Washington University Journal of Law & Policy

Volume 22 *Access to Justice: The Social Responsibility of Lawyers | Prison Reform: Commission on Safety and Abuse in America's Prisons*

January 2006

Internet Pharmacies and the Specter of the Dormant Commerce Clause

Laura Vanderstappen

Internet Pharmacies and the Specter of the Dormant Commerce Clause

Laura Vanderstappen*

I. INTRODUCTION

Americans today face a health care crisis of monumental proportions. Health care costs, particularly costs of prescription medications, are increasing at an alarming rate.[1] At the same time, however, estimates suggest that more than 18% of Americans, a total of nearly forty-five million individuals, lack health insurance of any kind and thus suffer an almost complete denial of access to health care.[2] An even larger percentage of Americans are significantly underinsured and similarly experience problems of access to health care.[3]

---

* J.D. (2006), Washington University in St. Louis School of Law; B.A. (2001), University of Urbana-Champaign. The author would like to thank Bonny Range and Mike Vanderstappen for their love and support.

1. According to recent estimates, health care spending accounts for nearly 15% of the nation's economy. Robert Pear, *Health Spending Rises to 15% of Economy, Record Level*, N.Y. TIMES, Jan. 9, 2004, at A16. In 2002 alone spending increased by 9.3%, reaching a total of $1.55 trillion. *Id.* Spending on prescription drugs in particular has contributed to much of the overall increase. *Id.*

2. KAISER COMM'N ON MEDICAID AND THE UNINSURED, THE UNINSURED: A PRIMER 1 (2006), *available at* http://www.kff.org/uninsured/7216.cfm. Medicare, Medicaid, and similar programs have been instrumental in guaranteeing that millions of elderly and low-income individuals receive health care coverage. *Id.* However, despite these gains, there remains a significant and undeniable gap in coverage that primarily affects "working families with low and moderate incomes, families for whom coverage is not available in the workplace or is unaffordable." *Id.*

3. *See* KAISER COMM'N ON MEDICAID AND THE UNINSURED, UNDERINSURED IN AMERICA: IS HEALTH COVERAGE ADEQUATE? 1 (2002), *available at* http://www.kkf.org/uninsured/4060-index.cfm. This report describes the underinsured as individuals who "have health insurance but face significant cost sharing or limits on benefits that may affect its usefulness in accessing or paying for needed health services." *Id.* Approximately 38% of insured individuals surveyed in 2002 reported access problems, *id*. at 1–2, and thus may be described as underinsured.

In response to these problems, Americans have begun to seek out cheaper and more convenient methods of acquiring health services and prescription medications. The Internet has provided a partial answer with the birth of "e-health." E-health broadly refers to any mode of technologically mediated health care.[4] With the rise of e-health, Americans increasingly rely on Internet services to obtain health-related information, speak with a physician, obtain a prescription, and even have the prescription filled without the discomfort, inconvenience, and expense associated with traditional methods of health care delivery.[5] Internet pharmacies in particular have proliferated as a viable solution to the current health care crisis.[6] Although Internet pharmacies may provide a beneficial solution, they also pose substantial risks to health and welfare.[7]

Individual states and the federal government have struggled to adopt a successful regulatory framework to address the significant problems posed by Internet pharmacies. Under the current framework, regulation of prescription medications, the prescribing physicians, and the dispensing pharmacists is divided between the federal government and individual states.[8] Further, states themselves have adopted various regulatory approaches aimed at restricting or controlling the activities of Internet pharmacies.[9] However, such state

4. Nicolas P. Terry, *Prescriptions sans Frontieres (or How I Stopped Worrying About Viagra on the Web But Grew Concerned About the Future of Healthcare Delivery)*, 4 YALE J. HEALTH POL'Y L. & ETHICS 183, 186 (2004). The term "e-health" encompasses various methods of technologically mediated health care, including "Internet-based prescribing and dispensing, e-prescribing, health advice websites, online continuing medical education and health care procurement." *Id.* (citations omitted). The term "telemedicine" can be used interchangeably with the term "e-health." However, as Terry points out, telemedicine initially referred more narrowly to "a consultation-based model of diagnosis and . . . treatment" in which a "primary . . . physician uses technology . . . to connect to a consulting . . . physician . . . ." *Id.* at 185. As such, it is conceptually more accurate to distinguish between these two terms.

5. *Id.* at 186–87.

6. Commentators suggest that Internet pharmacies represent "the fastest growing segment of the pharmacy industry." *Id.* at 188.

7. Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 RUTGERS L. REV. 119, 125–26 (2003). Fentiman notes that "Internet pharmacies . . . pose substantial risk to individual and public health, since their operations in the 'wild west' of cyberspace are largely out of reach of federal and state regulators, for both legal and technological reasons." *Id.* at 123 (citations omitted).

8. *See infra* Part III.

9. *See infra* Part III.B.

regulations raise significant concerns under the Dormant Commerce Clause,[10] which acts as a limitation on state regulatory authority.[11] Courts have disagreed on whether analogous regulations of Internet activity operate in violation of the Dormant Commerce Clause.[12] Most controversially, some courts have taken the position that all state regulations of Internet activity will fail because this area falls under the sole authority of the federal government.[13]

This Note argues that the Dormant Commerce Clause does not necessarily foreclose a state's ability to regulate Internet pharmacies, but that the state should keep this restriction in mind in adopting such regulations. Part II presents a brief overview of the phenomenon of Internet pharmacies, including the types of Internet pharmacies and the advantages and disadvantages that they present. Part III describes the current federal and state regulatory framework and presents several representative state regulatory responses to Internet pharmacies. Part IV presents an overview of the Dormant Commerce Clause and reviews a split of authority as to whether state regulations of the Internet represent a *per se* violation of this provision. Part V rejects at the outset a bright-line ban on all state regulations of Internet pharmacies and analyzes the validity of several representative state regulations under current Dormant Commerce Clause jurisprudence.

II. OVERVIEW OF INTERNET PHARMACIES

A. Types of Internet Pharmacies

There are two general types of Internet pharmacies: first, legitimate pharmacies that operate as an online version of traditional pharmacies; and second, illegitimate "rogue" pharmacies.[14] The first

10. *See infra* Part IV.
11. *See infra* Part IV.A.
12. *See infra* Part IV.B.
13. *See infra* notes 88, 90 and 92.
14. Fentiman, *supra* note 7, at 126. However, debate exists as to the number of "categories" of Internet pharmacies. For example, one commentator has suggested that there are four categories of online pharmacies: "'[1] online pharmacies that are partners with traditional brick and mortar pharmacies . . .; [2] online pharmacies that are themselves brick and mortar pharmacies . . .; [3] online pharmacies that operate solely on the Internet . . .; and [4] websites

type of online pharmacy is exactly like a traditional pharmacy, except that it operates online.[15] These pharmacies play a solely distributive role.[16] Customers of these legitimate pharmacies typically deliver a valid physician prescription to the online pharmacist, who then sends the filled prescription to the customer.[17]

The second type of Internet pharmacy is commonly known as a "rogue" pharmacy.[18] These pharmacies often concentrate on providing a select group of prescription drugs, such as Viagra or Prozac, to a target population.[19] Unlike legitimate online pharmacies, rogue pharmacies often do not require a prior examination or valid physician prescription to dispense the desired medications to the customer.[20] Instead, many rogue pharmacies simply require the customer to fill out an online questionnaire demonstrating his or her medical need for the desired medication.[21] Although these questionnaires are supposedly evaluated by a physician or pharmacist, it has become glaringly obvious that this screening procedure is a farce and that virtually anyone can easily obtain prescription medications from rogue pharmacies with little effort.[22]

. . . where consumers can order prescription drugs without a prescription . . . .'" Ivette P. Gomez, Note, *Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses*, 28 RUTGERS COMPUTER & TECH. L.J. 431, 433 (2002) (quoting Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. MED. & ETHICS 98, 98 (2000)). Although perhaps it is more accurate to divide the types of online pharmacies more narrowly, for purposes of this Note it is sufficient to broadly characterize online pharmacies as either traditional legitimate ventures or illegitimate "rogue" pharmacies.

15. Fentiman, *supra* note 7, at 126. An example of this type of pharmacy is drugstore.com. *Id*.

16. Terry, *supra* note 4, at 188 (noting that such legitimate Internet pharmacies "do not offer prescribing services but fill prescriptions that, while frequently electronically transmitted, are written by a traditional healthcare provider").

17. Fentiman, *supra* note 7, at 126. Customers may deliver valid prescriptions by mail or by fax, *id.*, or the prescribing physician may deliver the prescriptions to the online pharmacy by phone, Gomez, *supra* note 14, at 431. These pharmacies will not supply medication to the customer without a valid prescription obtained by a licensed physician, and they will often verify submitted prescriptions with the prescribing physician before the prescriptions are filled and sent to the customer. *Id*.

18. Fentiman, *supra* note 7, at 126.

19. *Id.* at 127.

20. *Id.*

21. *Id.*

22. *Id.* Fentiman notes that "[a]lthough this process is designed ostensibly to ensure that no patient receives . . . prescription drug[s] 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

B. Advantages and Disadvantages of Internet Pharmacies

Internet pharmacies clearly offer significant advantages to the average consumer.[23] First, by allowing consumers to submit prescriptions and receive medications electronically and through the mail, these pharmacies may provide a viable solution to the access to health care problem.[24] Similarly, Internet pharmacies allow consumers to save time and avoid inconvenience by not having to make a trip to a local pharmacy and wait on site for a prescription to be filled.[25] Internet pharmacies may also allow consumers to maintain a sense of privacy and avoid the potential embarrassment of picking up certain medications in person from a local pharmacy.[26] Finally, many Internet pharmacies offer medications at a reduced cost, thereby offering consumers a cost-effective alternative to the soaring costs of health care.[27]

Despite these advantages, Internet pharmacies, particularly rogue pharmacies, pose serious concerns that highlight the need for

---

purchase . . . [these] drug[s] online." *Id.* For example, some online questionnaires contain pre-checked "correct" answers, such that "only consumers who are supremely honest or extremely stupid will fail to receive the desired medication." *Id*. at 127–28. Further, there have been several notable instances in which individuals have obtained prescription medications from rogue pharmacies despite the fact that a cursory evaluation of the submitted questionnaires would have clearly shown the inappropriateness of such medications for these individuals. For example, an investigative journalist testified at a congressional hearing that he obtained Viagra after entering the actual height and weight of his cat in an online questionnaire. Ty Clevenger, *Internet Pharmacies: Cyberspace Versus the Regulatory State*, 15 J.L. & HEALTH 165, 165 (2001). As a result, the American Medical Association has criticized the use of such online questionnaires. *See infra* note 55.

23. *See* Fentiman, *supra* note 7; *see also A Prescription for Safety: The Need for H.R. 3880, The Internet Pharmacy Consumer Protection Act*, 108th Cong. 23–39 (2004) (statement of William K. Hubbard, Associate Commissioner for Policy & Planning) [hereinafter Hubbard Statement], *available at* http://www.fda.gov/ola/2004/internetdrugs0318.html.

24. Fentiman, *supra* note 7, at 126 ("Internet pharmacies . . . have the potential to increase access to health care, particularly for consumers for whom transportation or communication is otherwise difficult, expensive, or painful."); *see also* Hubbard Statement, *supra* note 23, at 27 (noting that Internet pharmacies provide "[a]ccess to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult").

25. Fentiman, *supra* note 7, at 129; *see also* Hubbard Statement, *supra* note 23, at 27 (noting that Internet pharmacies provide the convenience of twenty-four-hour-a-day shopping).

26. Fentiman, *supra* note 7, at 129; *see also* Hubbard Statement, *supra* note 23, at 27 (suggesting that Internet pharmacies ensure "[p]rivacy for those who don't want to discuss their medical needs in a public place").

27. *See* Fentiman, *supra* note 7, at 129.

effective regulation.[28] Most importantly, Internet pharmacies may pose an increased risk to public health by providing unsafe and dangerous prescription medications.[29] This concern is exacerbated by the fact that many Internet pharmacies are based in foreign countries.[30] These foreign medications are subject to the manufacturing and dispensing standards of the producing country, which are often less rigorous than those of the United States.[31]

A related concern is the potential for fraud.[32] Internet pharmacies may engage in fraud by failing to deliver purchased medications to the consumer.[33] Internet pharmacies may alternatively engage in fraud by intentionally supplying counterfeit or otherwise improper medications to consumers.[34] Fraud of this kind may subject a pharmacy to various criminal and civil prosecutions; however, such prosecutions often face numerous practical difficulties.[35]

---

28. *See* Hubbard Statement, *supra* note 23. Hubbard notes that "[w]hile Internet sites operated by legitimate, properly licensed pharmacies provide genuine benefits to consumers, sites that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens." *Id.* at 27–28; *see also* Fentiman, *supra* note 7, at 129–30.

29. Fentiman, *supra* note 7, at 129; *see also* Hubbard Statement, *supra* note 23, at 28 (indicating that Internet pharmacies pose risks to consumers such as "potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination," and that consumers "may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured").

30. Gomez, *supra* note 14, at 434 (indicating that "[a] survey of more than 2,000 online pharmacy services conducted in the year 2000 revealed that eighteen percent were based internationally").

31. Fentiman, *supra* note 7, at 130.

32. *Id.* at 132.

33. *Id.*

34. *Id.* (noting that fraud may result when a pharmacy delivers medications that are "counterfeit, adulterated, ineffective, or super-potent").

35. *Id.* For example, state attorneys general may attempt to bring civil actions against illegitimate Internet pharmacies alleging violation of consumer protection statutes and seeking injunctive relief. *Id.* at 152–53. In addition, private consumers may bring civil actions against Internet pharmacies alleging various tort or contract claims. *Id.* at 154. However, in civil actions such as these, "the practical problems of physically locating an Internet prescriber or pharmacist, as well as jurisdictional hurdles, may inhibit the bringing of suit." *Id.* These civil actions have also been criticized on the grounds that "the time and expense of investigating and prosecuting these cases . . . leave them with an inadequate response to illegitimate Internet prescribing and dispensing." *Id*. at 153.

In addition to civil actions, illegitimate pharmacies may be subject to criminal prosecutions alleging such crimes as "wire and mail fraud, and, therefore, RICO [Racketeer Influenced and

A final concern is the lack of medical oversight that often characterizes Internet pharmacies.[36] Consumers are often able to obtain prescription medications from Internet pharmacies without a physician examination.[37] As a result, Internet pharmacies increase the risk that consumers will practice self-diagnosis in choosing particular medications.[38] However, these self-diagnosed medications may, in reality, be ineffective for the particular patient or may pose a potential risk of complications of which the patient is unaware but that could be detected by a trained physician.[39]

III. CURRENT REGULATORY FRAMEWORK

The current regulatory framework concerning Internet pharmacies is a complicated mixture of both federal and state regulations.[40] Federal regulations focus primarily on the manufacture, sale, and distribution of pharmaceuticals,[41] while state regulations focus primarily on the licensing of pharmacists and prescribing physicians.[42] This "interlocking trellis"[43] of regulations poses numerous difficulties in ascertaining the proper realm of regulatory

---

Corrupt Organizations Act] violations." *Id.* at 132. Although perhaps less onerous, such criminal prosecutions face similar jurisdictional and practical enforcement hurdles to those mentioned above. *See id.* at 163–65. For a more detailed discussion of civil and criminal jurisdictional and practical enforcement obstacles, see Fentiman, *supra* note 7.

36. Fentiman, *supra* note 7, at 130; *see also* Hubbard Statement, *supra* note 23, at 29.

37. *See supra* notes 20–22 and accompanying text.

38. Fentiman, *supra* note 7, at 130 (noting that Internet pharmacies pose 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").

39. Hubbard Statement, *supra* note 23, at 28. In such situations, "the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified." *Id.* The concerns posed by self-diagnosis are particularly problematic when the "patient may be using a prescription drug for the first time or where the patient may be taking other medications." *Id.*

40. *See* Patricia Stolfi, Comment, *Caveat Emptor: Regulating the On-Line Medicine Man in the New Frontier*, 17 J. CONTEMP. HEALTH L. & POL'Y 377, 380–86 (2000); *see also* Clevenger, *supra* note 22. *See generally* Fentiman, *supra* note 7 (containing an overview of the current state and federal regulatory framework regarding pharmacies generally and Internet pharmacies more specifically).

41. *See infra* Part III.A.

42. *See infra* Part III.B.

43. Clevenger, *supra* note 22, at 173 (quoting the description by the Iowa Supreme Court in *State v. Rasmussen*, 213 N.W.2d 661 (Iowa 1973)).

authority for the state and federal governments, as well as in successfully applying and enforcing both sets of regulations.

A. Federal Regulations

The primary federal regulation that governs prescription pharmaceuticals is the Food, Drug, and Cosmetic Act (FDCA or "the Act").[44] Several federal agencies are responsible for enforcing the provisions of the FDCA,[45] the most dominant of which is the Food and Drug Administration (FDA).[46] The FDCA contains requirements for manufacturers and distributors (including prescribing physicians) as to packaging, labeling, and distributing pharmaceuticals.[47] The FDCA also dictates the approval process for distributing new pharmaceuticals within the United States.[48] The Act further imposes detailed registration requirements that manufacturers must follow.[49] Finally, the FDCA prohibits the sale or distribution of adulterated or misbranded drugs.[50] Manufacturers and distributors must comply

44. 21 U.S.C. §§ 301–397 (2000).

45. In addition to the Food and Drug Administration (FDA), other agencies that aid in regulating pharmaceuticals include the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Customs Service, and the Postal Service. *See* Fentiman, *supra* note 7, at 133.

46. The establishment of the FDA and the enumeration of its mission and regulatory authority can be found in the FDCA itself. 21 U.S.C. § 393. Under the FDCA, the mission of the FDA is to "protect the public health by ensuring that . . . human . . . drugs are safe and effective [and that] there is reasonable assurance of the safety and effectiveness of devices intended for human use." *Id.* § 393(b)(2)(B)-(C). The United States Supreme Court has approved FDA regulatory oversight of pharmaceuticals. *See* United States v. Sullivan, 332 U.S. 689 (1948).

47. *See* 21 U.S.C. § 352. The FDCA also regulates physician distribution of certain categories of drugs. *Id.* § 353(b). The Act provides that selected categories of drugs shall only be prescribed under certain circumstances and by specified individuals. *Id.* The Act further provides that drugs falling into the following category are subject to these requirements: "(1) A[ny] drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; . . . ." *Id.* § 353(b)(1). Drugs subject to the requirements of this section are exempt from specified labeling and packaging requirements of section 352. *Id.* § 353(b)(2).

48. *Id.* § 355.

49. *Id.* § 360.

50. *See id.* §§ 351–352 (defining when a drug is considered adulterated or misbranded, respectively).

with all of the FDCA's requirements to legally operate within the United States.[51]

B. State Regulations

Traditionally, a state may regulate matters that fall under its police power authority, which encompasses all matters that concern the health or welfare of its citizens.[52] This includes authority over certain aspects of physician and pharmacist practice despite the FDA's broad regulatory authority over the sale, distribution, and manufacture of pharmaceuticals. In particular, states remain wholly responsible for regulating, monitoring, and licensing prescribing physicians and individual pharmacists.[53]

---

51. Although the FDCA maintains strict requirements as to who may manufacture or distribute pharmaceuticals and under what circumstances, the regulatory oversight of the Act is not without potential flaw. For example, the FDCA contains an exception allowing the importation of unapproved drugs for use by an individual under certain circumstances. *Id.* § 360bbb(b). Under this exception, the FDA allows patients, under the supervision of a licensed physician, to import a limited supply of unapproved investigational pharmaceuticals. *Id.* The treating physician must certify that there is no approved alternative treatment available, that there is sufficient evidence as to the safety of the proposed medication, and that he or she will supervise the patient's use of the imported drug. *Id.*

It has been argued that the FDA's importation policy should be extended to allow for the importation of cheaper drugs from other countries such as Canada or Mexico, especially given the fact that the FDA has tended to turn a blind eye toward importation. *See generally* Helkei Tinsley, *Current Public Law and Policy Issues—Prescriptions Without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., But is Importation Really the Solution?*, 25 HAMLINE J. PUB. L. & POL'Y 437 (2004). However, as Tinsley notes, "[t]his policy . . . is limited to importing *unapproved* drugs. It was never intended to allow the *reimportation* of cheaper versions of FDA approved drugs." *Id.* at 461.

52. *See, e.g.*, United States v. E.C. Knight Co., 156 U.S. 1 (1895). The Supreme Court stated that "[i]t cannot be denied that the power of a State to protect the lives, health, and property of its citizens, and to preserve good order and the public morals . . . is a power originally and always belonging to the States . . . ." *Id.* at 11. The Court further stressed that it is essential to protect the "independence of the commercial power and of the police power" in order to preserve the "autonomy of the States as required by our dual form of government." *Id.* at 13.

53. *See* Stolfi, *supra* note 40, at 383 (noting that "the FDA has never obtained any regulatory control over the licensure of pharmacists or doctors," and that "[t]hroughout the entire regulatory debate these responsibilities remained with the states"); *see also* Fentiman, *supra* note 7, at 145–52. As Fentiman notes, "[t]he current regulatory system relies on physician oversight as an essential aspect of ensuring that drugs are safely and appropriately prescribed." *Id.* at 146. Thus, without effective state regulations that ensure the integrity of physicians and pharmacists, federal regulations aimed at pharmaceutical sale and distribution would be largely meaningless.

States have pursued various regulatory approaches in response to the concerns raised by the growing proliferation of Internet medicine and Internet pharmacies. For example, with the rise of e-health, many have voiced concerns regarding the ease with which patients can obtain a prescription online without ever setting foot in a doctor's office.[54] In response to these concerns, many states have adopted policies regulating the circumstances under which physicians may prescribe or distribute prescription medications online.[55]

More specifically, with regard to the phenomenon of Internet pharmacies, states have likewise taken various approaches.[56] Several states have adopted strict statutes forbidding or severely restricting any pharmacist from dispensing pharmaceuticals via the Internet.[57] For example, a California statute prohibits any person (whether in-

54. *See* Fentiman, *supra* note 7, at 146–47. Internet pharmacies that allow patients to obtain prescriptions simply by filling out an online questionnaire undercut the ability of the physician to provide meaningful oversight. *Id.* These websites are particularly problematic "because the 'correct' answers may be pre-checked . . . [and] there is 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." *Id.* at 146–47 (footnote omitted).

55. *Id.* at 147–48. These policies were adopted largely in response to the recommendations of the Federation of State Medical Boards of the United States. *Id.* The Federation has urged that physicians who prescribe medication to patients without conducting a full physical examination and history evaluation "clearly fail[] to meet an acceptable standard of care and [are] outside the bounds of professional conduct." FED'N OF STATE MED. BDS. OF THE U.S., INC., REPORT OF THE SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS 8 (2000), *available at* http://www.fsmb.org/pdf/2000_grpol_professional_conducts_and_ethics.pdf. The American Medical Association has also stressed that online prescribing should be limited to only those circumstances in which a valid physician-patient relationship exists. AM. MED. ASSOC., REPORT OF THE BOARD OF TRUSTEES 7-A-03 2 (2003), *available at* http://www.ama-assn.org/ama1/upload/mm/annual03/bot7a03.doc. Several states have adopted regulations in response to these recommendations. For a complete list, see Fentiman, *supra* note 7, at 148 n.144.

Many states have taken disciplinary action against physicians who have practiced Internet prescribing. These proceedings have commenced either under the above-mentioned regulations or under long-standing laws requiring physician licensing in a particular state prior to prescribing medications to in-state patients. *Id.* at 148–49. However, because such online prescribers are often located out of state, "such [proceedings] are extremely difficult and resource-intensive, as each state must track down the out-of-state physician . . . and then initiate disciplinary proceedings" in cooperation with the physician's state of residence. *Id.* at 149.

56. *Id.* at 150. This Note will only examine a representative few of these regulatory approaches. For a more comprehensive discussion of the various state approaches to the regulation of Internet pharmacies, see *id.* at 149–52.

57. *See, e.g.*, CAL. BUS. & PROF. CODE § 4067 (West 2003).

state or out-of-state) from dispensing prescription drugs via the Internet to residents of California except when prescribed pursuant to a good faith physical examination.[58] This statute limits the circumstances under which an Internet pharmacist may dispense prescription medications. It also makes enforcement less difficult by requiring that the dispensing pharmacist inquire as to a prior examination.[59]

Other states have taken a slightly less strict approach, permitting Internet pharmacies to dispense medications so long as they are licensed and certified by the state's board of pharmacy.[60] For example, a Nevada statute prohibits any illegal Internet pharmacy (whether in-state or out-of-state) from filling or dispensing a prescription to any Nevada resident.[61] The statute defines "illegal Internet pharmacy" as any pharmacy that is not licensed and certified pursuant to Nevada regulations.[62] These two provisions read together establish that any pharmacist may fill or dispense medications via the Internet so long as he or she is properly licensed to do so by the state of Nevada.

---

58. *Id*. The statute provides in relevant part:

> No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous 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 or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination . . . .

Id. § 4067(a).

59. *Id.*; *see also* Fentiman, *supra* note 7, at 150. The language of the California statute "effectively establish[es] a duty to inquire about the nature of the physician-patient relationship that led to the prescription." *Id.* By doing so, the statute "makes it much easier for prosecutors and/or state licensing boards to succeed in reining in Internet pharmacies." *Id.*

60. *See, e.g.*, NEV. REV. STAT. § 453.3638 (2005).

61. The statute also prohibits any illegal pharmacy located in the state of Nevada from filling or delivering medication to anyone who is a resident of any other state. *Id*. § 453.3638(1)–(2) (prohibiting any illegal pharmacy—located either within the state of Nevada or within any other state—from "fill[ing] or refill[ing] a prescription for a prescription drug for another person located within or outside this State; or . . . [d]eliver[ing] or caus[ing], allow[ing] or aid[ing] in the delivery of a controlled substance, imitation controlled substance, counterfeit substance or prescription drug to another person located within or outside this State").

62. *Id.* § 453.3618 (defining an illegal Internet pharmacist as "a person located within or outside this State who is not licensed and certified by the board pursuant to [state regulation] to engage in the practice of pharmacy via the Internet . . . .").

Finally, several other states have enacted statues that prohibit out-of-state Internet pharmacists from dispensing medication to residents in the state unless they are validly licensed in their home state and follow other statutory requirements.[63] For example, a New York statute requires *inter alia* that all nonresident pharmacists be licensed and in good standing in their state of residence, maintain available records of all shipments to the state of New York, and provide a toll-free telephone number at which the pharmacist can be reached.[64] States that adopt this approach generally defer to the home state of the nonresident pharmacy to bring disciplinary actions.[65]

IV. THE DORMANT COMMERCE CLAUSE

A. Background and Analytical Framework

The Commerce Clause of the Constitution grants Congress the power to regulate interstate commerce.[66] Although the Constitution is

63. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 8, § 63.8 (2003). The New York statute applies generally to all nonresident pharmacies that "ship[], mail[], or deliver[] prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in New York State." *Id.* § 63.8(a)(1). However, the statue also specifically provides that "[s]uch establishments *shall include* . . . pharmacies that transact business through the use of the internet." *Id.* (emphasis added).

64. *Id.* § 63.8(b)(5)-(6). More specifically, the statute provides:

> (5) In order to be registered, nonresident establishments shall: (i) be licensed and/or registered in good standing with the state of residence; (ii) maintain, in readily retrievable form, records of drugs and/or devices shipped into New York State; . . . (iv) comply with all statutory and regulatory requirements of the state where the nonresident establishment is located . . .; (6) (i) . . . provide a toll-free telephone number that is available during normal business hours at least 40 hours per week . . . .

Id.

65. This assertion is supported by the above-quoted language requiring that all nonresident pharmacists comply with the statutory and regulatory requirements of their home state. *Id.* § 63.8(b)(5)(iv). As such, it can be assumed that the home state would similarly be responsible for commencing disciplinary or enforcement action against the pharmacy at issue. However, the statute more specifically notes that "for controlled substances shipped, mailed, or delivered into New York State, the nonresident pharmacy shall follow Federal law and New York State law." *Id.* This suggests that New York may commence disciplinary action against a nonresident pharmacist if the incident involves the distribution of controlled substances rather than prescription medication. However, the specific language of this provision in whole is somewhat ambiguous and does not specifically address New York's authority regarding disciplinary actions against nonresident pharmacies that dispense only prescription medications.

66. *See* U.S. CONST. art. I, § 8 (stating that "[t]he Congress shall have the power . . . [t]o

silent as to the Commerce Clause's limits on state regulation, courts consistently interpret the Commerce Clause as having a negative, or "dormant," sweep that limits state regulations that interfere with interstate commerce.[67] This negative sweep is known as the Dormant Commerce Clause.[68]

The Dormant Commerce Clause prohibits state regulations in two ways. First, it prohibits state regulations that discriminate against interstate commerce. Such prohibited discrimination may be facially evident,[69] or may be implied from discriminatory means[70] or

---

regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes").

67. *See, e.g.*, Gibbons v. Ogden, 22 U.S. 1, 227 (1824) (Johnson, J., concurring) (containing the earliest suggestion of this negative aspect of the Commerce Clause: "[T]he grant of [commerce] power [to the federal government] carries with it the whole subject, leaving nothing for the State to act upon.").

68. There are several principal justifications for interpreting the Commerce Clause as having an implied dormant aspect. *See* H.P. Hood & Sons, Inc. v. Du Mond, 336 U.S. 525 (1949). First, a historical argument suggests that the Framers, in adopting the Commerce Clause, necessarily intended that state laws interfering with interstate commerce could not stand. *Id*. at 533–34. Second, an economic justification asserts that prohibiting state regulation in the realm of interstate commerce promotes economic growth. *Id*. at 532–33. Third, a political argument suggests that citizens of one state should not be subject to potentially harmful regulations of another state in which they have no political representation. *See* ERWIN CHEMERINSKY, CONSTITUTIONAL LAW 321 (1st ed. 2001) (citing McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 429–30 (1819)).

However, the Dormant Commerce Clause has also received harsh criticism. For example, Supreme Court Justice Clarence Thomas has suggested that "[t]he negative Commerce Clause has no basis in the text of the Constitution, makes little sense, and has proved virtually unworkable in application." Camps Newfound/Owatonna, Inc. v. Town of Harrison, 520 U.S. 564, 610 (1997) (Thomas, J., dissenting).

69. *See, e.g.*, Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 522 (1935). *Baldwin* involved a challenge to a New York regulation that prohibited a milk distributor from selling milk obtained out of state if the price of such milk was lower than the required price of in-state milk. *Id.* at 519. In holding the state regulation unconstitutional, the Supreme Court declared that the regulation violated the Dormant Commerce Clause because "the avowed purpose . . . [was] to suppress or mitigate the consequences of competition between the states." *Id.* at 522. It can be assumed, by extending this holding, that any state regulation that facially discriminates against out-of-state competitors in an effort to prevent or discourage interstate competition will almost always be *per se* invalid. *See also* C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383, 392 (1994) (stating that "[d]iscrimination against interstate commerce in favor of local business or investment is *per se* invalid, save a narrow class of cases" (citations omitted)).

70. The Supreme Court has suggested that a state regulation may be impliedly discriminatory in means if it attempts to regulate activities occurring wholly outside of the state's borders. *See, e.g.*, Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 585 (1986). The Court considered a challenge to a New York law that required "every liquor distiller or producer that [sold] liquor to wholesalers within [New York] to sell at a price

effects.[71] If a court determines that a state regulation is discriminatory in nature, it will subject the regulation to stricter judicial review and the regulation will be found virtually *per se* invalid.[72] Second, the Dormant Commerce Clause prohibits state regulations that, although nondiscriminatory in nature, impose an undue burden on interstate commerce.[73] In determining the validity of such nondiscriminatory regulations, courts apply less stringent review by beginning with a presumption in favor of the statute.[74]

Given these alternative prohibitions on state regulation, analysis under the Dormant Commerce Clause requires a two-pronged inquiry.[75] First, one must ask whether the regulation is

---

that [was] no higher than the lowest price the distiller charge[d] wholesalers anywhere else in the United States." *Id.* at 575. The Court invalidated this law on the ground that New York impermissibly "project[ed] its legislation into [other States]," and therefore ran afoul of the Dormant Commerce Clause. *Id.* at 583 (quoting *Baldwin*, 294 U.S. at 521).

Similarly, the Supreme Court has indicated that a regulation may also be impliedly discriminatory in means if it imposes burdens on out-of-state competitors, but fails to impose similar burdens on in-state competitors. *See, e.g.*, City of Philadelphia v. New Jersey, 437 U.S. 617, 628 (1978). In *City of Philadelphia* the Court considered a New Jersey law that prohibited the importation of waste for disposal in New Jersey landfills. *Id.* at 618. Although the Court recognized that the regulation may have been designed to serve legitimate state interests, it held that these interests could not be served "by discriminating against articles of commerce coming from outside the State unless there is some reason, apart from their origin, to treat them differently." *Id.* at 626–27.

71. The Supreme Court has also suggested that a regulation may be discriminatory in effect when it affects interstate commerce more severely than intrastate commerce. *See, e.g.*, Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 350–52 (1977). In *Hunt*, a North Carolina statute prohibited containers of apples shipped into the state from displaying the shipping state's grade, requiring instead that all containers display the United States grade. *Id.* at 335. The Court invalidated the statute, noting that the North Carolina regulation had "the practical effect of not only burdening interstate sales of [another state's] apples, but also discriminating against them." *Id.* at 350.

72. *See* CHEMERINSKY, *supra* note 68, at 330. Chemerinsky notes that "if the Court concludes that a state is discriminating against out-of-staters, then there is a strong presumption against the law and it will be upheld only if it is necessary to achieve an important purpose." *Id.*

73. *See, e.g.*, Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (establishing that state regulations may be held invalid under the Dormant Commerce Clause if the burdens imposed by the regulations on interstate commerce outweigh the local benefits to be gained from them).

74. *See* CHEMERINSKY, *supra* note 68, at 330. "[I]f the Court concludes that the law is non-discriminatory, then the presumption is in favor of upholding the law, and it will be invalidated only if it is shown that the law's burdens on interstate commerce outweigh its benefits." *Id.* In analyzing these cases, the distinction between discriminatory and nondiscriminatory regulations is extremely blurry. It is often difficult to determine whether a particular regulation is to be subject to a higher or more relaxed standard of review.

75. *See, e.g.*, Pharm. Mfrs. Ass'n v. N.M. Bd. of Pharmacy, 525 P.2d 931, 935 (N.M. Ct. App. 1974).

discriminatory.[76] If so, the regulation will be subject to meticulous judicial review and will be virtually *per se* invalid. Second, one must ask whether a nondiscriminatory regulation imposes an undue burden on interstate commerce.[77] In such cases, courts must analyze the challenged regulation using the balancing approach mandated by the Supreme Court in *Pike v. Bruce Church, Inc*.[78] The *Pike* balancing test requires courts to evaluate the validity of a regulation by weighing the incidental burdens imposed on interstate commerce against the local benefits to be gained.[79] Only when the benefits gained exceed the burdens imposed will a state regulation be valid under the Dormant Commerce Clause.[80]

B. The Dormant Commerce Clause and the Internet

To date, there has been no case law concerning the validity of state regulations of Internet pharmacies.[81] However, there have been

---

76. *See* CHEMERINSKY, *supra* note 7, at 318.

77. *Pike*, 397 U.S. at 142.

78. *Id. Pike* involved a challenge to an Arizona statute that required all cantaloupes grown in the state to be packaged and shipped in closed containers. *Id.* at 138. The Supreme Court held this statute unconstitutional on the ground that it imposed a significant burden on interstate commerce but provided very limited local benefit to the state of Arizona. *Id.* at 143–46.

However, in recent years, several Justices and commentators have objected to the *Pike* balancing approach, arguing instead that all nondiscriminatory state regulations should be upheld. *See* Bendix Autolite Corp. v. Midwesco Enter., 486 U.S. 888, 897–98 (1988) (Scalia, J., concurring). Justice Scalia argues that "[w]eighing the governmental interests of a State against the needs of interstate commerce is . . . a task squarely within the responsibility of Congress, and ill suited to the judicial function." *Id.* at 898 (citations omitted); *see also* Donald H. Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091, 1101–02 (1986).

79. *See Pike*, 397 U.S. at 142 (citations omitted). "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 benefits." *Id*. The Court further noted that "the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities." *Id.*

80. *Id.*

81. However, there have been several cases that have analyzed state regulations of pharmacy activity more generally under the Dormant Commerce Clause. *See, e.g.*, State v. Rasmussen, 213 N.W.2d 661 (Iowa 1973); Pharm. Mfrs. Ass'n v. N.M. Bd. of Pharmacy, 525 P.2d 931 (N.M. Ct. App. 1974). These cases illustrate conflicting views as to whether state regulations that target pharmacies located out-of-state violate the Dormant Commerce Clause.

For example, in *Pharmaceutical Manufacturers Ass'n*, the court considered a challenge to a

several cases concerning the validity of state regulations of Internet activity on a more general level,[82] from which specific conclusions

---

New Mexico statute that imposed regulations and a licensing fee on out-of-state pharmacists who distributed medications to in-state residents. 525 P.2d at 934. The challenged provision stated:

> No manufacturer shipping dangerous drugs into New Mexico or who sells or distributes dangerous drugs in this state through any person or media, other than a wholesaler who has obtained a license, shall conduct the business of selling or distributing dangerous drugs without obtaining an out-of-state drug license from the board.

Id. The statute further required that out-of-state pharmacists pay a $100.00 licensing fee. *Id.* The court first found that the challenged provisions were not discriminatory in nature and thus did not represent a *per se* violation. *Id.* at 935. The court noted that at the time there were no drug manufacturers located within the state of New Mexico and therefore "only one class, out-of-state manufacturers, [was] affected by the regulation . . . ." *Id.* The court further noted that "since all persons in that class [were] treated equally, there [was] no discrimination." *Id.* The court also analyzed the challenged provisions under the *Pike* balancing test and concluded that the provisions were valid. *Id.* The court noted that the primary purpose of the provision was "the protection of the public from dangerous drugs" and that "[this] purpose [was] well within the traditional definition of police power." *Id.* (citations omitted). However, the court conceded that the registration fee may have affected small manufacturers that sought to ship products into New Mexico. *Id*. Despite this, the court also noted that "the fee [was] not large and only the manufacturers and wholesale distributors, not salesmen, [were] required to pay it." *Id.* As such, the court held that this "small burden [did] not outweigh the substantial state benefit derived from the control." *Id.*

In *Rasmussen*, the court considered an Iowa provision that, as interpreted by both parties, "prohibit[ed] the filling by Iowa pharmacists of prescriptions written by nonresident physicians who are not registered by the Iowa authorities to prescribe controlled substances." 213 N.W.2d at 663. However, the *Rasmussen* court interpreted the statute to also effectively prohibit Iowa pharmacists from filling prescriptions written by out-of-state unregistered physicians. *Id*. at 664. The court invalidated this provision on the narrow ground that the registration requirement conflicted with federal registration requirements and thus was preempted. *Id*. at 666. However, the court noted in dicta that the challenged provision would also run afoul of the Dormant Commerce Clause. *Id*. at 667–68. The court first noted that the statute "[did] not discriminate in its language between foreign practitioners and those registered in Iowa" and thus did not represent a *per se* violation of the Dormant Commerce Clause. *Id.* at 667. However, the court further noted that although it "[did] not question the right of a state to regulate for the health and safety of its citizens," the "need for uniformity in registration for practitioners" outweighed Iowa's interest. Therefore, the court held the provisions unconstitutional. *Id*. at 667–68 (citations omitted). This suggestion resembles to the *Pataki* court's argument that regulation of Internet pharmacies is necessarily a matter of federal, rather than state, concern. *See infra* note 90 and accompanying text. For further discussion of these cases and the Dormant Commerce Clause, see Clevenger, *supra* note 22, at 175–79; Fentiman, *supra* note 7, at 165–76.

82. *See, e.g.*, Ford Motor Co. v. Tex. Dep't of Transp., 264 F.3d 493 (5th Cir. 2001); Am. Civil Liberties Union v. Johnson, 194 F. 3d 1149 (10th Cir. 1999); PSINet, Inc. v. Chapman, 167 F. Supp. 2d 878 (W.D. Va. 2001), *aff'd*, 362 F.3d 227 (4th Cir. 2004); Cyberspace Commc'ns, Inc. v. Engler, 142 F. Supp. 2d 827 (E.D. Mich. 2001); Am. Libraries Ass'n v. Pataki, 969 F. Supp. 160 (S.D.N.Y. 1997).

may be drawn regarding the validity of state regulations of Internet pharmacies.[83] A review of the current case law in this area reflects a split of authority as to whether such regulations pose an impermissible burden on interstate commerce, thus violating the Dormant Commerce Clause.[84]

The first line of cases suggests that state laws that regulate Internet activities necessarily violate the Dormant Commerce Clause. The preeminent case representing this line of reasoning is *American Libraries Association v. Pataki*.[85] In *Pataki*, the court invalidated under the Dormant Commerce Clause a law that prohibited the communication of certain types of sexually offensive material via the Internet.[86] The *Pataki* court invalidated the regulation using three alternative theories.[87] First, the court found that the regulation was discriminatory in nature and thus represented a *per se* violation of the Dormant Commerce Clause.[88] Second, the court suggested that even if the regulation were not a *per se* violation, it would be invalid under

---

83. It may be argued that these cases involving the general regulation of Internet activities are not completely analogous and thus should not be dispositive of the fate of regulations specifically regarding Internet pharmacies. However, this debate is beyond the scope of this Note.

84. *See* Clevenger, *supra* note 22, 175–76; Fentiman, *supra* note 7, at 172; Terry, *supra* note 4, 235–39.

85. *Pataki*, 969 F. Supp. 160.

86. *Id.* The *Pataki* court noted that Dormant Commerce Clause analysis was appropriate because of the "similarity between the Internet and more traditional instruments of interstate commerce." *Id.* at 161. The court also noted that this analysis was proper given the Commerce Clause's goal of preventing the "menace of inconsistent state regulation." *Id.* at 169. The statute in question provides in pertinent part that it is a crime for any individual who:

> [k]nowing 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.

Id. at 163 (quoting N.Y. PENAL LAW § 235.21(2) (McKinney 2006)).

87. *Pataki*, 969 F. Supp. at 169. It is unclear which of these three theories led to the invalidation of the challenged regulation in this case. It is thus likewise unclear which of these theoretical routes is merely dicta.

88. *Id.* at 173–77. The court noted that because "[t]he nature of the Internet makes it impossible to restrict the effects of the New York Act to conduct occurring within New York," the challenged regulation impermissibly extended its reach by seeking to regulate conduct occurring wholly outside of the state's borders. *Id.* at 177. As such, the act was discriminatory in means and *per se* invalid. *Id.*; *see also supra* note 70.

the *Pike* balancing test.[89] Finally, and most importantly for purposes of this analysis, the court suggested that given the amorphous nature of the Internet, laws that regulate the Internet should fall within the sole realm of federal, rather than state, government.[90]

Several other federal courts that have considered the issue of Internet regulation have followed *Pataki*'s reasoning.[91] However, these cases differ as to which theory of *Pataki* was used to invalidate the regulations in question. For example, one court rested its holding on the fact that the state regulation impermissibly regulated out-of-state conduct, and was thus discriminatory in nature.[92] Another court, ambiguously and with hesitation, suggested that the current nature of the Internet prohibits any state regulation in this area.[93] Finally, a

---

89. *Id.* at 177–81. In applying the *Pike* balancing test, the *Pataki* court posited that although the protection of children against exposure to objectionable sexual material via the Internet was a legitimate state interest, "[t]he local benefits likely to result from the New York Act are not overwhelming," *id.* at 178, whereas the act posed an "extreme burden on interstate commerce," *id.* at 179. For a discussion of the *Pike* balancing test, see *supra* notes 73–74, 78–79 and accompanying text.

90. *Pataki*, 969 F. Supp. at 181–83. The court argued that "courts have long recognized that certain types of commerce demand consistent treatment and are therefore susceptible to regulation only on a national level" and that "[t]he Internet represents one of those areas." *Id.* at 181. The court further argued that a national regulatory scheme in regards to Internet activities would ensure "that users are reasonably able to determine their obligations." *Id.* at 182. Alternatively, "[r]egulation on a local level . . . will leave users lost in a welter of inconsistent laws . . . ." *Id.*; *see also* State v. Rasmussen, 213 N.W.2d 661, 668 (Iowa 1973) (using a similar argument to invalidate a state regulation targeting pharmacy activities more generally).

91. *See, e.g.*, ACLU v. Johnson, 194 F.3d. 1149 (10th Cir. 1999); PSINet, Inc. v. Chapman, 167 F. Supp. 2d 878 (W.D. Va. 2001), *aff'd*, 362 F.3d 227 (4th Cir. 2004); Cyberspace Commc'ns, Inc. v. Engler, 142 F. Supp. 2d 827, 830–31 (E.D. Mich. 2001).

92. *Cyberspace*, 142 F. Supp. 2d at 830–31. The *Cyberspace* court considered a Michigan statute that prohibited the communication of certain types of objectionable sexual materials to minors via the Internet. *Id.* at 830 (analyzing the statute described in *Cyberspace Communications, Inc. v. Engler*, 55 F. Supp. 2d 737, 739–40 (E.D. Mich. 1999)). In granting the plaintiff's motion for summary judgment, the *Cyberspace* court noted, *inter alia*, that the regulation violated the Dormant Commerce Clause. 142 F. Supp. 2d at 831. Specifically, the court noted that the regulation "attempt[ed] to control Internet communications which might originate . . . in other states, or in other countries." *Id.* at 830–31. Because the Dormant Commerce Clause forbids such an extraterritorial extension of state regulation, the law in question could not stand. *Id.* at 831.

93. *PSINet*, 167 F. Supp. 2d at 891. As in *Cyberspace*, the *PSINet* court was faced with a Virginia statute that prohibited the display or communication of sexually offensive material to minors. *Id.* at 882. The court seemingly invalidated the regulation because it "burden[ed] interstate commerce unduly by placing restrictions on electronic commercial materials in *all* states" and therefore violated the Dormant Commerce Clause. *Id.* at 890–91 (emphasis added). However, the *PSINet* court also suggested that it may support the *Pataki* court's view that

third court applied all three *Pataki* theories.[94] These differences highlight the difficultly that *Pataki* poses in terms of precedential value.[95]

The second line of cases suggests that state regulations of Internet activities do not necessarily violate the Dormant Commerce Clause. The preeminent case representing this line of reasoning is *Ford Motor Company v. Texas Department of Transportation*.[96] The *Ford* court upheld a state law that had been applied so as to prohibit the operation of an Internet website.[97] Although the court upheld the regulation under the *Pike* balancing test,[98] the court also explicitly disapproved of the *Pataki* court's blanket invalidation of all state regulations of Internet activity.[99]

Internet activities are uniquely within the regulatory realm of the federal government, and as such all state regulations thereof must be invalid. *Id.* at 891. The *PSINet* court specifically noted that the current nature of the Internet makes it "technologically infeasible for a Web site [sic] operator to limit access to online materials by geographic location." *Id.* However, by explicitly referring to the "*current* status of geographic filtering technology," *id.* at 891 (emphasis added), the court exhibited a reluctance to permanently foreclose all state regulations in this realm, arguably suggesting that with future technological advancements, such regulations may be permissible.

94. *Johnson*, 194 F.3d at 1160–61.

95. For a discussion of the precedential difficulties posed by the *Pataki* holding, see *supra* note 87.

96. 264 F.3d 493 (5th Cir. 2001).

97. The regulation at issue in *Ford* did not specifically target Internet activity. Instead, the regulation swept more broadly by prohibiting an automobile manufacturer or distributor from engaging in activities of or acting as a dealer without a license. *Id*. at 498. Ford Motor Company sold pre-owned vehicles via an Internet site maintained and operated by Ford. *Id*. However, the state of Texas alleged that this practice violated the above-mentioned statute. *Id*. In response, Ford maintained that this state regulation violated the Dormant Commerce Clause and thus was invalid. *Id*.

98. *Ford*, 264 F.3d at 503–04. The court first considered whether the challenged regulation was discriminatory in nature. *Id.* at 499–502. After determining that the challenged regulation was nondiscriminatory, the court analyzed the regulation under the *Pike* balancing test. *Id*. at 503–04. The court upheld the regulation under this test and noted that "Ford ha[d] failed to establish that the burden [on interstate commerce was] clearly excessive in relation to the putative local benefits." *Id*. at 503.

99. *Id.* at 505. The *Ford* court accepted the *Pataki* court's argument for uniformity in regulation. *Id.* However, the court countered this assertion by noting that "application of this principle in circumstances like the instant case would lead to absurd results. It would allow corporations or individuals to circumvent otherwise constitutional state laws and regulations simply by connecting the transaction to the internet." *Id.*

The decision of the lower court in this case also contains an emphatic rejection of the *Pataki* reasoning. Ford Motor Co. v. Tex. Dep't of Transp., 106 F. Supp. 2d 905, 909 (W.D. Tex. 2000). Specifically, the court noted that it would be illogical to hold, as *Pataki* suggests,

V. ANALYSIS AND PROPOSAL

A. Pataki*'s Bright Line Invalidation of All State Regulations of the Internet*

This Note rejects at the outset the *Pataki* court's[100] suggestion that regulation of the Internet falls solely under the authority of the federal government and therefore any state regulation in this area must necessarily fail.[101] This suggestion cannot be dispositive of future cases for several reasons. First, in addition to a blanket invalidation of all state regulations of the Internet, the *Pataki* court also suggested two additional theories upon which to invalidate the challenged regulation.[102] It is unclear upon which of these three justifications the *Pataki* holding is based, and thus equally unclear which of these theoretical justifications are merely dicta. This problem may best be exemplified by the difficulty experienced by subsequent courts that have attempted to follow *Pataki*'s holding.[103] Several courts have ostensibly followed the *Pataki* holding, but have vastly differed as to which of the three alternate *Pataki* theories was appropriate. Indeed, only one such court adopted *Pataki*'s blanket invalidation alone to invalidate a challenged regulation, and it did so with noticeable hesitation.[104] Given these precedential concerns, the blanket justification proposed by *Pataki* cannot be dispositive of future cases.

---

that "an activity which is appropriately regulated when accomplished through any other medium becomes sacrosanct when accomplished through the internet." *Id.* The court cautioned that if the *Pataki* court's reasoning were accepted, "all state regulatory schemes would fall before the mighty altar of the internet," a consequence which surely could not have been intended by the creation of the Dormant Commerce Clause. *Id.* However, unlike the regulation in *Pataki*, the regulation in *Ford* was not directed solely at Internet activities but was merely applied as such in the particular case at hand. *See supra* note 97. With this distinction in mind, it is unclear how the Fifth Circuit would analyze a similar regulation directed exclusively at Internet activities.

100. Am. Libraries Ass'n v. Pataki, 969 F. Supp. 160 (S.D.N.Y. 1997).

101. For a detailed discussion of the *Pataki* holding, see *supra* Part IV.B and notes 85–90.

102. The *Pataki* court also suggested that the challenged regulation may by invalid by acting to discriminate against out-of-state competitors, or by imposing an undue burden on interstate commerce in violation of the *Pike* balancing test. *See supra* notes 88–89.

103. For a list of cases that have followed the *Pataki* holding, see *supra* note 91.

104. PSINet, Inc. v. Chapman, 167 F. Supp. 2d 878, 891 (W.D. Va. 2001), *aff'd*, 362 F.3d 227 (4th Cir. 2004); *see also supra* note 93 and accompanying text.

Moreover, the *Pataki* court's underlying assumption is necessarily flawed in several respects and thus is shaky ground upon which to invalidate all state regulations of Internet activity. The *Pataki* court rested its blanket invalidation in part on the fact that the amorphous nature of the Internet inextricably links it to interstate commerce, and thus requires the oversight of the federal government pursuant to its Commerce Clause powers.[105] As the *Ford* court recognized, although the *Pataki* court's premise that the nature of the Internet necessarily implicates interstate commerce may be valid, it does not support the blanket invalidation of all state regulations in this area.[106]

The appropriate analysis under the Dormant Commerce Clause is not simply whether the state regulation affects interstate commerce.[107] Instead, Dormant Commerce Clause analysis requires a two-pronged inquiry: first, whether the challenged regulation discriminates against out-of-state commerce; and second, whether or not the challenged regulation poses an undue burden on interstate commerce.[108] By imposing a blanket invalidation on all state regulations of Internet activity without a showing that they are either discriminatory or unduly burdensome on interstate commerce, the *Pataki* court ignored and effectively eviscerated decades of Dormant Commerce Clause jurisprudence.

In addition, the blanket invalidation of all state regulations of the Internet would contravene fundamental principles of federalism, which the FDA itself has traditionally respected.[109] The vast nature of the Internet allows it to reach into all aspects of life, such that

---

105. *See supra* note 90. The *Pataki* court noted that the Internet exhibits a "chaotic, random structure" such that it is uniquely immune from effective organization or control by a unified body. *Pataki*, 969 F. Supp. at 164. The *Pataki* court further noted that "[o]nce a provider posts content on the Internet, it is available to all other Internet users worldwide." *Id.* at 167 (citations omitted). Therefore, a user who posts information on the Internet has "no way of knowing the location of the recipient of his or her communication." *Id.* Given this geographically amorphous nature, the *Pataki* court held that traditional geographical limits on state regulation could not be meaningfully applied to Internet regulations, and thus attempted state regulations must necessarily fail. *Id.* at 168–73.

106. For a discussion of the decision in *Ford* and the court's rejection of *Pataki*'s underlying assumption, see *supra* note 99.

107. *See supra* Part IV.A.

108. *See supra* Part IV.A.

109. Generally, states retain regulatory authority over police power matters, that is, those matters which concern the public health and welfare. *See supra* note 52 and accompanying text.

virtually every activity will in some way be connected to the Internet. Therefore, if the *Pataki* court's theory is accepted, a state could easily and unjustifiably be robbed of virtually all of its traditional regulatory authority over police power matters simply because the activities are in some way intertwined with or carried out via the Internet. For example, the regulation of pharmacists and pharmacies has traditionally fallen under states' police power authority over matters affecting public health and welfare.[110] Allowing the federal government to assume regulatory power when the pharmacy happens to conduct business over the Internet represents an unjustified intrusion into the traditional regulatory rights of the states. This is a result that surely cannot be supported.

Finally, state participation and regulation is vital to the effective control of Internet pharmacies.[111] The problems posed by Internet pharmacies are massive and sweeping in nature. Consequently, it is simply unreasonable to presume that the already overworked and understaffed FDA can effectively tackle this problem without the assistance of individual states. For example, it is clear that states have thus far been the driving force behind implementing new and experimental regulations and initiating successful disciplinary actions against unsafe pharmacies.[112] States should continue to play an indispensable role in attacking the problems associated with illegitimate Internet pharmacies.

B. Analysis of Representative State Regulations

Given the rejection of the *Pataki* court's *per se* invalidation, it is necessary to analyze the validity of representative state regulations under the traditional two-pronged Dormant Commerce Clause inquiry.[113]

---

110. *See supra* notes 52–53 and accompanying text.

111. States are responsible for bringing enforcement and disciplinary actions against Internet pharmacies. *See supra* notes 35, 53.

112. For examples, see *supra* note 35.

113. Dormant Commerce Clause cases must be evaluated under a two-pronged test: first, whether the regulation acts in a discriminatory manner; and second, whether the regulation imposes an undue burden on interstate commerce. *See supra* Part IV.A and accompanying notes.

1. Nevada Statute

Of the three representative statutes,[114] the Nevada statute most easily passes muster under this inquiry and would likely satisfy the requirements of the Dormant Commerce Clause. The Nevada statute requires that all Internet pharmacies that supply medication to Nevada residents be licensed with the state of Nevada.[115] These requirements apply equally to both in-state and out-of-state Internet pharmacies and do not regulate extraterritorially because they limit their reach only to transactions that involve Nevada residents. Therefore, the Nevada statute is likely nondiscriminatory, and thus passes the first prong of the Dormant Commerce Clause inquiry.

The Nevada statute will also likely survive the second prong of the Dormant Commerce Clause inquiry, the *Pike* balancing test. The Nevada statute provides immense local benefits by protecting the public health and welfare from unscrupulous Internet pharmacists and unsafe prescription medications. In contrast, the Nevada statute imposes only a minor burden on interstate commerce by simply requiring that Internet pharmacists obtain a Nevada license prior to doing business in the state. It is likely that this small burden on interstate commerce will be outweighed by the immense local benefits to be gained, and thus the Nevada statute would also pass the second prong of the Dormant Commerce Clause analysis.

2. New York Statute

In contrast, the New York statute is somewhat more problematic and thus may not pass the two-pronged Dormant Commerce Clause inquiry as written. The New York statute requires *inter alia* that out-of-state Internet pharmacies be licensed with their home state, maintain available records of shipments to New York residents, and maintain a toll-free number where a pharmacist can be reached.[116] However, the New York requirements apply only to out-of-state

114. *See infra* Part III.B.

115. NEV. REV. STAT. § 453.3638 (2005); *see also supra* notes 61–62 and accompanying text.

116. N.Y. COMP. CODES R. & REGS. tit. 8, § 63.8 (2003); *see also supra* note 64.

pharmacies. It is therefore arguable that the statute operates in a facially discriminatory manner with the goal of deterring out-of-state business. Similarly, there is no language in the New York statute that limits its application to only those pharmacists who conduct business within the state of New York; therefore the statute also arguably regulates extraterritorially. Given these two problems, the New York statute may be found discriminatory and thus *per se* invalid. It is unclear whether the New York statute would pass even the first prong of Dormant Commerce Clause inquiry.

If these concerns are insufficient to cause the statute to be held discriminatory and thus *per se* invalid, the New York statute would likely pass muster under the second prong's *Pike* balancing test. As above, the statute provides immense local benefits by protecting New York residents from unsafe medications. At the same time, the burdens imposed are very few. Indeed, by merely requiring the Internet pharmacy to be licensed in its home state, the New York statute arguably requires no more from the Internet pharmacy wishing to do business in New York than it would otherwise be required to do if it were to limit its business to its home state. As such, it is likely that the New York statute would survive the *Pike* balancing test.

3. California Statute

The California statute is also problematic and therefore may be held invalid as written under current Dormant Commerce Clause jurisprudence. The California statute requires that all Internet pharmacists establish that there has been a good faith physical examination by a physician prior to supplying any medication to a California resident.[117] Like the Nevada statute, the requirements of the California statute apply equally to both in-state and out-of-state Internet pharmacies. Likewise, the California statute imposes requirements only upon those pharmacies that conduct business with California residents, and therefore it does not attempt to impermissibly extend its reach extraterritorially. Given this, the California statute on its face operates in a nondiscriminatory fashion

117. CAL. BUS. & PROF. CODE § 4067 (West 2003); *see also supra* note 58.

and therefore would likely pass the first prong of the Dormant Commerce Clause inquiry.

In contrast, it is unclear whether the California statute would pass the second prong's *Pike* balancing test. As above, the statute potentially provides immense local benefits by protecting California residents from unsafe prescription medications. However, the California statute also requires that the pharmacist inquire as to a prior good faith physical examination before completing any transaction via the Internet. In practice, this requirement, although perhaps useful, imposes an extremely onerous burden on Internet pharmacies by requiring that a pharmacist or another employee contact the prescribing physician to verify the validity of the prescription for each transaction. This requirement is even more daunting for the Internet pharmacy that is located out-of-state or perhaps even out of the country. The necessary effect of such a requirement would be to discourage Internet pharmacies from doing business in California. As such, the California statute arguably poses an undue burden on interstate commerce. It therefore possibly fails the *Pike* balancing test.

C. Proposal

Future courts should follow the *Ford* court in rejecting *Pataki*'s blanket invalidation of all state regulations of Internet pharmacies. Instead, courts should analyze challenged regulations under the traditional two-pronged Dormant Commerce Clause inquiry. First, courts should consider whether the challenged regulations operate discriminatorily. If so, the regulation should be found *per se* invalid. If not, the court should apply the *Pike* balancing test to evaluate the benefits to be gained from the regulation in comparison with the burdens that the regulation will impose on interstate commerce. If the burden imposed on interstate commerce outweighs the benefits to be gained, the regulation should likewise be held invalid.

Because the Dormant Commerce Clause does not necessarily foreclose the possibility of state regulations of Internet pharmacies, states should be encouraged to adopt regulations that best alleviate the concerns posed by these entities. However, states should keep the restrictions of the Dormant Commerce Clause in mind when adopting

such regulations. Additionally, several current state regulations may run afoul of the Dormant Commerce Clause as written and thus should be revised.[118]

VI. CONCLUSION

Internet pharmacies may potentially provide a viable solution to the current health care crisis. However, these entities are not without fault, and they pose numerous dangers to the public health and welfare. In response, many states have adopted regulations that oversee and control the activities of these pharmacies. However, these regulations, like all state regulations, must not exceed the constraints of the Dormant Commerce Clause. Although courts have not yet had occasion to consider the validity of state regulations of Internet pharmacies, as more states adopt and attempt to apply such regulations, it is only a matter of time before they come under attack on Dormant Commerce Clause grounds.

In response to analogous challenges against more general Internet regulations, courts have taken various approaches. Several courts have invalidated such regulations. Most controversially, some have invalidated the regulation in question on the grounds that because of the amorphous nature of the Internet, regulations thereof fall under the sole regulatory authority of federal, rather than state, government. Such courts take the position that state regulations of the Internet must necessarily be invalidated for this reason. This Note has demonstrated that this argument is flawed and thus should be rejected by future courts. Instead, state regulations of Internet pharmacies should continue to be evaluated under the traditional Dormant Commerce Clause two-pronged inquiry.

---

118. *See supra* Part V.B.