licensed in those states. Occasionally, the attorneys general have obtained significant money damages, but more typically, they have attained only modest civil penalties, restitution of online “consultation” fees to consumers, and repayment of

164. Christopher Heridia, *2 L.A. druggists draw \$88.7 million fine*, S.F. CHRON., May 29, 2002, at A1. Other states have acted to impose relatively minor sanctions. *See, e.g.,* Tammie Smith, *Roanoke Pharmacist Disciplined; She Filled Internet Prescriptions For Patients She Had Never Met*, RICHMOND TIMES DISPATCH, July 23, 2002, at B-2; *Virginia Pharmacist Disciplined for Filling Online Prescriptions*, IHEALTHBEAT.COM, July 26, 2002 (on file with author) (describing the Virginia Board of Pharmacy’s action against Tommie Jo Nichols, who was reprimanded, placed on three years’ probation and fined \$12,000 for “filling ‘dozens’ of prescriptions of diet pills over the Internet”).

165. FEDERAL & STATE ENFORCEMENT ACTIVITIES, ARENT FOX, at <http://www.arentfox.com/quickGuide/businessLines/telemed/e-health-telemed/e-health-enforcementaction/e-health-enforcementaction.html> (last visited Sept. 26, 2003).

166. Press Release, Mo. Att’y Gen., Nixon Obtains Injunction Against Texas Pharmacy to Stop Illegal Drug Sales; Restitution, Penalties Ordered (Oct. 25, 1999), at <http://www.ago.state.mo.us/102599.htm> (describing a permanent injunction prohibiting the pharmacy from doing business in Missouri unless specified regulatory requirements were met).

investigative costs to the state.¹⁶⁷ Arizona successfully employed a novel legal theory, alleging that an Internet pharmacy “misrepresented to consumers that it was safe to take [certain medications] without first having a doctor conduct a full medical examination,” in violation of the state’s consumer fraud act.¹⁶⁸

In the only published state court opinion on Internet-based drug prescription and sales, *Kansas v. Confimed.Com, L.L.C.*,¹⁶⁹ the Kansas Supreme Court awarded the Kansas Attorney General a pyrrhic victory. The case began with a “sting” operation by the state attorney general’s office against an out-of-state physician, who charged a \$75 fee for an Internet “consultation,” and then dispensed Viagra to a minor and a woman, without conducting a physical examination or offering further treatment oversight.¹⁷⁰ The Court affirmed the trial court’s injunction prohibiting the physician from prescribing or dispensing medicine within Kansas, but rebuffed the Attorney General’s charge that the doctor’s conduct was unconscionable under the Kansas Consumer Protection Act.¹⁷¹ The court found that under these circumstances, there was not unequal bargaining power between the parties or any indicia of unconscionability, and because it *was* a sting operation, the minor was unlikely to use the Viagra he received.¹⁷² Thus, the Kansas Supreme Court served notice that in Kansas even though a health practice affecting consumers is undesirable or unwise, it does not automatically become unconscionable.

While many state attorneys general have been successful in obtaining injunctive relief against individual physicians, pharmacists, and pharmacies, they have also expressed concern that the time and expense of investigating and prosecuting these cases, combined with the limited jurisdictional reach of even successful lawsuits, leave them with an inadequate response to illegitimate Internet prescribing and dispensing.¹⁷³ Because most of the suits have

167. *Arizona: State Settles Consumer Fraud*, *supra* note 67, at 580; *Pennsylvania Bars Online Pharmacy from Doing Business with State Residents*, Health Law Pol’y Rep. (BNA), at 580 (Apr. 12, 2001); *New Jersey: Three Online Pharmacies to Pay Penalties, Stop Advertising, Selling Drugs in State*, Health Law Pol’y Rep. (BNA), at 1801 (Nov. 6, 2000); Press Release, Tex. Att’y Gen., Cornyn Gets Judgment Against Online Company, available at <http://www.oag.state.tx.us/newspubs/releases/2001/20010409renew.html>.

168. *Arizona: State Settles Consumer Fraud*, *supra* note 67.

169. 38 P.3d 707 (Kan. 2002).

170. *Id.* at 709-10.

171. *Id.* at 710-15.

172. *Id.* at 714-15 (interpreting the Kansas Consumer Protection Act, KAN. STAT. ANN. §§ 50-623-643 (2002)).

173. *Review of Consumer Safeguards*, *supra* note 15, at 141-50 (testimony of Richard Blumenthal, Attorney General of Connecticut); *see also* Press Release, Kan.

concluded with consent decrees or other court orders prohibiting future transactions with consumers in that state but without significant money payments, state authorities may conclude that the investment of scarce law enforcement and health agency resources is not worthwhile, particularly in a time of mounting state budget deficits. The National Association of Attorneys General has asked for Congressional action, seeking not to "federalize" the substantive law governing Internet pharmacies, but to authorize each state attorney general to sue in federal court, which would permit nationwide injunctive relief if the suits are successful, comparable to that available under the federal Telemarketing and Consumer Fraud and Abuse Prevention Act.¹⁷⁴

In addition to suits brought by the states, private litigants injured by a transaction with an Internet pharmacy have state common law and statutory remedies available. These include contract and tort remedies for fraud and misrepresentation,¹⁷⁵ for breach of warranty under the Uniform Commercial Code,¹⁷⁶ or for malpractice by the health care professional who prescribed or dispensed a drug online. However, just as with actions brought by state attorneys general, the practical problems of physically locating an Internet prescriber or pharmacist, as well as jurisdictional hurdles, may inhibit the bringing of suit.¹⁷⁷ Plaintiffs may also be discouraged by the limited remedies available for breach of contract or violation of consumer protection laws, which may persuade many individuals, particularly those whose damages are confined to the

Att'y Gen., Attorney General Stovall Testifies Before Congress on Internet Pharmacies (March 21, 2000), at <http://www.accesskansas.org/ksag/contents/news-releases/2000news/senate-test.htm>.

174. 15 U.S.C. §§ 6101-6108 (2000); see *Review of Consumer Safeguards*, *supra* note 15, at 141-50 (testimony of Richard Blumenthal, Attorney General of Connecticut); cf. *Online Pharmacies: State Attorneys General Still Seeking Internet Policy Consensus*, *Leader Says*, Health Law Pol'y Rep. (BNA) (Jan. 26, 2001).

175. Tort remedies permit recovery for damages caused by the misrepresentation or fraud, while the standard contract remedy is rescission, or undoing of the contract. See, e.g., JOHN D. CALAMARI & JOSEPH M. PERILLO, *CONTRACTS* §§ 9-13 to 9-24, at 355-78 (3d ed. 1987); E. ALLAN FARNSWORTH, *CONTRACTS* § 4.15, at 472-77 (2nd ed. 1998); W. PAGE KEETON, ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 105, at 725-27 (5th. ed. 1984). For a purchaser of drugs via an Internet pharmacy whose injury (physical harm or death) is greater than the mere non-receipt of the drug ordered, damages for breach of warranty will prove highly inadequate. For such a consumer, the only remedy is suit for professional malpractice.

176. U.C.C. §§ 2-312 to 2-318 (2002). The Uniform Commercial Code (U.C.C.) provides a variety of remedies for breach of warranty, including the implied warranty of merchantability, § 2-314, and warranty of fitness for a particular purpose, § 2-315, but none include recovery for consequential damages.

177. See *infra* Part IV.A, C (discussing these jurisdictional and enforcement barriers).

loss of the value of the bargain or other relatively minor harm, that it is not worth the effort to sue.¹⁷⁸

IV. OBSTACLES TO SUCCESSFUL ACTION AGAINST INTERNET PHARMACIES

A. *Civil Jurisdiction*

Lack of jurisdiction is a potential obstacle to successful civil suit against a foreign Internet pharmacy. As every civil procedure student knows, a state court may not exercise personal jurisdiction over an out-of-state defendant unless that defendant has minimum contacts with the forum state.¹⁷⁹ Thus, the issue in Internet pharmacy cases is whether the defendant's activities in the forum state, carried out through the Internet or other means, support a court's exercise of jurisdiction consistent with principles of due process.¹⁸⁰ Jurisdiction may be either "general," predicated on a defendant's "continuous and systematic" contacts with the forum state,¹⁸¹ or "specific," i.e., when the cause of action is based on the defendant's contacts with the forum.¹⁸² Most suits brought against

178. See Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 817 (2001) (discussing the reasons that private civil actions may not be filed in Internet child pornography cases, and why criminal actions brought by the states might be preferable).

179. The same rules apply to federal courts in which jurisdiction is asserted based on diversity of citizenship or federal question jurisdiction. See, e.g., *Arrowsmith v. United Press Int.*, 320 F.2d 219, 222-23 (2d Cir. 1963).

180. Most courts and scholars have analyzed Internet jurisdiction cases within the Supreme Court's due process framework. See, e.g., *Cybersell, Inc. v. Cybersell, Inc.*, 130 F.3d 414 (9th Cir. 1997); Roger J. Johns, Jr. & Anne Keaty, *Caught in the Web: Websites and Classic Principles of Long Arm Jurisdiction in Trademark Infringement Cases*, 10 ALB. L.J. SCI. & TECH. 65 (1999). However, at least one commentator, Allan Stein, has suggested that the jurisdictional limits of state power in such cases might be better analyzed under the dormant commerce clause. Allan R. Stein, *Frontiers of Jurisdiction: From Isolation to Connectedness*, 2001 U. CHI. LEGAL F. 373, 389-92; see also *infra* Part IV.C.

181. In *Gorman v. Ameritrade Holding Corp.*, 293 F.3d 506 (D.C. Cir. 2002), the court observed in dicta, that it is possible that a defendant's practice of doing business over the Internet could actually support a plaintiff's claim of general jurisdiction, because a website that permits real-time transactions between the defendant and residents of the forum at any hour of the day has the potential for "continuous and systematic" contacts that are much greater than those of a traditional foreign defendant. *Id.* at 513.

182. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984). A finding of specific jurisdiction generally involves a three-pronged test: "(1) the defendant must have sufficient 'minimum' contacts with the forum state, (2) the claim asserted against the defendant must arise out of those contacts, and (3) the exercise of jurisdiction must be reasonable." *Zippo Manufacturing Co. v. Zippo Dot Com, Inc.*, 952 F. Supp. 1119, 1122-23 (W.D. Pa. 1997).

foreign Internet pharmacies are likely to be based on a theory of specific jurisdiction because of the defendant's acts within the state vis-à-vis the plaintiff. Plaintiffs who are state attorney generals would seek injunctive relief, as well as fines, against a defendant's unlawful business activity in the state, while individual plaintiffs would seek damages in tort or contract based upon prescription drug sales.

While none of the published cases involving Internet pharmacies has yet raised the question of jurisdiction, plaintiffs should be successful in asserting jurisdiction under traditional Supreme Court due process analysis and recent lower court decisions involving jurisdiction based on Internet "conduct." Since *International Shoe Co. v. Washington*,¹⁸³ the Supreme Court has made it clear that for a court to exercise specific jurisdiction pursuant to a state long-arm statute in a dispute with a foreign defendant, the defendant must have had sufficient minimum contacts with the forum state that subjecting the defendant to litigation there comports with "traditional [notions] of fair play and substantial justice' embodied in the Due Process clause of the Fourteenth Amendment."¹⁸⁴ Over the last fifty years, the Court has noted that expanding interstate commerce and improved transportation and communication make it increasingly reasonable to exercise jurisdiction over an out-of-state defendant¹⁸⁵ if the defendant has "purposefully availed" itself of the benefits of being in the forum jurisdiction.¹⁸⁶ Applying this notion of purposeful availment to contract disputes in diversity cases, the

183. 326 U.S. 310 (1945).

184. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 464 (1985) (quoting *International Shoe*, 326 U.S. at 320). The Court in *Burger King* held that a Michigan accountant who entered into a franchise relationship with Burger King, a Florida corporation could, by reason of a contractual choice of law clause and the course of negotiations between the parties, expect to be subject to suit in Florida. *Id.* at 462-63. Thus, jurisdictional analysis is formally a two-step process: first determine whether the state's long-arm statute permits the invocation of jurisdiction, and second, determine whether the assertion of jurisdiction under that statute comports with due process. In practice, the two steps are conflated, as many states' long-arm statutes explicitly provide that jurisdiction is to be found "to the fullest extent permitted by the due process clause of the Fourteenth Amendment to the United States Constitution." See, e.g., UTAH CODE ANN. § 78-27-22 (2003); see also 735 ILL. COMP. STAT. ANN. 5/2-209(c) (West 2003) (providing that, "[a] court may also exercise jurisdiction on any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States").

185. See *McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 222-23 (1957); cf. *Asahi Metal*, 480 U.S. at 108-11 (stating that "minimum contacts must be based on a . . . [purposeful] act of the defendant"); *Shaffer v. Heitner*, 433 U.S. 186, 211-12 (1977) (holding that due process demands that the existence of *in rem* jurisdiction must be evaluated according to the minimum contacts approach of *International Shoe*.).

186. *Hanson v. Denckla*, 357 U.S. 235, 253 (1958).

Court has “emphasized that parties who ‘reach out beyond one state and create continuing relationships and obligations with citizens of another state’ are subject to regulation and sanctions in the other State for the consequences of their activities.”¹⁸⁷ Alternatively, if the defendant’s product causes injury within a state, and the defendant has otherwise “deliver[ed] its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State,” jurisdiction may exist.¹⁸⁸ Taken together, the Supreme Court’s decisions emphasize two concepts at the heart of appropriate exercise of jurisdiction: choice to participate in business in the forum state and foresight of the likelihood of being sued there.¹⁸⁹

Two widely followed decisions¹⁹⁰ have established the parameters of jurisdictional analysis in Internet cases: *Cybersell, Inc. v. Cybersell, Inc.*,¹⁹¹ and *Zippo Manufacturing Co. v. Zippo Dot Com*,

187. *Burger King Corp.*, 471 U.S. at 473 (quoting *Travelers Health Ass’n v. Virginia*, 339 U.S. 643, 647 (1950)).

188. *World-Wide Volkswagen Corp.*, 444 U.S. at 298. As the Court explained in that case:

the foreseeability that is critical to due process analysis is not the mere likelihood that a product will find its way into the forum State. Rather, it is that the defendant’s conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.

Id. at 297. In *World-Wide Volkswagen Corp.*, the Court applied this view of foreseeability to hold that where a regional automobile wholesale distributor and local automobile dealer did not sell any vehicles in Oklahoma, the forum state, and had not made any effort to establish business relationships there, the exercise of jurisdiction was improper. *Id.* at 298-99. The Court rejected the argument that because it was remotely foreseeable that a product sold in one state, New York, could be moved to Oklahoma and subsequently become involved in an accident there, jurisdiction in a products liability suit was appropriate. *Id.* In contrast, in *Calder v. Jones*, 465 U.S. 783 (1984), the Supreme Court upheld the exercise of jurisdiction by a California court over two Florida defendants on the theory that the defendants could anticipate that the tortious effects of their allegedly defamatory story about plaintiff would be felt in California. *Id.* at 788-89. The court found that the defendants’ “intentional, and allegedly tortious, actions were expressly aimed at California,” *id.* at 790, given that the newspaper had its largest circulation there and plaintiff, an actor, lived and worked in California, where the entertainment industry was centered. *Id.* at 789-90.

189. *World-Wide Volkswagen Corp.*, 444 U.S. at 295-97; see also N.Y. C.P.L.R. § 302(a)(3)(ii) (McKinney 2001) (limiting the jurisdiction exercised by New York courts to cases in which persons “expect[] or should reasonably expect the [tortious] act to have consequences in the state and in addition derive substantial revenue from interstate . . . commerce”). In *Bensusan Restaurant Corp. v. King*, 126 F.3d 25 (2d Cir. 1997), the court concluded that even apart from due process concerns, the New York statute could not support the exercise of long-arm jurisdiction over a Missouri defendant whose website advertised for a local jazz club. *Id.* at 29.

190. See, e.g., *Toys “R” Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 452-55 (3d Cir. 2003) (citing *Cybersell, Zippo*, and other cases that have followed them).

191. 130 F.3d 414 (9th Cir. 1997).

*Inc.*¹⁹² In *Cybersell*, an Arizona Internet service provider brought a trademark infringement suit in federal court in Arizona against an identically named Florida corporation, based on the defendant's use of the same name on its website.¹⁹³ The Ninth Circuit held that the Arizona court could not exercise jurisdiction over the Florida corporation based solely on what it deemed to be an "essentially passive" website,¹⁹⁴ concluding that the plaintiff had not shown that the Florida corporation had reached out "to encourage people in Arizona to access its site" or offered "evidence that any part of its business . . . was sought or achieved in Arizona."¹⁹⁵ The court's analysis relied significantly on the decision of the federal district court for Western Pennsylvania in *Zippo*.¹⁹⁶

In *Zippo*, Zippo Manufacturing Company, a maker of cigarette lighters, sued for trademark infringement against a similarly named California Internet news service provider, which had registered the domain names "zipp.com," "zippo.net," and "zipponews.com."¹⁹⁷ The court found that the plaintiff had demonstrated the minimum contacts necessary to support its jurisdiction, observing that "the likelihood that personal jurisdiction can be constitutionally exercised is directly proportionate to the nature and quality of commercial activity that an entity conducts over the Internet."¹⁹⁸ The court recognized a "sliding scale" of personal jurisdiction contacts, with at least three discrete points:

At one end of the spectrum are situations where a defendant clearly does business over the Internet. If the defendant enters into contracts with residents of a foreign jurisdiction that involve the knowing and repeated transmission of computer files over the Internet, personal jurisdiction is proper. At the

192. 952 F. Supp. 1119 (W.D. Pa. 1997).

193. *Cybersell*, 130 F.3d at 415. When the Florida corporation launched its website, the plaintiff's website was "down" for reconstruction and its application to register "Cybersell" as a service mark had not yet been granted. *Id.*

194. Although the court labeled the web site as "passive," this was not entirely accurate, as the website permitted a viewer to send his "name and address and an indication of interest" in the web design services offered by the defendant. *Id.* at 419.

195. *Id.* The court also observed that:

No Arizonan except for [the plaintiff] "hit" Cybersell FL's web site. There is no evidence that any Arizona resident signed up for Cybersell FL's . . . services. It entered into no contracts in Arizona, made no sales in Arizona, received no telephone calls from Arizona, earned no income from Arizona, and sent no messages over the Internet from Arizona . . . No money changed hands on the Internet from (or through) Arizona.

Id.

196. 952 F. Supp. at 1119.

197. *Id.* at 1121.

198. *Id.* at 1124 (cited with approval in *Cybersell*, 130 F.3d at 419).

opposite end are situations where a defendant has simply posted information on an Internet Web site which is accessible to users in foreign jurisdictions. A passive Web site that does little more than make information available to those who are interested in it is not grounds for the exercise [of] personal jurisdiction. The middle ground is occupied by interactive Web sites where a user can exchange information with the host computer. In these cases, the exercise of personal jurisdiction is determined by examining the level of interactivity and commercial nature of the exchange of information that occurs on the Web site.¹⁹⁹

Applying this rubric, the *Zippo* court held that by accepting orders and entering into contracts with Pennsylvania residents who visited its web site,²⁰⁰ the defendant had consciously chosen to do business in Pennsylvania, and thus had “clear notice” that it could be sued there.²⁰¹

Thus, following the principles of *Cybersell* and *Zippo*, one might expect that establishing specific jurisdiction over a foreign Internet pharmacy would be straightforward.²⁰² The very *raison d'être* of Internet pharmacies is to enter into commercial transactions²⁰³ to sell drugs to buyers in various states. Accordingly, an Internet pharmacy that solicits, accepts, and fills consumers' orders to purchase prescription drugs would satisfy the purposeful availment test by

199. *Id.* at 1124 (citations omitted).

200. *Zippo.Dot com, Inc.* entered into contracts with approximately 3,000 individuals and seven access providers. *Id.* at 1126.

201. *Id.* (quoting *World-Wide Volkswagen*, 444 U.S. 286 at 297).

202. In the Internet context, the only realistic obstacle to successful assertion of jurisdiction, which was not litigated in *Cybersell* or *Zippo*, is a defendant's use of a contractual choice of law or forum selection clause. The Supreme Court has upheld the use of such clauses, *The Bremen v. Zapata Off-Shore Co.*, 407 U.S. 1, 15 (1972), and their use is widespread, Ray August, *International Cyber-Jurisdiction: A Comparative Analysis*, 39 AM. BUS. L.J. 531, 566 (2002). They are recommended by corporate counsel, Beth I. Boland & Diane Gwin, *The Internet and Personal Jurisdiction Under the Constitution: In What State, Exactly, Is the Internet Located?* 44 BOSTON B. J. 16, 32 (2000), and endorsed by the American Bar Association and the National Conference of Commissioners on Uniform State Laws. August, *supra*, at 566-67 n.185. However, these clauses raise potential unconscionability issues in the consumer contract context, *id.* at 567, and for that reason, the European Union has largely rejected them. *Id.* at 555-56. Under the European Union's Regulation on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, in consumer contracts the consumer may sue the merchant either in the country where the merchant or the consumer is domiciled but the merchant may sue the consumer only in the latter country, and “a forum selection clause is valid only if it is entered into ‘after the dispute has arisen’ or it specifies additional places where the consumer may sue.” *Id.* at 554-55 (citation omitted).

203. Under U.C.C. § 2-105 (2002), a prescription medication is included in the definition of a good.

entering into sales contracts and thus choosing to do business in the states where the consumers reside.²⁰⁴ Internet pharmacies that solicit customers via spam email²⁰⁵ are even more likely to be found to have chosen to do business in a particular state, since new technology, known as “geo-location software,” makes it quite easy either to target or to block email addresses in particular locations.²⁰⁶ In addition, Internet pharmacies that provide online medical “consultations” via an electronic questionnaire should anticipate being subject to jurisdiction in the consumer’s state under the *Calder v. Jones* “effects” test, since the Internet pharmacy is arguably practicing medicine within that state through such “consultations”, and, as in *Calder*, should foresee that any tortious consequences of its conduct will occur there.²⁰⁷

B. Criminal Jurisdiction

1. State Jurisdiction

Defendants might also assert a lack of jurisdiction in criminal prosecutions, as Internet pharmacies and those who work for them might claim they never acted “in” the prosecuting state, but only “in the borderless environment of cyberspace.”²⁰⁸ In the criminal, as well as civil, realm, prosecutors must establish both personal and subject matter jurisdiction.²⁰⁹ Personal jurisdiction is established through the defendant’s “physical presence before the court,” achieved either

204. See *Zippo*, 952 F.Supp. at 1125-26; see also *International Shoe*, 326 U.S. at 318-20.

205. The author, like many others, frequently receives unsolicited offers to buy drugs such as Viagra. See, e.g., E-Mail from Dana Ferris, hygynjn23ph@hotmail.com, to Linda C. Fentiman (Oct. 17, 2003) (on file with author). For a discussion of how spam email works, see *infra* note 268.

206. August, *supra* note 202, at 568-70. Indeed, although this is not likely to be the prevailing view, one court has suggested in dicta that a court could potentially exercise general jurisdiction against an Internet entity, since Internet enterprises by definition are capable of operating “24/7” days a week and, depending on their volume of sales to residents of a particular state, could be found to have “continuous and systematic” contacts there. *Gorman v. Ameritrade Holding Corp.*, 293 F.3d 506, 513 (D.C. Cir. 2002). Of course, ascertaining the extent of defendant’s conduct with the forum state may require “jurisdictional discovery,” a practice that has been approved in a number of recent cases. See, e.g., *Toys “R” Us, Inc. v. Two Step, S.A.*, 318 F.3d 446, 455-58 (3d Cir. 2003); *GTE New Media Services Inc. v. Bellsouth Corp.*, 199 F.3d 1343, 1351-52 (D.C. Cir. 2000).

207. See *Zippo*, 952 F.Supp. at 1127; cf. *Calder*, 465 U.S. at 789-90.

208. Cf. *Gorman*, 293 F.3d at 510, a civil case in which the court in dicta rejected the defendant’s challenge to jurisdiction, based on the argument that because his transactions occurred “in . . . cyberspace” he has not acted within the jurisdiction.

209. See *Rios v. State*, 733 P.2d 242, 244 (Wyo. 1987) (investigating whether the state had subject matter jurisdiction over the crime).

through voluntary appearance or by involuntary means such as extradition.²¹⁰ Prosecutors can establish subject matter jurisdiction, based on the Anglo-American view of sovereignty that governments only have jurisdiction over actions taking place within their territorial borders,²¹¹ by demonstrating either that at least one of the defendant's actions took place within the jurisdiction²¹² or that the defendant, while acting outside the state, intended those actions to have effects within the jurisdiction.²¹³

Using either of these theories, a state attorney general should be successful in prosecuting an Internet pharmacy and its principals. Under the theory that "at least one element of the crime" must be committed within the jurisdiction, state courts have found jurisdiction to prosecute defendants for crimes of theft and fraud committed against state residents by use of the mail or telephone.²¹⁴ Courts have concluded that even defendants who were physically

210. *Id.*

211. *See, e.g.*, MODEL PENAL CODE § 1.03 (1985); MODEL PENAL CODE, cmt. 1 nn.3-4 (1985) (explaining that the Anglo-American approach is narrower than that of international law, which provides that jurisdiction may be predicated on non-territorial theories).

212. *See infra* notes 213-15 and accompanying text (indicating that this approach is the product of common law doctrine or a statute, such as N.Y. CRIM. PROC. § 20.20(1), (2)(a) (McKinney 2003). This approach is recommended by the Model Penal Code section 1.03(1)(a), which provides that:

Except as otherwise provided in this Section, a person may be convicted under the law of this State of an offense committed by his own conduct or the conduct of another for which he is legally accountable [e.g., an accomplice or innocent agent] if:

(a) either the conduct that is an element of the offense or the result that is such an element occurs within this State

213. This latter theory, the "detrimental effects" doctrine, was announced by the Supreme Court in *Strassheim v. Daily*, 221 U.S. 280 (1911). In *Strassheim*, the Court upheld the jurisdiction of Michigan courts over a defendant who, while in another state, offered Michigan officials a bribe, which then led to injury within Michigan. *Id.* at 283-85. As the Court explained, "Acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a State in punishing the cause of the harm as if he had been present at the effect." *Id.* at 285. This doctrine has been codified in some state laws, *see, e.g.*, N.Y. CRIM. PROC. § 20.20(2)(b), while other states have adopted it as a matter of common law, *see, e.g.*, *People v. Blume*, 505 N.W.2d 843 (Mich. 1993) (following *Strassheim* but finding that its test was not met under the circumstances of this case).

214. *See, e.g.*, *State v. Cain*, 757 A.2d 142 (Md. 2000) (detailing 19th and 20th century cases in the course of holding that Maryland courts had criminal jurisdiction over a Georgia resident in an allegedly fraudulent Internet sale), *and Keselica v. Commonwealth*, 480 S.E.2d 756, 759-60 (Va. Ct. App. 1997) (upholding the embezzlement conviction of the defendant Maryland resident based on the "detrimental effects" theory, because when he made phone calls from Maryland to Virginia residents, he intended his statements to inflict harm on the victims in Virginia).

outside the forum state when they made representations intended to induce the victim to mail them money constructively received the money in the state when the victims placed the check or other instrument in the mail there, and thus committed an element of the crime within the jurisdiction.²¹⁵

Thus, state courts will likely uphold criminal jurisdiction against out-of-state defendants who act via the Internet to cause harm to residents of their state, either by prescribing or dispensing prescription medication to a resident in violation of state criminal law,²¹⁶ or by sending drugs that were counterfeit or otherwise not the ones ordered or by failing to send any medications at all, for violating a "theft by deception" statute.²¹⁷ Such a prosecution would be justified either under the *Strassheim* "detrimental effects" theory²¹⁸ or that the defendants "acted" within the state by constructively receiving the victim's money, check, or credit card authorization there.²¹⁹

2. Federal Jurisdiction

The federal government's criminal jurisdiction over Internet pharmacies should be easy to establish, since it is a criminal violation of the Food, Drug, and Cosmetic Act to dispense a drug that

215. *Id.* In *Cain*, the Maryland Court of Appeals found that there was jurisdiction to prosecute a case against an out-of-state defendant who, via the Internet, sold a Maryland resident a set of Barbie dolls ostensibly in "mint" condition when in fact they were not, because the defendant obtained control over the money in Maryland "through the agency of the [U.S.] Postal Service when" the victim mailed a check to her in Maryland. 757 A.2d at 147. In *State v. Amoroso*, 975 P.2d 505 (Utah Ct. App. 1999), a modern application of the "detrimental effects" approach, the Utah Court of Appeals found that an out-of-state defendant who shipped beer into Utah in violation of the state's law prohibiting sale of alcohol to a minor met the requirements of subject matter criminal jurisdiction in Utah because he caused an unlawful result there. 975 P.2d at 508-09 (citing *Strassheim* and applying Utah Code Ann. § 76-1-201(1)(a), (2), which permits the exercise of criminal jurisdiction if either prohibited conduct or a prohibited result takes place within the state); *see also* *Lamar v. United States*, 240 U.S. 60, 65-66 (1916) (finding that the defendant was properly charged in the Southern District of New York for the crime of impersonation of an officer of the United States, "with intent to defraud" when the hearer of the false representation was within that jurisdiction, regardless of where the defendant was located).

216. *See, e.g.*, NEV. REV. STAT. ANN. § 453.3643(6) (Michie Supp. 2001) (making it a felony to prescribe a Schedule I controlled substance or to prescribe any medication which results in death or serious bodily injury).

217. *See, e.g.*, ALASKA STAT. § 11.46.180 (Michie 2002) (the statute is violated when someone intentionally acquires another's property through deception); GA. CODE ANN. § 16-8-3 (2003) (theft by deception is committed when "he obtains property by any deceitful means or artful practice with the intention of depriving the owner of property").

218. *See supra* note 213 and accompanying text.

219. *See supra* note 215 and accompanying text.

has not been properly prescribed.²²⁰ Using the Internet to defraud will also violate the federal wire fraud statute,²²¹ and most likely the mail fraud statute as well,²²² potentially giving rise to a RICO prosecution if a pattern of racketeering activity is shown.²²³ In addition, dispensing a controlled substance without a valid prescription is a crime under the Controlled Substances Act.²²⁴

C. Practical Enforcement Obstacles

Yet even where civil or criminal jurisdiction is theoretically present, prosecutors still face substantial hurdles in finding defendants (and their assets) and bringing them into the forum state.²²⁵ The Internet's unique technology makes it easy for Internet pharmacies and their principals to obscure their geographic location and to make it both expensive and time consuming for investigators to track them down. For example, Internet pharmacy sites can be created in one state, and hosted on multiple web servers, each located in a different state. Sometimes data are transmitted via satellite telephone communications providers, which may also be in different states or foreign countries.²²⁶ The physician who participates in online "consultations" may be physically located (and licensed) in a different jurisdiction than the server on which the website is hosted, which may not be the same state where the dispensing pharmacist and pharmacy can be found. Sophisticated but fraudulent web operators have set up complex interlinked websites, which enhance

220. Under the Food, Drug & Cosmetic Act, a drug is "misbranded" if it is dispensed without a valid prescription. 21 U.S.C. §§ 331(a), 353(b)(1) (2000). Any such misbranding may be punished as a misdemeanor, § 333(a)(1), while any misbranding after a previous conviction or misbranding "with the intent to defraud or mislead" is punishable as a felony, § 333(a)(2). *See supra* notes 63-64 and accompanying text.

221. 18 U.S.C. § 1343 (2000).

222. *Id.* § 1341.

223. Under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968 (2000), a criminal prosecution may be brought if the prosecutor can show a pattern of racketeering activities, which require at least two "predicate offenses," including mail fraud and wire fraud. *Id.* § 1961(1), (5); *see, e.g.,* *Salinas v. United States*, 522 U.S. 52, 62 (1997) (stating that under 18 U.S.C. § 1961, a "pattern of racketeering activity" requires two predicate acts of "racketeering activity").

224. 21 U.S.C. §§ 801-966, discussed in *supra* notes 110-17 and accompanying text.

225. Asset tracing and seizure is an essential part of a civil or criminal investigation. Without the ability to locate and seize assets (hardware, software, accounts receivable, real estate, and cash) it is difficult for the government to permanently shut down an Internet pharmacy. *See, e.g., Review of Consumer Safeguards, supra* note 15, at 141-50 (testimony of Richard Blumenthal, Attorney General of Connecticut).

226. *Berg, supra* note 13, at 1354.

their apparent legitimacy to consumers and also make it more difficult to track down their actual ownership and location.²²⁷

Further, state investigators must issue a subpoena or obtain a warrant for each location they want to search, which is valid only in the issuing jurisdiction. Receiving assistance with execution in a sister state or foreign jurisdiction requires good will and substantial interest on the other jurisdiction's part, which may be lacking if there are no victims in the second jurisdiction or if that jurisdiction has a policy or practice of being a haven for those who seek to evade United States law.²²⁸

Once a human defendant is located, he or she must be brought to the forum for trial. Under the Constitution, every state must extradite accused criminals to a sister state when requested, so that obtaining the physical presence of an American defendant in the forum is relatively straightforward.²²⁹ However, defendants who are not United States citizens can only be extradited to an American court if the United States has an extradition treaty with the country where the defendant is located. Many of the extradition treaties that the U.S. has signed operate under the principle of "dual criminality," that is, in order for extradition to take place, the defendant's alleged act must be a crime in both jurisdictions.²³⁰ While "mail fraud" is a crime in many nations, as it is in the United States,²³¹ the relative novelty of many types of crimes committed via the Internet, may make it impossible to meet the dual criminality requirement, and

227. See *Review of Consumer Safeguards*, *supra* note 15, at 11B (testimony of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy). Part of the problem reflects the ephemeral nature of Internet communications, which are frequently not saved for long periods of time, although investigators can avail themselves of a federal statute that requires Internet service providers and other communications media to "freeze" records upon request, pending the issuance of legal process. Berg, *supra* note 13, at 1359 (citing 18 U.S.C. § 2703(f)(1) (1994)). The same cookie technology that is used to capture personal information from unwary consumers may also make it possible to identify a complex web of transactions by the Internet pharmacy once the appropriate server is located. *Id.* at 1327; *cf.* August, *supra* note 202, at 573 (describing the use of geolocation software).

228. See Berg, *supra* note 13, at 1353-54.

229. Henry H. Perritt, Jr., *Jurisdiction in Cyberspace*, 41 VILL. L. REV 1, 38 (1996) (citing U.S. Const. art. IV, § 2, cl. 2, and noting that almost every state has adopted the Uniform Criminal Extradition Act). Of course, defendants may still challenge the jurisdiction of the forum seeking their extradition. See, e.g., *In re Vasquez*, 705 N.E.2d 606 (Mass. 1999) (affirming the denial of a petition for a writ of habeas corpus and upholding the extradition of petitioner from Massachusetts to Oregon, based on a finding that Oregon could assert jurisdiction over the petitioner based, *inter alia*, on *Strassheim*).

230. Perritt, Jr., *supra* note 229, at 57-58.

231. See, e.g., 18 U.S.C. §1341 (2000) (stating that anyone intending to defraud via the use of the mail will be fined or imprisoned); Perritt, Jr., *supra* note 229, at 15.

thus, extradition will be unsuccessful. The International Convention on Cybercrime, adopted in November 2001, has not yet been ratified by any nation.²³² In practice, shutting down the operations of an Internet pharmacy in a foreign country will require the enthusiastic and efficient cooperation of officials there.²³³

D. *The Dormant Commerce Clause*

By far the greatest potential impediment to state action against Internet pharmacies or the individual physicians and pharmacists who made their operation possible is the Constitution's "dormant" Commerce Clause.²³⁴ Beginning with *Gibbons v. Ogden*,²³⁵ the Supreme Court has emphasized that federal power to regulate interstate commerce is very broad, in recognition of the need for a uniform, national approach to activities that affect either foreign or interstate intercourse.²³⁶ The Court has recognized a latent, or "dormant," aspect of federal commerce power, so that even when Congress has not acted, states are precluded from regulating if such legislation would unduly burden interstate or foreign commerce.²³⁷

Thus, every state action may be analyzed to ascertain whether it has, or threatens to have, an effect on interstate or foreign commerce. If a statute clearly discriminates against interstate commerce by providing differential treatment for in-state and out-of-state entities, it will be struck down, "unless the discrimination is demonstrably

232. See *supra* note 123.

233. See *supra* notes 119-24 and accompanying text (focusing especially on the FDA's issuance of "cyberletters" that warn foreign Internet pharmacies that their actions are unlawful in the United States).

234. The Constitution gives Congress the power to "regulate Commerce with foreign Nations, and among the Several States, and with the Indian Tribes." U.S. CONST. art. I, § 8, cl. 3. In ratifying the Constitution, the states ceded this authority to the federal government in order to ensure that the United States could develop a unified national market and a uniform economic policy, thus eliminating one of the major weaknesses of the Articles of Confederation. See, e.g., *General Motors Corp. v. Tracy*, 519 U.S. 278, 299-300 (1997) (discussing the "dormant Commerce Clause's fundamental objective of preserving a national market"). The loose economic and political association of the United States under these Articles had permitted states to enact inconsistent and conflicting state regulatory and taxing schemes, which made conducting interstate and foreign commerce extremely difficult for the fledgling American nation. See, e.g., *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 571 (1997) (discussing the genesis of the Commerce Clause, particularly its dormant aspects).

235. 22 U.S. (9 Wheat.) 1 (1824).

236. *Id.* (invalidating a New York law granting certain individuals the exclusive right to operate steamboats in New York waters because this statute interfered with interstate commerce between New York and New Jersey).

237. *Camps Newfound/Owatonna, Inc.*, 520 U.S. at 571-72.

justified by a valid factor unrelated to economic protectionism."²³⁸ Such a statute is "virtually *per se*" unconstitutional.²³⁹ More importantly, even state laws which are facially neutral, and address concerns traditionally within the state's police powers, such as criminal laws, "inspection laws, quarantine laws, health laws [, and] . . . laws regulating the internal commerce of a state,"²⁴⁰ will be invalidated if they impose "an undue burden on interstate commerce."²⁴¹

The Supreme Court has articulated several tests for evaluating state laws alleged to interfere with interstate or foreign commerce. Under the balancing test set forth in *Pike v. Bruce Church, Inc.*,²⁴² when a statute is facially neutral and "regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."²⁴³ The Court has emphasized that commerce clause analysis requires a realistic assessment of a state law's potential extraterritorial effects.²⁴⁴ Even state laws imposing burdens, which are ostensibly intrastate, will be struck down if in practice they interfere with the goal of a uniform national market.²⁴⁵

238. LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 1066 (3d ed. 2000) (emphasis removed) (citing *Wyoming v. Oklahoma*, 502 U.S. 437, 454-55 (1992)); see also *Healy v. The Beer Institute*, 491 U.S. 324 (1989) (invalidating a Connecticut "price affirmation" statute that, although it was ostensibly designed to secure lower prices for Connecticut consumers for their in-state beer purchases, had an effective reach far beyond the Connecticut borders, affecting the prices that beer manufacturers and distributors could charge in neighboring states and through those states' laws, nationwide).

239. TRIBE, *supra* note 238, at 1063 (quoting *Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality*, 511 U.S. 93, 99 (1994)) (emphasis added).

240. *Gibbons*, 22 U.S. at 203.

241. *Dean Milk Co. v. City of Madison*, 340 U.S. 349, 353 (1951).

242. 397 U.S. 137 (1970).

243. *Id.* at 142. The Supreme Court struck down an Arizona law requiring that all fruit grown in Arizona be packed there and in a certain manner, finding that even though the state had a legitimate interest in having Arizona produce packed to ensure that it was high quality, it was not sufficiently important to outweigh the heavy costs of complying with this law for both the individual grower involved and interstate commerce generally. *Id.* at 146.

244. *Id.* at 142.

245. See *Healy v. The Beer Institute*, 491 U.S. 324, 336 (1989). The Supreme Court held:

First, the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State" . . . [A] State may not adopt legislation that has the practical effect of establishing "a scale of prices for use in other states. . ." Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent

As the Internet has become a major means of communication and commerce, the courts have divided on the question of whether it is possible for states to assert a legitimate and compelling interest in activities that affect their citizens, even though these activities are conducted via the Internet, or whether the Internet is *per se* invalid as a subject of state regulation. Although initially the courts tended toward the first point of view, the tide appears to be turning, with several federal appeals courts and state supreme courts upholding state laws against dormant commerce clause challenges.

In *American Libraries Association v. Pataki*,²⁴⁶ the District Court enjoined the enforcement of a New York law which made it a felony to knowingly and intentionally communicate certain types of sexual material to a minor via a computer.²⁴⁷ In holding that this statute ran afoul of the commerce clause, the court spoke very broadly:

First, the Act represents an unconstitutional projection of New York law into conduct that occurs wholly outside New York.^[248] Second, the Act is invalid because although protecting children from indecent material is a legitimate and indisputably worthy subject of state legislation, the burdens on interstate commerce resulting from the Act clearly exceed any local benefit derived

limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended Third, the practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation. . . . [T]he Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State. . . . [and] dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another.

491 U.S. at 336-37 (citations omitted).

246. 969 F. Supp. 160 (S.D.N.Y. 1997).

247. The law under challenge, N. Y. PENAL. § 235.21 (McKinney 2000), provided that it was a crime for a person:

Knowing the character and content of the communication which, in whole or in part, depicts actual or simulated nudity, sexual conduct or sado-masochistic abuse, and which is harmful to minors, [to] intentionally use any computer communication system allowing the input, output, examination or transfer, of computer data or computer programs from one computer to another, to initiate or engage in such communication with a person who is a minor.

Am. Libraries Ass'n, 969 F. Supp. at 163.

248. This would be contrary to the principle that a state may not "export" its domestic policy to out-of-state conduct. *See, e.g., Healy*, 491 U.S. at 336-37 (stating that "the Commerce Clause protects against . . . the projection of one state regulatory regime into the jurisdiction of another State").

from it.²⁴⁹ Finally, *the Internet is one of those areas of commerce that must be marked off as a national preserve to protect users from inconsistent legislation that, taken to its most extreme, could paralyze development of the Internet altogether.* Thus, the Commerce Clause ordains that only Congress can legislate in this area, subject, of course, to whatever limitations of the Constitution (such as the First Amendment) may require.²⁵⁰

In *Pataki*, the court did far more than simply apply classic principles of commerce clause analysis in the Internet context, *i.e.*, to consider whether the statute explicitly discriminated against interstate as opposed to intrastate commerce, and to weigh the burdens of complying with the New York statute against the benefit sought to be achieved.²⁵¹ In setting forth its third ground for invalidating the statute—that the Internet is inherently a subject for national legislation because “[it] is wholly insensitive to geographic distinctions”²⁵²—the court articulated a principle of extraordinary breadth. The acceptance of this principle would mean that no state law that attempts to regulate conduct or content mediated through the Internet could survive a dormant commerce clause challenge.

Pataki has been followed by three other federal courts that invalidated state laws criminalizing the distribution of sexual materials to minors via the Internet.²⁵³ These courts declared that the Internet’s unique technology invalidated state efforts to prohibit the dissemination of sexually offensive material to minors, finding that, as compared to people acting in real time and space, those who communicate via the Internet cannot limit their communications to recipients in particular geographic locations and thus are inevitably participating in interstate commerce.²⁵⁴ Under this view, an Internet communicator can only comply with state laws regulating the type of materials which may be communicated via the Internet (and the

249. Following the approach of *Healy*, the court in *Pataki* found that the New York statute violated the commerce clause because it imposed an impossible burden on anyone communicating via the Internet to ensure that the contents of that communication do not depict conduct “harmful to minors,” and further, would subject all Internet communicators to the conflicting commands of different states’ laws relating to Internet communications. *Am. Libraries Ass’n*, 969 F. Supp. at 177-81.

250. *Id.* at 169 (emphasis added).

251. *See supra* notes 245-49.

252. *Am. Libraries Ass’n*, 969 F. Supp. at 170.

253. *See* *ACLU v. Johnson*, 194 F.3d 1149 (10th Cir. 1999); *Cyberspace Communications, Inc. v. Engler*, 142 F. Supp. 2d 827 (E.D. Mich. 2001); *PSINET Inc. v. Chapman*, 167 F. Supp. 2d 878 (W.D. Va. 2001).

254. *See Johnson*, 194 F.3d at 160-62; *Cyberspace Communications Inc.*, 142 F. Supp. 2d at 830-31; *PSINET Inc.*, 167 F. Supp. 2d at 890-91.

manner in which they are communicated)²⁵⁵ by meeting the requirements of the most stringent state law. This extraterritorial reach of state law is precisely what the commerce clause forbids.²⁵⁶

In *Knoll Pharmaceutical Co. v. Sherman*,²⁵⁷ a federal district court invoked the dormant commerce clause to invalidate an Illinois consumer protection law prohibiting the advertising of controlled substances by name.²⁵⁸ Illinois officials had used the law to ban Knoll's advertising of the prescription weight-loss drug Meridia.²⁵⁹ The court applied the *Pike* balancing test and found that the state had failed to demonstrate that the advertising ban would be "of any value in protecting . . . [its] citizens from the dangers of drug abuse, illegal drug trafficking, or unethical medical practice," whereas it would have a significant negative impact on interstate commerce, since the only practical way to prevent Internet, television, and print advertising of Meridia in Illinois was to limit such advertising in other states.²⁶⁰

However, many courts have upheld state legislation governing communication and commerce via the Internet. Three recent state cases—one from New York and two from California—considered laws criminalizing the use of the Internet to reach children with prohibited sexual material.²⁶¹ In each case the court rejected the

255. The dormant commerce clause analysis does not address the important First Amendment objections that are made to many state (as well as federal) efforts to control the content of Internet communications, particularly communications of a sexual nature. See, e.g., *Reno v. ACLU*, 521 U.S. 844, 874-81 (1997) (holding that certain portions of the federal Communications Decency Act of 1996, 47 U.S.C. §§ 223 (2000), violated the First Amendment due to overbreadth, because in trying to prevent minors from receiving certain sexual content via the Internet interfered with communications that would only reach adults); *Am. Libraries Ass'n*, 969 F. Supp. at 182-84 (declaring the state law unconstitutional on commerce clause grounds, but declining to address the First Amendment claim).

256. See *Johnson*, 194 F.3d at 1161 (holding that the state statute actually regulates conduct outside of the state in violation of the commerce clause); *PSINET Inc.*, 167 F. Supp. at 890-91. At the same time, if a state seeks to preserve its statute by interpreting it narrowly, limiting its application to communications that the sender knows will reach minors in a particular state, this will undercut the state's argument that the law confers a major benefit on its residents, because then the law will not reach most of the harmful communications, which are not knowingly sent to minors residents. *Johnson*, 194 F.3d at 1162.

257. 57 F. Supp. 2d 615 (N.D. Ill. 1999).

258. *Id.* at 623-24.

259. *Id.* at 618-19.

260. *Id.* It was perhaps significant to the court, reflecting the federalism concerns at stake in the case, that such advertising was permitted by at least thirty-six other states. *Id.* at 623.

261. See *Hatch v. Superior Court*, 94 Cal. Rptr. 2d 453 (Ct. App. 2000); *People v. Hsu*, 99 Cal. Rptr. 2d 184 (Ct. App. 2000); *People v. Foley*, 731 N.E.2d 123 (N.Y. 2000), *cert. denied*, 531 U.S. 875 (2000).

argument that the statutes were facially invalid as violative of the commerce clause or the First Amendment.²⁶² The two California decisions also rejected *Pataki's* assertion that any state effort to regulate conduct on the Internet was a *per se* violation of the dormant commerce clause, stressing that the state statutes were not attempting to affect out-of-state commerce, but only such conduct as took place in, and affected consumers and citizens of, California.²⁶³ In the courts' view, the existing rules limiting states' extraterritorial criminal jurisdiction²⁶⁴ were sufficient to eliminate any commerce clause problem.²⁶⁵ Finally, the New York Court of Appeals dismissed the commerce clause argument as irrelevant, observing, "We are hard pressed to ascertain any legitimate commerce that is derived from the intentional transmission of sexually graphic images to minors for the purpose of luring them into sexual activity. Indeed, the conduct sought to be sanctioned . . . is of the sort that deserves no 'economic' protection."²⁶⁶

Similarly, in *State v. Heckel*,²⁶⁷ the Washington Supreme Court upheld a consumer protection statute prohibiting the transmission of "spam" email²⁶⁸ to Washington residents. The court explicitly disapproved *Pataki's* reasoning, and determined that the statute, which limited its applicability to computers located in Washington, did not place an undue burden on interstate commerce.²⁶⁹ Applying the *Pike* test, the court found that the statute accomplished a legitimate local public interest (the avoidance of the time and expense spent deleting spam e-mail) and imposed only the minimal cost of being truthful on Internet communicators like *Heckel*.²⁷⁰ The

262. *Hsu*, 99 Cal. Rptr. 2d at 190-98; *Hatch*, 94 Cal. Rptr. 2d at 469; *Foley*, 731 N.E.2d at 128-34.

263. *Hsu*, 99 Cal. Rptr. 2d at 191-92; *Hatch*, 94 Cal. Rptr. 2d at 472-73.

264. See discussion *supra* Part IV.B.

265. *Hsu*, 99 Cal. Rptr. 2d at 191-92 (declaring, "Statutes 'must be construed in the light of the general principle that, ordinarily, a state does not impose punishment for acts done outside its territory'" (citations omitted); *Hatch*, 94 Cal. Rptr. 2d at 472-73; see also discussion *infra* Part IV.B.

266. *Foley*, 731 N.E.2d at 133 (citations omitted). Further, all three courts specifically distinguished *Pataki*, because the state statutes at issue imposed a *scienter* requirement not present in *Pataki*: to wit, using the Internet or other prohibited media with the intent to seduce or lure a minor into sexual activity. See *Hsu*, 99 Cal. Rptr. 2d at 191; *Hatch*, 94 Cal. Rptr. 2d at 472; *Foley*, 731 N.E. 2d at 133.

267. 24 P.3d 404 (Wash. 2001). Defendant was an Oregon resident, who was charged with sending spam advertising to Washington residents despite repeated cease and desist warnings by the state attorney general. *Id.* at 406-07.

268. "Spam" is unsolicited commercial (*i.e.* advertisements) or non-commercial (*i.e.* jokes or chain letters) e-mails. *Id.* at 406 n.1.

269. *Id.* at 412-13.

270. *Id.* at 410-12. The court found that this was not a burden at all, declaring that the law "actually 'facilitates . . . [commerce] by eliminating fraud and deception.'" *Id.*

court emphasized that given the available technological fixes, which permitted a communicator to identify email addresses from a particular state by using the addresses' domain names, the statute should not be construed to have an extraterritorial effect.²⁷¹

In *Ford Motor Co. v. Texas Department of Transportation*,²⁷² the Fifth Circuit affirmed a state's ability to legislate in a traditional area of state concern even if such legislation implicated Internet communication.²⁷³ A Texas statute prohibited automobile manufacturers from having an interest in a car dealership or acting in the capacity of a dealer.²⁷⁴ A Ford Internet site advertised pre-owned cars to consumers, who could view a car on the Internet, place a deposit on it, test-drive the car at a local Ford dealership, and ultimately, purchase it.²⁷⁵ When Texas invoked the law, Ford challenged it on the ground that enforcement violated the dormant commerce clause.²⁷⁶ The Fifth Circuit found that the statute did not discriminate among similarly situated in-state and out-of-state interests, and upheld its application as a valid exercise of state power to protect Texas citizens by equalizing market power between auto dealers and auto manufacturers, wherever located.²⁷⁷

Deference to state police power was also shown in *Brown & Williamson Tobacco Corp. v. Pataki*.²⁷⁸ The Second Circuit rejected a challenge to a New York statute that limited retail cigarette sales to face-to-face transactions, and thus made mail-order and Internet purchases unlawful.²⁷⁹ Several out-of-state direct mail and Internet sellers challenged the law, claiming that it unfairly protected in-state cigarette sellers.²⁸⁰ Applying the *Pike* test,²⁸¹ the court upheld the

at 411 (quoting Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 819 (2001)).

271. *Id.* at 412-13.

272. 264 F.3d 493 (5th Cir. 2001) (affirming the decision of the lower court).

273. *Id.* at 499-503.

274. *Id.* at 498 (discussing TEX. REV. CIV. STAT. ANN. art. 4413(36), §§ 4.01, 4.06, 5.02C (Vernon 1987)).

275. *Id.* at 498-99.

276. *Id.* at 499.

277. *Id.* at 499-503 (citing *Oregon Waste Sys., Inc. v. Dep't. of Env't Quality*, 511 U.S. 93, 99 (1994), *see also Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 125-26 (1978)).

278. 320 F.3d 200 (2d Cir. 2003).

279. *Id.* at 203-04 (referring to N.Y. PUB. HEALTH LAW § 1399-II(1)-(2) (McKinney 2002)).

280. *Id.* at 203-06. This argument was based on the statute's limited exception for the delivery of 800 cigarettes (four cartons) by a person other than a common or contract carrier. § 1399-II(2). The majority and the concurring judge disagreed on whether this exception would permit retail merchants to deliver cigarettes to a consumer's home without violating the law. *Compare Brown & Williamson*, 320 F.3d at 214-16, *with* 320 F.3d at 221-26 (Cabranes, J. concurring). The plaintiff, out-of-state

law.²⁸² Significantly, the court declared that the *Pike* test is not a license for a court to second-guess a legislature's assessment of the putative benefits of a statute, and that the New York legislature's judgment that the statute would decrease the number of minors who smoked would be upheld.²⁸³

Predicting whether state actions against physicians, pharmacists, and Internet pharmacies can be successfully challenged under the dormant commerce clause is difficult. The answer will obviously depend on the particular state statute and policy at issue, as well as whether the state law explicitly distinguishes between interstate and intrastate activities, whether the state law appears to be directed at protecting the public health under the state's police power, whether the law refers explicitly to the Internet, and whether the statute raises First Amendment as well as dormant commerce clause considerations.

Most courts have used the *Pike* test in analyzing the commerce clause problem. Laws which are facially neutral, serve a legitimate state interest, and do not distinguish between intrastate and interstate commerce will be upheld unless the burdens imposed on interstate and foreign commerce outweigh the benefits to be obtained from the state law.²⁸⁴ Although the courts are likely to defer to state criminal laws as a classic exercise of police power, they are less likely to do so when the law implicates the First Amendment, which will trigger strict scrutiny analysis, and make it more likely that the law will be invalidated.²⁸⁵ Particularly if the Supreme Court continues to treat "commercial speech" similarly to "political" or "expressive"

merchants, and the district judge went much further, and argued that this exception meant, either by design or in practice, that in-state merchants could deliver small numbers of cigarettes without either checking the age of the purchaser or collecting the state excise tax on tobacco sales, and thus, undercut the state's key health-based justifications for the statute. *Id.* at 214-16.

281. "Where the statute regulates even-handedly to effectuate a legitimate local public interest and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefit." *Pike v. Bruce, Inc.* 397 U.S. 137, 142 (1970).

282. *Brown & Williamson*, 320 F.3d at 219.

283. *Id.* at 209.

284. *Id.* at 142.

285. See, e.g., *Am. Civil Liberties Union v. Johnson*, 194 F.3d 1149, 1161-64 (10th Cir. 1999) (invalidating New Mexico law criminalizing the use of a computer system to disseminate sexual material to a minor); *Am. Libraries Ass'n v. Pataki*, 969 F. Supp. 160, 169-84 (S.D.N.Y. 1997) (invalidating similar New York law); cf. *Foley*, 731 N.E. 2d at 127 (upholding New York penal law that criminalized the use of "any computer communication system . . . to initiate or engage in . . . [harmful sexual communication with] a minor).

speech, and thus entitled to similar protection,²⁸⁶ then even state laws designed to protect the health of their citizens may be challenged on First Amendment, as well as commerce clause, grounds.²⁸⁷

Another issue is whether the state statute regulates in regard to health, an area of traditional state police power. Only two Internet commerce clause cases involved enforcement of state public health statutes. In *Knoll Pharmaceutical Co. v. Sherman*,²⁸⁸ the court applied *Pike* to determine that the enforcement of Illinois' facially neutral law prohibiting the advertising of controlled substances would substantially burden interstate commerce, because in the context of modern advertising, Illinois' ban on advertising was effectively exported to states where such advertising was legal.²⁸⁹ Further, the court found that there was no countervailing health benefit, observing that the ability of the statute to achieve its goal of protecting Illinois citizens from potentially misleading advertising

286. Since *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (striking down a Virginia law prohibiting the advertising of prices of prescription drugs), the Supreme Court has recognized that states may not broadly limit truthful commercial speech on paternalistic grounds. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 53-70 (2001). Instead, following the analysis set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980), a state may only limit nonmisleading speech about a lawful activity by demonstrating that it has a compelling interest in limiting such speech and that its limitation is narrowly tailored to achieve that interest. *Id.* Several members of the Court have questioned whether commercial speech should be treated any differently than political or other expressive speech. See, e.g., *Lorillard Tobacco*, 533 U.S. at 572-90 (Thomas, J., concurring in part and concurring in the judgment); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518 (1996) (Thomas, J., concurring in part and concurring in the judgment). However, courts need not embark upon a *Central Hudson* analysis unless the speech at issue is commercial speech, i.e., speech about lawful activity that is not misleading. *Lorillard Tobacco*, 533 U.S. at 554. Since dispensing a prescription medication without a valid prescription and/or a doctor's examination is unlawful under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b)(1) (2000), as well as many of the new state laws directed at Internet pharmacies, such a pharmacy will not be able to raise a First Amendment challenge to state or federal efforts to regulate the content of their Internet communications.

287. There is a clear conflict between cases like *Foley*, 731 N.E. 2d at 123, and *Hatch*, 94 Cal. Rptr. 2d at 453, in which state courts upheld state laws criminalizing the use of a "computer communication system" to disseminate harmful sexual materials to minors and cases like *American Civil Liberties Union*, 194 F.3d at 1149, and *American Libraries Association*, 969 F.Supp. at 160, in which federal courts invalidated similar state criminal laws. Although one could distinguish the statutes which were upheld in those cases by saying, as did the court in *Foley*, 731 N.E. 2d at 129-30, that the law implicated a narrow criminal law interest because it had a scienter requirement, that distinction is frankly dubious.

288. 57 F. Supp. 2d 615, 623-24 (N.D. Ill. 1999).

289. *Id.* at 622.

about potentially addictive drugs was “speculative” at best.²⁹⁰ In contrast, in *Brown & Williamson Tobacco Corp. v. Pataki*,²⁹¹ the court upheld New York’s law prohibiting all but direct face-to-face retail sales of tobacco products, deferring to the state’s announced public health goal of limiting tobacco consumption by imposing higher taxes and making it difficult for minors to evade the law’s age-verification requirement. Also relying on *Pike*, the court announced that since the statute was not facially discriminatory, and its practical effect was not to discriminate against interstate commerce generally, the legislature’s judgment of health benefit must be accepted as rational, and the law upheld.²⁹²

Courts that have invalidated statutes because of their forbidden impact on interstate commerce have not all taken the same analytical route. In *American Libraries Ass’n. v. Pataki*,²⁹³ the court declared that that any statute mentioning or regulating conduct or content on the Internet must be invalidated under the dormant commerce clause, because the “menace of inconsistent state regulation” that was the genesis of the commerce clause mandated a national solution.²⁹⁴ In contrast, in *Ford Motor Co. v. Texas Department. of Transportation*,²⁹⁵ the trial court emphatically “reject[ed] . . . the plaintiffs argument that an activity which is appropriately regulated when accomplished through any other medium becomes sacrosanct when accomplished through the internet.”²⁹⁶ The court declared that if *Pataki*’s reasoning were accepted, “all state regulatory schemes would fall before the mighty altar of the internet,” a result which it found was not mandated by the dormant commerce clause.²⁹⁷

If we were to apply the foregoing cases to the range of state actions taken against Internet pharmacies, the following are likely results. Examining a statute, such as Nevada’s, which prohibits licensed health care professionals from prescribing a drug if they have not examined the patient within the previous six months and either know or have reason to know that the prescription will be delivered to the patient via an Internet pharmacy that is not licensed in Nevada, we see the state legislating within a traditional area of

290. *Id.*

291. 320 F.3d 200 (2d Cir. 2003).

292. *Id.* at 209-16.

293. 969 F. Supp. 160 (S.D.N.Y. 1997).

294. *Id.* at 169.

295. 106 F. Supp. 2d 905 (W.D. Tex.2000), *aff’d*, 264 F.3d 493 (2001).

296. *Id.* at 909.

297. *Id.*

state interest, the regulation of health care professionals.²⁹⁸ Thus, the law will be given deference under dormant commerce clause analysis as a rational exercise of legislative power.²⁹⁹ It could be argued that the statute is invalid under the reasoning of *Knoll Pharmaceutical* and *Pataki*, on the ground that Nevada is effectively exporting its health policy (requiring health care professionals to examine patients before prescribing medication) to health care professionals in other states, and subjecting them to potentially conflicting legal obligations. However, Nevada would assert that its strong interest in protecting its citizens' health by ensuring that they only receive drugs through a legitimate physician-patient encounter can only be achieved by regulating the conduct of all health care professionals who treat Nevada patients, whether or not they are licensed there, relying on the decisions in *State v. Heckel*³⁰⁰ and *People v. Foley*.³⁰¹ Nevada would argue further that readily available technological fixes, such as geo-location software, permits health care professionals in other states to limit their practice to patients who reside in states where online prescribing is not prohibited.

An even stronger case can be made in favor of upholding the California statutes governing physicians, pharmacists, and pharmacies, which prohibit them from prescribing or dispensing via the Internet for delivery to any person in California unless the patient has received a "good faith" medical examination.³⁰² It could be

298. See *supra* notes 129-35 and accompanying text; see also *Pegram v. Herdrich*, 530 U.S. 211, 235-36 (2000) (observing, in the course of deciding the scope of ERISA fiduciary duties in the HMO context, that the regulation of medical practice was the classic domain of state common law).

299. See *Brown & Williamson Tobacco Corp.*, 320 F.3d at 209 (holding that courts should not second-guess a legislature's determination that a particular regulatory scheme will advance a state's interest in protecting the health of adults and minors within the state); *Ford Motor Co. v. Texas Dep't of Transp.*, 264 F.3d 493, 503-04 (5th Cir. 2001) (holding that Texas could rationally choose to equalize the economic and power relationship between automobile manufacturers and automobile dealers by imposing certain limitations on manufacturers' activities within the state).

300. 24 P.3d 404 (Wash. 2001) (affirming unconstitutionality of dissemination of indecent material to minors).

301. 731 N.E.2d 123 (N.Y. 2000).

302. Under California's Business & Professional Code section 2242.1(a):

No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices . . . on the Internet for delivery to any person in this state, without a good faith prior examination and medical indication therefore, except as authorized by Section 2242 [which enumerates certain limited exceptions for prescribing without an examination].

In addition, California law provides that:

No person . . . shall dispense . . . dangerous drugs or devices . . . on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person . . . either *knew or*

argued, in light of *Pataki*, that these statutes violate the dormant commerce clause because they explicitly refer to the Internet, and thus implicate interstate and foreign communication and commerce.³⁰³ However, California would counter that the statutes are neutral as to where the physician, pharmacist, or pharmacy is licensed, and also that the statutes are limited in their effect to California citizens, whom we would surely expect to be protected by California law against unprofessional actions of health care workers, wherever located.³⁰⁴ Given the availability of technological fixes to identify California consumers, and the tendency of many courts to defer to the legislature's judgment if minimally rational, these statutes are likely to be upheld.

V. WHY A NEW FEDERAL APPROACH IS NECESSARY

Yet, as the previous discussion demonstrates, the current patchwork system of federal and state regulation of access to pharmaceuticals is inadequate to address either the health and safety concerns raised by Internet pharmacies or the jurisdictional and commerce clause problems that are barely acknowledged by lawmakers and prosecutors. As consumers face an ever-growing cost burden in paying for drugs to enhance the quality or quantity of their lives, they are increasingly tempted to go to the Internet for an alternative source of medications. However, Internet pharmacies can put patients' health at risk by threatening to sever the connection between health care professionals and their patients, leaving patients vulnerable to receiving an inappropriate or defective medication,³⁰⁵ the wrong dosage of an appropriate drug, or simply being ripped-off.

reasonably should have known that the prescription was not issued pursuant to a good faith prior examination.

CAL. BUS. & PROF. CODE § 4067 (West 2001).

303. Under the Uniform Commercial Code, dispensing medication is the sale of a good. U.C.C. § 2-105 (2002). Under the reasoning of *American Libraries Ass'n*, 969 F. Supp. at 170, this discrimination against out-of-state commerce would constitute a fatal flaw, as it renders the statutes violative of the commerce clause.

304. Cf. *Foley*, 731 N.E.2d at 123. But note that the *Foley* Court sustained the statute against a dormant commerce clause challenge in part based on the statute's scienter requirement: intent to transmit sexually graphic images to minors for the purpose of luring them into sexual activity, which is a distinction of dubious merit. *Id.* at 132-33. Further, the California codes' scienter require, "knew or should have known that the prescription was not issued pursuant to a good faith prior examination," is in essence a negligence standard, which might not be considered sufficient to meet the requirement of scienter. *Id.* at 132.

305. This includes medications which are not the right ones to treat the patients' medical condition, as well as drugs that they are not entitled to receive because they are controlled substances, not approved for use in the United States by the Food and Drug Administration, counterfeit, and therefore "misbranded," or otherwise illegal.

The Internet is indisputably a vehicle for interstate and foreign commerce, and it must, therefore, be regulated by the government in the best position to develop a comprehensive and effective law enforcement scheme: that is, the federal government. Unfortunately, the actions taken by federal agencies over the last several years demonstrate how hard this can be. Significant resource constraints and the overlapping jurisdiction of a number of agencies have made it difficult to develop and implement a comprehensive and effective federal strategy to deal with Internet pharmacies, particularly those located in foreign countries.³⁰⁶ The present allocation of regulatory authority between the states and the federal government exacerbates the problem. When the current system was designed, more than fifty years ago, prevailing notions of federalism made a system of concurrent state and federal authority an easy and appropriate fix.³⁰⁷ It made sense that states should regulate the practice of medicine and pharmacy within their borders (which, at the time, was the only place where such practice could take place), and the federal government would take care of overseeing the big picture—that is, the expensive job of regulating broad issues of safety and efficacy by overseeing clinical trials, drug labeling, and advertising.

This balance no longer works, either for state governments or for the consumers and patients they are trying to protect. As states seek to exercise their police power through oversight of medical and pharmacy practice affecting their citizens, they face formidable practical and theoretical obstacles to the exercise of prescriptive and adjudicative jurisdiction.³⁰⁸ While many states have enacted or promulgated new statutes, regulations, or policies, demanding that the drug prescribing and dispensing processes be overseen by licensed professionals within that state and have brought actions under existing criminal and civil laws, these prosecutions are expensive and inefficient. Despite an occasional highly publicized successful action, the very fact that even a successful judgment or consent decree is only effective within one state³⁰⁹ means that state

306. Indeed, what is really demanded is an international approach to this problem, but at this time, international agreement and action seems a long way off. Thus, whether seen as a necessary fall back position or as a chance to experiment and learn from it, a comprehensive federal approach seems to be a desirable first step.

307. See discussion *supra* Part III.

308. As used here, prescriptive jurisdiction refers to establishing a state's policy on a particular issue (e.g., by mandating a physical examination or a pre-existing physician patient relationship before any medication is prescribed), while adjudicative jurisdiction refers to the ability to hale a defendant into the forum state's courts and apply that state's criminal or civil laws.

309. Indeed, the actions that have so far been brought by individual states exemplify this problem, as multiple states go after the same pharmacies. See *supra* notes 162-67 and accompanying text.

attorneys general will only rarely use the scarce investigative resources available to them and that many risky Internet pharmacies will escape detection and/or prosecution.

Further, even successful actions against Internet pharmacies raise important federalism concerns, regardless of the particular legal label applied: "due process," "minimum contacts," "detrimental effects," or "dormant commerce clause." As Allan Stein has pointed out, the real concern in deciding the reach of a state's long arm statute is one of fundamental fairness in a federal system.³¹⁰ How far should a state's jurisdiction extend, either prescriptively or adjudicatively? Should the outcome depend, as stated in *American Libraries Ass'n v. Pataki*,³¹¹ on whether the state statute invoked mentions the "I word"—the Internet—or is the underlying substantive concern more cosmic: under what circumstances, if any, may a state adopt a domestic policy which has impacts in other states, through the enforcement of a law designed to protect its citizens against actors physically located in other jurisdictions?

During the last four years, Congress has held numerous hearings on the subject of Internet pharmacies.³¹² At each hearing, a familiar litany of concerns is recited.³¹³ These include: 1) the ease of access to drugs via Internet pharmacies, particularly controlled substances and other potentially dangerous medications; 2) the lack of health care professional oversight of the drugs dispensed by some Internet pharmacies; 3) inadequate investigative and enforcement resources; 4) unclear lines of authority for federal agencies (as one reads between the lines of the testimony, one is struck by each agency's hesitation to expend resources in an area not within its core mission without express Congressional direction); 5) the concern of state attorneys general that the states should be the primary locus of law enforcement, even as they seek a law authorizing them to seek nationwide injunctive relief;³¹⁴ and 6) the concomitant, if inconsistent assertion, that the states and private entities, such as "legitimate" Internet pharmacies, can police these matters themselves, without a federal solution.³¹⁵

310. Stein, *supra* note 180, at 391-92.

311. 969 F. Supp. 160 (S.D.N.Y. 1997).

312. See *supra* notes 6, 15, 21, 23, 29, 33, 38.

313. Indeed, in reading the hearing testimony, one cannot help but be struck by what Yogi Berra referred to as "déjà vu all over again."

314. *Illegal Online Pharmacies*, *supra* note 33 (testimony of Carla J. Stovall, Attorney General of Kansas); *Review of Consumer Safeguards*, *supra* note 15, at 141-50 (testimony of Richard Blumenthal, Attorney General of Connecticut).

315. See *supra* note 23 and accompanying text (discussing the VIPPS Internet pharmacy program).

Congress should act decisively to adopt comprehensive changes in the Food, Drug, and Cosmetic Act³¹⁶ to achieve its purpose of protecting the public from unsafe and ineffective pharmaceutical products. First, the Act should provide that a drug is “misbranded”³¹⁷ unless it is prescribed by a physician³¹⁸ licensed to practice medicine within any state of the United States who has examined the patient within the last six months.³¹⁹ This would bring federal drug safety policy in line with the law in a growing number of states and would also be in accord with the position of the American Medical Association and the Federation of State Medical Boards. The law should also provide that pharmacists may not dispense prescription medications without evidence that the prescribing physician has physically examined the patient within the past six months.³²⁰

The law should be enforceable either in federal or state court by any state attorney general or United States Attorney, and should have nationwide effect. In addition, the law should provide a mechanism for temporarily securing electronic information generated in the course of an Internet pharmacy transaction in order to permit prosecutors to follow and preserve a defendant’s “electronic trail.”³²¹ Such a new law will provide a uniform national policy governing all Internet sales of prescription medications and expand access to necessary medications under the supervision of licensed health care professionals. By ensuring that legitimate commerce in

316. 21 U.S.C. §§ 301-360 (2000).

317. See *supra* text accompanying notes 63, 136 (discussing 21 U.S.C. § 353(b)(1)).

318. The statute should also authorize prescribing by nurse practitioners and other licensed prescribers, consistent with the law of the state where the patient resides.

319. The statute should make appropriate exception for emergency situations and cases in which the physician has a bona fide preexisting relationship with the patient. See AMA BD. OF TR. REP. 7-A-03, *supra* note 44, announcing “Criteria for an Acceptable Patient . . . Encounter.”

320. Such evidence could be provided in the form of an attestation by the prescribing physician, made in writing, orally, or electronically, with appropriate safeguards to ensure authenticity. In order to impose criminal, as opposed to civil sanctions, the law should require the prosecution to show that pharmacist defendants were reckless about the possibility that the prescription they were being asked to fill was not the product of a medical examination within the last six months, rather than the negligence standard used in the California statute. See discussion *supra* text accompanying notes 155-56.

321. See Berg, *supra* note 13, at 1358. It has been suggested that the law could authorize freezing the existing assets of a potential defendant and include provisions to limit the Internet pharmacy’s access to consumers’ money; such as requiring credit card vendors to interrupt the flow of funds to Internet pharmacies suspected of engaging in illegal activities. However, this approach might be too Draconian, as it could easily put legitimate Internet pharmacies out of business, and it could be unfair to consumers, who could be denied access to medications that they need. At a minimum, the law should require the government to show probable cause that the defendants were violating the statute.

pharmaceutical products can take place over the Internet, Congress will be taking an important step toward increasing competition, potentially lowering prices and expanding access to such medication, and simultaneously protecting the public health.