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Internet Pharmacies: Cyberspace versus the Regulatory State

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INTERNET PHARMACIES: CYBERSPACE VERSUS THE REGULATORY STATE

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I. INTRODUCTION

At a July 30, 1999 Congressional hearing, an investigative journalist testified that he was able to order Viagra for his cat, Tom, using the cat's actual height and weight.[2] In other instances, the reporter and a colleague were able to obtain Viagra for a ninety-eight year old man and a prescription diet drug for a seven-year-old girl.[3] In testimony before the same Congressional subcommittee, Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration [hereinafter "FDA"] said FDA investigators have found websites offering kits for making homemade drugs, home abortion kits, and unapproved HIV home test kits.[4] Woodcock complained of doctors who work with (or for) online pharmacies, sending prescriptions across the Internet on the basis of an electronic questionnaire.[5] Woodcock said some of the physicians prescribe to anyone sight unseen – perhaps like "Tom" – without even requiring a questionnaire.[6]

As Woodcock and her colleagues have learned, Internet pharmacies are a nightmare for regulators. The unique qualities of e-commerce make it difficult to regulate under any circumstances, but the growth of online pharmacies in particular is far outpacing the ability of government officials to investigate and enforce existing

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[2]*Congressional Panel Discusses Online Pharmacies*, 11 LOY. CONSUMER L. REV. 212 (1999).

[3]*Id.*

[4]Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Statement before the Subcommittee on Oversight and Investigations, U.S. House of Representatives (July 30, 1999).

[5]*Id.*

[6]*Id.*

drug laws. In 1999, Americans spent an estimated $44 million purchasing prescription drugs from online pharmacies, a figure that is projected to reach $1 billion per year by 2003.[7] In December of 1999, President Clinton proposed $10 million in new funding for the FDA to regulate Internet pharmacies and hire 100 new employees,[8] but the FDA has yet to explain whether this would be enough to keep up with the rapid growth of online pharmacies. Clinton also proposed raising civil fines as high as $500,000 for pharmacies and pharmacists who violate state and federal drug laws, and he proposed giving the FDA administrative subpoena authority.[9] Several members of Congress have proposed their own legislation,[10] and last year Democrats on the House Commerce Committee asked the General Accounting Office to investigate online pharmacies.[11] This paper will consider the current laws governing online pharmacies (to the limited extent the state of the law can be discerned), the practical limits of traditional regulation and enforcement, and possible legal and regulatory responses to online pharmacies.

II. THE NEW TELEMEDICINE

"Telepharmacy" could have an enormous impact on the legal and regulatory boundaries of the overall field of telemedicine and perhaps electronic commerce in general. Online pharmacies are a collision in progress between the free-wheeling atmosphere of the Internet and one of the most tightly regulated industries in the United States. On December 28, 1999, when President Clinton proposed the new enforcement powers for the FDA, it marked the first major attempt by the federal or state governments to regulate electronic commerce other than child pornography.[12] Even at this early stage, online pharmacies are capable of raising Constitutional questions of state police powers versus federal regulation of interstate commerce. State and federal officials will be forced to reconsider what constitutes the practice of medicine and who should regulate it. Legal and ethical questions for physicians – not just pharmacists – appear to be arising much more quickly in the context of telepharmacy than the traditional realm of telemedicine.[13]

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[7]Phil Galewitz, *Web Pharmacies Mull Regulations*, ASSOCIATED PRESS ONLINE, Dec. 29, 1999, *at* 1999 WL 28153972.

[8]OFFICE OF THE PRESS SECRETARY, THE WHITE HOUSE, THE CLINTON ADMINISTRATION UNVEILS NEW INITIATIVE TO PROTECT CONSUMERS BUYING PRESCRIPTION DRUG PRODUCTS OVER THE INTERNET (1999); Robert Pear, *Clinton to Encourage Congress to Regulate Online Pharmacies*, N.Y. TIMES, Dec. 28, 1999 at A1.

[9]*Id*.

[10]Marilyn Werber Serafini, *Drugs on the Web*, NAT'L J., Nov. 3, 1999, *available at* 1999 WL 28248187.

[11]Letter from U.S. Congressman John D. Dingell to Hon. David M. Walker, U.S. Comptroller General (March 2, 1999), *available at* <http://www.house.gov/commerce_democrats/press/ 106ltr16.htm>.

[12]*States Should Control Internet Drug Sales*, S.F. CHRON., Jan. 3, 2000, *available at* <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2000/01/03/ED59969.DTL>.

[13]*See*, *e.g*., Sheryl Gay Stolberg, *Virtual Druggists: Internet Prescriptions Boom in the 'Wild West' of the Web*, N.Y. TIMES, June 27, 1999, at A1; Center for Telemedicine Law,

Yet to some extent, the recent regulatory hoopla about Internet pharmacies can be misleading. To be sure, online pharmacies raise plenty of novel legal questions, but many of the legal issues pertinent to online pharmacies have already been raised in analogous areas of practice, such as mail-order pharmacy and telemedicine. What appears to have changed is the volume of activity and the practicality of enforcement: the amount of prescription drugs intercepted by the U.S. Customs Service is a good indicator of the growth in sales. "We've been deluged with prescription drugs coming in from overseas," said U.S. Customs Service Commissioner Raymond Kelly in an interview with the *New York Times*.[14] "It's a major challenge to deal with this huge increase in volume."[15] In 1999, the Customs Service seized 9725 packages with prescription drugs, up from 2145 packages the year before.[16] The number of pills and tablets impounded jumped from 760,720 in 1998 to 1.9 million in 1999.[17] And federal officials say the impounded drugs probably represent only a small fraction of what consumers import illegally.[18]

Though regulators and academics have been trying to anticipate the impact of telemedicine for twenty years or more, the phenomenon of online pharmacies seems to have caught them off guard. That is probably because commentators focused almost exclusively on "traditional" telemedicine, namely the role of practitioners who use telecommunications to consult with other practitioners or with patients. Issues of interstate health care delivery are not new, but the case law is not particularly well developed for the very reason that cases involving interstate medicine did not arise that often. Many of the appellate cases, for example, dealt with choosing the correct state forum for a medical malpractice case.[19] Regulatory concerns seem to have been an afterthought. Even now, regulators and legislators are focusing far less attention on traditional telemedicine because it doesn't seem to have been the source of any major public health problems. By contrast, regulators fear online pharmacies in the United States and overseas pose a substantial threat to public health.[20]

In 1998, after police in Illinois found a man lying unconscious in a hotel parking lot, FDA officials learned he had purchased a kit to make GHB (an illegal steroid

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Online Prescriptions by Physicians Undergoing Increased Scrutiny (1999), *at* <http://www.ctl.org/html/alert07191999.htm> (citing several cases involving sanctions against doctors and pharmacists practicing on the Internet).

[14]Robert Pear, *Government Warning on Buying Pills Online: Overseas Bargains Probably Also Illegal*, S.F. CHRON. Jan. 10, 2000, *available at* <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2000/01/10/MN17567.DTL>.

[15]*Id.*

[16]*Id*.

[17]*Id*.

[18]*Id*.

[19]*See*, *e.g*., Wright v. Yackley, 459 F.2d 287 (9th Cir. 1972); Kennedy v. Freeman, 919 F.2d 126 (10th Cir. 1990); McGee v. Riekhof, 442 F. Supp. 1276 (D. Mont. 1978).

[20]*See*, *e.g*., John Hinkel, *Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites'*, FDA CONSUMER (Jan.-Feb. 2000).

frequently used by bodybuilders) and overdosed on his homemade drugs.[21] A fifty-two year-old Illinois man with episodes of chest pain and a family history of heart disease died of a heart attack in March 1999 after buying Viagra from an online source, even though Viagra is not recommended for anyone with heart disease.[22] FDA officials say there is no proof linking the man's death to the drug, but add the problems likely would have been discovered within the traditional doctor-patient relationship.[23] In any event, FDA official Woodcock said the sheer volume of electronic drug sales forces FDA officials to rely on "triage" in deciding which cases to investigate.[24]

States have also joined the fight against unregulated pharmacies. The attorneys general of Kansas, Illinois, and Missouri sued out-of-state pharmacies and doctors who were operating online, and the courts in Kansas and Missouri have issued injunctions.[25] Kansas Attorney General Carla J. Stovall sued seven companies, six doctors, four other individuals, and three out-of-state pharmacies after a state investigation uncovered online vendors willing to sell prescription drugs directly to minors.[26] A minor, acting under the direction of one of the agents, was able to purchase Viagra and the diet-drug Meridia using his true age and his mother's credit card.[27] The companies did not require parental consent and required no examination or consultation with a physician.[28]

Meanwhile, libertarians and even state governments have warned that the FDA may be trying to extend its regulatory reach too far. One group, the "Life Extension Foundation," assailed the FDA for citing the Illinois man who died of a heart attack:

> The FDA is using this one death as an example of why the FDA needs to impose dictatorial power over all health websites. One problem with this position is that, as of November 1998, at least 130 Americans died from taking Viagra legally prescribed by their doctors…. The FDA failed to detect the lethal side effects of Viagra, yet it is now seeking gestapo-like

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[21] *Id.*

[22] Hinkel, *supra* note 20.

[23] *Id.*

[24] *Id.*

[25] OFFICE OF THE ATTORNEY GENERAL OF KANSAS, ATTORNEY GENERAL FILES LAWSUITS TO PROHIBIT INTERNET DRUG SALES (June 9, 1999), *available at* <http://www.ink.org/public/ksag/contents/news-releases/news99/internetdrugsales.htm>; OFFICE OF THE ATTORNEY GENERAL OF ILLINOIS, RYAN SUES TO PROTECT CONSUMERS AGAINST ILLEGAL SALES OF PRESCRIPTION DRUGS OVER THE INTERNET (Oct. 21, 1999), *available at* <http://cait.wiu.edu/press/pressfrm.html>; OFFICE OF THE ATTORNEY GENERAL OF MISSOURI, NIXON OBTAINS INJUNCTION AGAINST TEXAS PHARMACY TO STOP ILLEGAL INTERNET DRUG SALES; RESTITUTION, PENALTIES ORDERED (Oct. 25, 1999), *available at* <http://cait.wiu.edu/press/pressfrm.html>.

[26] OFFICE OF THE ATTORNEY GENERAL OF KANSAS, *supra* note 25.

[27] *Id.*

[28] *Id.*

> power to attack any Internet health company it wishes to, without due process.[29]

Representatives of state pharmacy boards have been considerably less strident in their criticism, but are nonetheless wary of a larger FDA role. [30] The National Assocation of Boards of Pharmacy, which represents the boards of pharmacy of all U.S. states and territories, and the District of Columbia, has created its own voluntary certification program and does not want the FDA trying to duplicate state functions.[31]

III. WHERE IS CYBERSPACE AND WHAT HAPPENED THERE?

The allegations in the Kansas suit illustrate some of the jurisdictional questions facing not only pharmacy regulators, but Internet regulators generally. For example, Attorney General Stovall claimed the defendants sold, and prescribed Viagra "in the state of Kansas."[32] But the defendant corporation was actually located in Nevada – so where did the actual sale take place?[33] In Kansas, in Nevada, or in the nebulous realm of cyberspace? Defining "prescribed" and "dispensed" are even more problematic for Stovall. One could argue that the doctor does the prescribing – the patient only receives the prescription – and the doctor was not in Kansas. Moreover, Stovall accused the defendant doctors of practicing medicine in Kansas without a license from Kansas medical authorities.[34] But if the doctor had legal authority to prescribe in Nevada (leaving aside the issue of whether Nevada allows doctors to prescribe without an examination) and the prescription was filled in Nevada, then the question of whether he practiced medicine in Kansas becomes even more complex.

Prior cases in interstate medicine do not really address these issues directly, but instead the state courts analyzed whether sufficient minimum contacts occurred between the patient and an out-of-state physician to justify *in personam* jurisdiction over the out-of-state physician. Perhaps the most widely cited of these cases is *Wright v. Yackley*.[35] While living in South Dakota, the plaintiff was treated by the defendant, a South Dakota doctor.[36] The plaintiff later moved to Idaho and asked the South Dakota doctor to send a copy of her prescription to an Idaho pharmacy.[37] The plaintiff alleged she was injured by the drugs and filed suit against the South Dakota

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[29]Statement of William Faloon, Vice President, Life Extension Foundation, *at* <http://www.lef.org/magazine/mag2000/march00-awsi.html>.

[30]Chris Adams, *Plan to Curb Drugstores On Web Is Hit*, WALL ST. J., Dec. 29, 1999, at A3.

[31]*Id.*

[32]Stoval v. Focus Med. Group, Inc., No. ___ (Shawnee County Dist. Ct. June 9, 1999). (unreported Kansas trial court opinion) (copy on file with the author).

[33]*Id.*

[34]*Id.*

[35]459 F.2d 287.

[36]*Id.* at 287.

[37]*Id.*

doctor in Idaho court.[38] The Ninth Circuit cited § 37 of the Restatement (Second) of Conflict of Laws (1971):

> A state has power to exercise judicial jurisdiction over an individual who causes effects in the state by an act done elsewhere with respect to any cause of action arising from these effects unless the nature of the effects and of the individual's relationship to the state make the exercise of such jurisdiction unreasonable.[39]

The court held that jurisdiction in Idaho would be unreasonable because the defendant was not one who "purposely avails itself of the privilege of conducting activities within the forum State."[40] However, the court left open the question of "diagnosis by mail":

> The balance of factors involved in a due process determination might be different if a doctor could be said to have treated an out-of-state patient by mail or to have provided a new prescription or diagnosis in such fashion. In that event, the forum state's interest in deterring such interstate medical service would surely be great.[41]

The court foresaw, quite correctly, that subsequent jurisdictional analyses would necessarily be made on a case-by-case basis.[42] But the court also concluded (albeit in dicta) that intentionally practicing across state lines would subject the practitioner to the jurisdiction of the patient's home state.[43]

Courts are fairly uniform in finding *in personam* jurisdiction over practitioners who deliberately practice across state lines. This is clearly the issue most relevant to online practitioners, since they are intentionally creating a practice that will cross jurisdictional boundaries. In *McGee v. Riekhof*, for example, the defendant was a Utah surgeon who had performed surgery on a Montana resident in Utah.[44] The U.S. District Court upheld jurisdiction in Montana because the surgeon had, via telephone, provided a new diagnosis to the patient while the patient was in Montana.[45] This raises an interesting question (one not addressed by the court), namely whether the Utah surgeon should have held a Montana license to consult with his patient there. Could Montana medical officials bring charges against the Utah doctor for practicing in Montana? If so, specialists who treat patients from around the country – and the world – would need a license in each of the fifty states in order to consult with a patient by phone. One could argue that a court's standard

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[38] *Id.*

[39] *Id.* at 289.

[40] *Wright*, 459 F.2d at 290 (citing Hanson v. Denckla, 357 U.S. 235, 253 (1958)).

[41] *Id.* at 289.

[42] *See* Prince v. Urban, 49 Cal. App. 4th 1056 (1996) (providing an overview of the case law regarding in personam jurisdiction over out-of-state practitioners).

[43] *Wright*, 459 F.2d at 289 n.4.

[44] 442 F. Supp. at 1277.

[45] *Id.*

for *in personam* jurisdiction is different from the regulatory jurisdiction of a state medical board. Even so, current case law will encourage states to continue asserting their jurisdiction aggressively (as the states seem to be doing) over out-of-state practitioners.

IV. WHO GETS TO REGULATE?

Perhaps because of their wariness of the FDA, state boards of pharmacy have moved quickly to maintain their role in regulating online pharmacies. Acting through the National Association of Boards of Pharmacy [hereinafter "NABP"], the states created the Verification of Internet Pharmacy Practice Sites program, or VIPPS, which will provide a NABP "seal of approval" to sites meeting the organization's standards.[46] To earn the seal, online pharmacies must be registered with the pharmacy boards of each of the fifty states and approved to operate in all the states. [47] To date, only four pharmacies have earned the NABP's approval.[48] In her July 30, 1999 testimony, Woodcock praised VIPPS – a voluntary partnership between pharmacies and state regulators – and said "government should encourage private sector leadership in achieving a safe marketplace."[49] Five months later, the FDA's strategy apparently shifted to favor more federal regulation; the White House released a proposal on Dec. 28, 1999 to increase federal regulation of Internet pharmacies and to enhance civil penalties.[50]

Current federal law, i.e. the Food, Drug and Cosmetic Act [hereinafter "FDC"],[51] certainly was not written with the Internet in mind. When the first federal food and drug law was adopted near the turn of the century, pharmacies were the domain of local merchants, not unlike banks or grocery stores, and regulators were trying to get a handle on snake oil salesmen. Snake oil salesmen were probably a lesser concern when the FDC was revised in 1970, but pharmacy still was primarily a local retail business. (Based on Dr. Woodcock's testimony, regulators now seem to be shifting their concern back to the snake oil salesmen…or saleswomen). Though retail pharmacy has traditionally dominated the market, interstate pharmacy has been around for quite a while. In fact, Congress made reference to mail-order pharmacy as early as 1951.[52]

One might argue that mail-order pharmacies deal only with filling prescriptions written by a doctor after a traditional, face-to-face encounter with a patient, and therefore there are no similarities to the online "appointments" between patients and doctors hired by the online pharmacies. However, Congress inserted a reference to "diagnosis by mail" in the 1951 amendment to the FDC.[53] Interestingly, not a single

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[46]Website of VIPPS, *at* <http://www.nabp.org/vipps/intro.asp>.

[47]*Id*.

[48]*Id*.

[49]Woodcock, *supra* note 4.

[50]OFFICE OF THE PRESS SECRETARY, *supra* note 8.

[51]21 U.S.C. § 301, *et seq*. (1999).

[52]*See* S. REP. NO. 82-946 (1951).

[53]*Id*.

case or commentary on Westlaw makes reference to this brief passage in the FDC, even though many state and federal courts have grappled with the interstate practice of medicine. The legislative history does not offer much detail either. According to the committee report on the 1951 bill that amended the FDC, a representative of a mail-order company that delivered phenobarbitol to epileptics was present during the bill's hearing and objected to some of its provisions.[54] The report does not make clear the portions to which he objected, but the committee altered the bill upon his recommendation.[55]

The actual text of the bill (now law) exempts prescriptions from some labeling requirements, but adds that those filled as part of "diagnosis by mail" are not exempt.[56] The statute certainly does not explicitly authorize anyone to engage in diagnosis by mail, but instead regulates labeling requirements when diagnosis by mail occurs.[57] A similar Iowa statute was examined by that state attorney general's office in 1978, but the opinion did not address the meaning or significance of diagnosis by mail.[58] On the other hand, one might argue that Congress clearly knew that diagnosis by mail was occurring (a mail-order company representative testified at the committee hearing), and that Congress took steps to regulate it, therefore Congress implicitly was sanctioning the practice. Moreover, interstate commerce and mail-related commerce are the primary domain of Congress, so states arguably couldn't impede what Congress had sanctioned. On the whole, however, that argument seems a bit of a reach.

An explanation of this statute would be helpful because the legal issues surrounding online pharmacies are so similar to those faced by mail-order pharmacies. The regulation concerning diagnosis by mail implicitly concedes that the practice of pharmacy is not clearly divided from the practice of medicine. "Diagnosis by mail" indicates a physician has diagnosed a patient remotely and is personally filling and labeling the prescription for delivery to the patient.[59] Thus

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[54]*Id.*

[55]*Id.*

[56]Federal Food, Drug, and Cosmetic Act § 9, 21 U.S.C. § 353(b)(2) (1999). The Act reads in relevant part:

> any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title… if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. *This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.*

Id. (emphasis added).

[57]*Id.*

[58]Iowa Op. Att'y Gen. 548 (1978), *available at* 1978 WL 17419.

[59]*Id.* (citing DeFreese v. United States, 270 F.2d 730, 734 n.7 (2d Cir. 1959)) ("It has always been the rule that a physician who does his own dispensing is also acting in the capacity of a pharmacist.").

legal opinions on the interstate practice of medicine can be relevant to the interstate practice of pharmacy. But, as previously mentioned, no court has cited this portion of the statute, much less attempted to apply it, so it is difficult to determine its significance.

Much of the legal uncertainty concerning interstate pharmacy arises from the difficulty in determining where state regulation ends and federal regulation begins. The Supreme Court of Iowa described an "interlocking trellis" of federal and state regulations governing prescription drugs, and no one seems to dispute that federal and state roles are intermingled.[60] Federal preemption of pharmaceutical regulation is essentially a patchwork, with Congress expressing a clear intent to dominate some areas (such as the regulation of nonprescription drugs) but denying any desire to occupy the field generally. Congress' failure to explain just how much of the field it intended to occupy has made issues of preemption difficult to resolve.

All authorities seem to agree that drug regulation is within the traditional police power of the state and that federal law reserves at least some role for the states.[61] Congress stated rather clearly, in fact, that it did not intend to preempt the states' involvement in drug regulation:

> No provision of this title shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together. [62]

Nonetheless, courts have varied widely when asked to decide what does and does not constitute a "positive conflict" between state and federal laws that govern prescription drugs.

The Iowa court struck down a state regulation that forbade Iowa pharmacies from filling prescriptions written by out-of-state practitioners, in part because the court believed such a rule conflicted with federal policy.[63] The court relied on a description of the federal law's purpose, as summarized by the *U.S. Code Congressional and Administrative News*:

> The bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[64]

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[60]Iowa v. Rasmussen, 213 N.W.2d 661 (Iowa 1973).

[61]*See*, *e.g.*, 25 AM. JUR. 2D *Drugs and Controlled Substances* § 17 (1996).

[62]21 U.S.C. § 903 (1999).

[63]*Rasmussen*, 213 N.W.2d at 666.

[64]*U.S. Code Congressional and Administrative News*, 91st Cong., 2d Sess., 1970, Vol. 3, at 4571-72.

The court seemed to conclude that out-of-state physicians who complied with the licensing requirements of their respective states had also met the requirements of the federal act; therefore, Iowa's additional requirements impeded the effort to create a nationalized drug distribution system.[65] In an advisory opinion, the Ohio Attorney General reached a similar conclusion.[66]

The Texas Attorney General's Office disagreed with the Iowa court's conclusion regarding federal preemption, describing it as "no longer persuasive."[67] However, Texas officials cited no basis for this conclusion, but instead referred to the portion of the federal statute dealing with preemption: 21 U.S.C. § 903, the same portion of the law cited by the Iowa court.[68] Thus state courts disagreed on the intended purpose of the act and therefore disagreed on its intended breadth – i.e., how much of the field was occupied if Congress did not intend to occupy the entire field.[69] The state courts also disagreed about how much conflict constituted a "positive conflict."[70]

The Court of Appeals of Oregon, for example, expressly rejected the conclusion of the Iowa Supreme Court in *Nichols v. Board of Pharmacy*: "Because the Oregon statute does not authorize what federal law prohibits, and because the limitation it imposes is consistent with the purpose of the federal statute, we believe that the two statutes can 'consistently stand together' within the meaning of 21 U.S.C. § 903."[71]

The court upheld the suspension of an Oregon pharmacist's license because he filled a prescription written by an out-of-state practitioner.[72] In *National Pharmacies, Inc. v. DeMelecio*, the U.S. District Court held that Puerto Rico's stringent licensing requirements were within the traditional police powers of the state and had not been preempted by federal law.[73] The court concluded that the preempted portions of pharmaceutical regulation dealt only with controlled substances, with "controlled substances" defined as "drugs or medication which have the potential for abuse and which can cause dependency."[74] Other classes of prescription medication would not fall within that definition, the court concluded, therefore Puerto Rico could continue to require that all prescriptions be filled by pharmacists in Puerto Rico.[75]

Perhaps unwittingly, the *National Pharmacies* court raises a strange prospect. If the court was correct, one can argue that Congress intended to "federalize"

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[65]*Rasmussen*, 213 N.W.2d at 666.

[66]*See* Ohio Op. Att'y Gen. No. 82-032 (1982).

[67]*See* Texas Op. Att'y Gen. No. JM-555 (1986).

[68]*Id*.

[69]*Id*.

[70]*Id*.

[71]657 P.2d 216 (Or. Ct. App. 1983).

[72]*Id*.

[73]51 F. Supp. 2d 45 (D.P.R. 1999).

[74]*Id*. at 54.

[75]*Id*. This case seems to be an aberration, as will be discussed hereinafter.

regulation of some prescription drugs ("controlled substances") but not others.[76] This is particularly true if the *Rasmussen* court's interpretation of the purpose of the federal act – to create a national "closed system" essentially administered by the states – is correct.[77] Thus federal law would permit a Puerto Rican pharmacist to fill a New Jersey physician's prescription for a controlled substance (e.g. morphine) because that part of the federal regime has preempted state regulation, yet a Puerto Rican pharmacist could not fill an antibiotic prescription from a New Jersey physician because that part of the state regulations had not been preempted. Conversely, a resident of Puerto Rico would be able to purchase morphine from a nonresident Internet pharmacy but unable to purchase an antibiotic from the same pharmacy. To date, no court has addressed this potential dichotomy.

In *Ferndale Laboratories, Inc. v. Cavendish*, the only federal appellate case dealing with the role of states in interstate pharmaceutical regulation, the Sixth Circuit (in dicta) favored federal preemption.[78] The court concluded the Prescription Drug Marketing Act of 1987 [hereinafter "PDMA"] granted states only the authority "to follow federal requirements in licensing wholesale distributors."[79] The PDMA had been intended to prevent dangerous drugs from escaping the wholesale distribution system (a sizeable market involving interstate commerce) into the black market.[80] Accordingly, the *Ferndale* case dealt only with wholesale distributors,[81] though one might argue that the principle would apply to all pharmaceutical distributors dealing in interstate commerce. If that is true, then one could conclude that states are essentially administrative agents for purposes of interstate drug regulation. Some support for that argument can be found in the PDMA itself, which specifically authorizes state and local governments to act as agents of the federal government in enforcement matters.[82] Accordingly, part of the argument for insisting that states recognize prescriptions from nonresident practitioners might rest indirectly on the Full Faith and Credit Clause of the Constitution, i.e. if one state certifies that a practitioner is authorized to act within the federal regime, then another state must give full faith and credit to the acts of that practitioner. To date, no court has cited the Full Faith and Credit Clause as having any effect on the interstate regulation of pharmacies.

V. THE COMMERCE CLAUSE

Several courts have wrestled with the impact of the Commerce Clause – specifically the "Dormant" Commerce Clause – on regulation of out-of-state pharmacies. The U.S. Supreme Court set forth the general criteria for Dormant Commerce Clause decisions in *Pike v. Bruce Church, Inc.*,[83] though much of the case

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[76] *Id.*

[77] *Rasmussen*, 213 N.W.2d at 665.

[78] 79 F.3d 488, 493 (6th Cir. 1996).

[79] *Id.*

[80] *Id.* at 492-93.

[81] *Id.* at 488.

[82] Federal Food, Drug, and Cosmetic Act § 9, 21 U.S.C. § 372(a) (1999).

[83] 397 U.S. 137 (1970).

law applied to out-of-state pharmacies has been developed in the state courts or by state attorneys general. The *Pike* Court struck down a statute which stated a primary purpose of promoting the reputation of Arizona cantaloupe growers by prohibiting deceptive packaging and requiring a certain type of packaging before out-of-state shipment.[84] The practical result, as stipulated by the parties, was to require the plaintiff to build a processing plant in Arizona.[85]

The Court expressed particular suspicion for regulations that required business operations be performed in the home state when they could be performed more efficiently elsewhere:

> Where the statute regulates evenhandedly 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. If a legitimate local purpose is found, then the question becomes one of degree. And 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.[86]

In a 1986 opinion for the Texas Board of Pharmacy, the state attorney general's office offered a concise summary of the divergent applications of Commerce Clause doctrine.[87] In *Pharmaceutical Manufacturers Ass'n v. New Mexico Board of Pharmacy*, for example, the court held that regulations and a licensing fee imposed by New Mexico on out-of-state pharmacists were reasonable compared with the state's interest in drug control.[88] The regulations dealt with safe storage and labeling of drugs and with registration or licensing of pharmacists.[89] Similarly, the Wisconsin Attorney General concluded that the purpose of Wisconsin's regulations was to protect the public and that any effect on interstate commerce was incidental.[90]

In contrast, the Iowa Supreme Court struck down regulations that effectively prohibited Iowa pharmacists from filling prescriptions written by nonresident physicians who were not registered with Iowa authorities.[91] As noted previously, the Iowa court struck down the regulation in part because (the court believed) the state regulations conflicted with federal drug control law.[92] But the court also concluded the regulation was an unnecessary barrier to interstate commerce.[93] The Nebraska

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[84]*Id*. at 139.

[85]*Id*. at 140.

[86]*Id*. at 145.

[87]Tex. Op. Att'y Gen., *supra* note 67.

[88]525 P.2d 931 (N.M. Ct. App. 1974).

[89]*Id*. at 935.

[90]Wis. Op. Att'y Gen. No. 33-83 (1983). *See also* 61 Cal. Op. Att'y Gen. 192 (1978).

[91]*Rasmussen*, 213 N.W.2d 661.

[92]*Id*. at 666.

[93]*Id*. at 667.

and Ohio Attorneys General similarly concluded that their state's regulatory schemes were unconstitutional.[94] All the authorities agreed that regulation of prescription drugs meets the first part of the Commerce Clause test, namely that the regulation must effect a legitimate local interest. However, under the *Pike* standard, a regulation that does not discriminate against out-of-state commerce on its face can nonetheless violate the Dormant Commerce Clause if its application burdens interstate commerce beyond the benefits the state derives from the regulation.[95] This latter determination – what constitutes an unreasonable burden – is a mixture of fact and law that usually is left for the courts to resolve.

One could argue that the Dormant Commerce Clause is now more relevant than ever to telemedicine because the standards of practice are, in effect, national standards.[96]

> Although administrative practices might vary from state to state, in the past 30 years there has been a remarkable convergence in licensing requirements stipulated by states to license physicians. *All* states require the United States Medical Licensing Examination (USMLE). *All* recognize appropriate credentials from nationally accredited medical schools and residency programs regardless of location. *All* specialty board certification is conferred by national organizations and are based on national standards…. In fact, there is little, if any data to support the claim that physicians of one state are more or less qualified than those of any other state.[97]

This is all the more true of pharmacy, which has long been subject to uniform federal standards. While states regulate practitioners, the federal government has long had an active role in governing the content of drugs, the labeling of prescriptions, and even the advertising of prescription and non-prescription drugs. Accordingly, online pharmacies can argue that the states' interest in asserting their police powers against out-of-state pharmacies is moot.

Not surprisingly, different jurisdictions reach different conclusions. For its part, the Texas Attorney General's Office advised the state pharmacy board that any rules it adopted should be "the least burdensome regulation which well effect the state's objectives" in order to comply with the Commerce Clause.[98] Most courts seem to agree with this proposition.[99] Texas officials also concluded the board "may regulate out-of-state mail-order pharmacists only to the extent that they actually engage in the practice of pharmacy or dispense, deliver, or distribute prescription drugs within the

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[94]Neb. Op. Att'y Gen. 57 (1985); Ohio Op. Att'y Gen., *supra* note 66.

[95]397 U.S. at 145.

[96]One might even argue that states such as Florida violate the Constitutional right to travel freely when they make it burdensome for out-of-state doctors to obtain a license (ostensibly to keep retiring doctors who move to Florida from competing part-time with local practitioners).

[97]AMERICAN TELEMEDICINE ASS'N, POLICY REGARDING STATE MEDICAL LICENSURE (1999).

[98]Tex. Op. Att'y Gen., *supra* note 67.

[99]*See* author's summary of cases discussed herein.

state of Texas," i.e. the Texas board could not physically inspect nonresident facilities that shipped prescriptions into Texas.[100]

Recent cases seem to support those views. As noted before, the Sixth Circuit concluded that the PDMA of 1987 granted states only the authority "to follow federal requirements in licensing wholesale distributors."[101] The case dealt only with wholesale distributors,[102] and wholesale distributors (as opposed to retailers) presumably would not have nearly the impact on the consumers of other states. But even in this context, the court concluded it was not unreasonable for Ohio to require a Michigan distributor to pay a $100 annual registration fee and to keep a record of the drugs it shipped into Ohio.[103] At the very least, states will likely be able to require registration and production of records that relate to the receiving state. This is particularly important if the VIPPS program (discussed previously) of the NABP is to be successful.

But the Sixth Circuit apparently did not persuade the U.S. District Court for the District of Puerto Rico. The *National Pharmacies* court upheld rather stringent local regulations that substantially affect interstate commerce.[104] The local regulations establish strict requirements for the practice of pharmacy that effectively prevent any pharmacy/pharmacist outside Puerto Rico from filling prescriptions for Puerto Rico residents.[105]

In all cases where a pharmacist is practicing his profession, he shall be a member of the College of Pharmacists of Puerto Rico,[106] of age, shall manage in person the establishment under his supervision, and shall reside in the town in which he is practicing.[107]

Section 402 requires that every pharmacy be managed by a pharmacist authorized to practice in Puerto Rico.[108] That section even limits the number of hours per week that the pharmacist may be absent from the pharmacy.[109]

The *National Pharmacies* case arose when Blue Cross of Puerto Rico entered a contract with National Pharmacies, Inc. of New Jersey for mail-order drug delivery to Blue Cross customers in Puerto Rico.[110] The Puerto Rican government sought to ban National from serving customers in Puerto Rico because it was located in New

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[100]Tex. Op. Att'y Gen. Op., *supra* note 67.

[101]*Ferndale*, 79 F.3d at 493.

[102]*Id.*

[103]*Id.* at 494.

[104]51 F. Supp. 2d 45.

[105]*Id.* at 56.

[106]The "Colegio de Farmaceuticos" is "a quasi-public corporation charged with governing the conduct and defending the rights of pharmacists practicing in Puerto Rico." *Nat'l Pharm.*, 51 F. Supp. 2d at 47.

[107]20 P.R. LAWS ANN. § 401 (1999).

[108]§ 402.

[109]*Id.*

[110]51 F. Supp. 2d at 47-48.

Jersey and it and its pharmacists did not meet the requirements of Puerto Rican law.[111] In siding with the government, the court concluded Puerto Rican law was not preempted by federal drug law (as discussed previously).[112] The court also held that Puerto Rican law did not violate the Dormant Commerce Clause.[113] This latter holding seems particularly difficult to reconcile with prior case law, particularly *Pike*:

> For the Court has viewed with particular suspicion state statutes requiring business operations to be performed in the home State that could more efficiently be performed elsewhere. Even where the State is pursuing a clearly legitimate local interest, this particular burden on commerce has been declared to be virtually per se illegal.[114]

Interestingly, the *National Pharmacies* court cites none of the cases cited thus far except *Ferndale*, and it cites that case only with reference to the police powers of Puerto Rico.[115] The plaintiffs seem to have had strong grounds for an appeal though apparently none was filed.

VI. LIMITS TO REGULATION

Whatever laws the states or federal government adopt, the practical barriers to regulation are enormous. First and foremost, regulators in the United States are dealing with pharmacies that can appear on the Internet without warning and then disappear overnight. Even if regulators can figure out the location of the host computer, they still may not know the state – or country – in which the drugs are stored and dispensed. In the unusual event regulators close an online pharmacy, the owners can reopen under another name, through another corporation, and/or from a different location. Federal regulators acknowledge the seemingly insurmountable obstacles,[116] but are nonetheless asking for an additional $10 million to hire new personnel to regulate online pharmacies.[117] Interestingly, former President Clinton's fellow Democrats questioned whether the Administration really knew what it needed, or whether it arrived at the $10 million figure arbitrarily.[118]

VII. FOREIGN PHARMACIES

Pharmaceuticals frequently cost far less outside the U.S. market, even when the drug is the same and is manufactured by the same company.[119] To dramatize the

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[111] *Id.*

[112] *Id.* at 54.

[113] *Id.* at 55.

[114] 397 U.S. at 145.

[115] 51 F. Supp. 2d at 55.

[116] Krista Foss, *Have Modem, Will Medicate*, GLOBE & MAIL, June 22, 1999, at C8.

[117] OFFICE OF THE PRESS SECRETARY, *supra* note 8.

[118] *See* Correspondence of House Committee on Energy and Commerce (various dates), *available at* <http://www.house.gov/commerce_democrats/pharmacy/onlinepharm.shtml>.

[119] Michael F. Conlan, *Bring 'Em Home*, 143 DRUG TOPICS 50 (1999), *available at* 1999 WL 10021878.

difference between U.S. and foreign drug prices, Congressman Bernard Sanders accompanied six senior citizens from Vermont to a Montreal pharmacy in July 1999; one woman in the group paid $12.08 for sixty tamoxifen pills (used to treat breast cancer), but she would have paid more than $100 for that amount in the United States.[120] Internet entrepreneurs have used these price differences to their advantage. For a $10.95 monthly subscription to the BDZI Pharmacy Watch Web site, the company provides access to pharmacies worldwide and advice on getting the drugs into the United States.[121] "Access to Mexican, Foreign and American Doctors from our web site that will write you prescriptions, if needed," claims the site.[122] One group that favors deregulating prescription drugs publishes on its Web site a comparison of brand-name drugs in Europe that cost as little as one-tenth the price of the same drug in the United States.[123] On the other hand, proponents of regulation argue that products available in some countries, particularly Mexico, may be of inferior quality or may be held for retail sale in sub-optimal conditions.[124]

Whether good or bad, the fact remains that the drugs are imported. Furthermore, if online pharmacies in the United States seem difficult to regulate, they are hardly as unregulated as online pharmacies in other countries. Most countries, including those of the European Union, have always been far less stringent regulators of prescription drugs than the United States.[125] Many drugs available only by prescription in the U.S. can be purchased over the counter elsewhere, so it should come as no surprise that many pharmacies in those countries put forth little effort (if any) to insure U.S. patients have a prescription.[126]

Thus foreign pharmacies present all the practical regulatory hurdles of any other online pharmacy, plus additional jurisdictional and legal obstacles. On the practical side, Internet entrepreneurs in Europe have been sending marijuana seeds to the United States via mail for years, and the same methods are readily transferable to online pharmacies outside the United States.[127] The seller may be located in a country that does not cooperate with U.S. enforcement efforts or, if not, the seller may store its server and customer information in a third country. A secure online transaction can protect a purchaser in the United States from government detection, and the seller simply ships the illicit item in a nondescript container with no return address or a bogus return address. Some pharmacies in Mexican border towns even

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[120] *Id.*

[121] Website of BDZI Pharmacy Watch, *at* <http://www.bdzipharmacywatch.com>.

[122] *Id.*

[123] *See*, *e.g.*, Bill Faloon, *The Great American Rip-Off*, LIFE EXTENSION MAGAZINE, June 1999, *available at* <http://www.lef.org/magazine/mag99/june99-awsi.html>.

[124] *See*, *e.g.*, Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1313 (1997).

[125] Dennis Cauchon, *Americans Pay More for Prescription Drugs: Here's Why*, USA TODAY, A1 (Nov. 10, 1999).

[126] *See*, *e.g.*, H.G. Reza, *Dangerous Medicine: On the Trail of Black Market Drugs*, L.A. TIMES, May 24, 1999, at A1. *See also*, Noah, *supra* note 124, at 94.

[127] *See*, *e.g.*, Website of Yahoo! Commercial Directory, *at* <http://dir.yahoo.com/Business_and_Economy/Companies/Home_and_Garden/Lawn_and_ Garden/Seeds/Marijuana/>.

offer packaging of illegal drugs in tamper-proof sealed aspirin bottles to allay the suspicions of Customs officials.[128] Undoubtedly these techniques have been adopted by online pharmacies as well.

Free-trade treaties may also pose problems for regulators, particularly the North American Free Trade Agreement [hereinafter "NAFTA"]. Though NAFTA generally does not preclude federal public health regulations, including prescription drug regulations, it does nonetheless preclude state governments from enacting regulations on Mexican and Canadian imports, i.e. only the federal government can regulate imports from a NAFTA partner.[129] No state government has yet tried to act against a pharmacy in Mexico or Canada, but any such effort would almost certainly fail even if an injunction were sought in federal court. The state laws enforced by the Kansas, Missouri, and Illinois courts on pharmacies in other states would presumably be preempted by NAFTA if the courts sought to apply them to a pharmacy in Mexico or Canada.

On the other hand, one could argue that states are entitled to act against imports from a Mexican or Canadian pharmacy via the FDC, which specifically authorizes state and local governments to act as agents in enforcing federal drug laws.[130] Accordingly, a state attorney general might have standing to bring a claim in *federal* court under *federal* drug control laws against a Mexican or Canadian pharmacy because the state official is acting in a *federal* capacity. The state might argue that the practitioners and pharmacies outside the U.S. are not licensed within the meaning of the FDC because it implicitly referred to professional licenses granted by the States. That argument has not been confronted, much less resolved, by U.S. courts. In any event, state governments appear to have more authority to prevent imports from other states than from Canada or Mexico.

This begs the question why any state official should want to regulate online pharmacies in the first place. Internet commerce is unique in that the smallest vendor immediately becomes a nationwide and perhaps worldwide vendor. Enforcement incentives are altered dramatically because geography loses its relevance. Prior to e-commerce, a rogue pharmacist and his customers probably were all within driving distance of the pharmacy. Thus the harm was almost exclusively local, and local regulators had incentive to act. Conversely, the online pharmacy that sells Viagra to teenagers in Kansas will also sell Viagra to teenagers in the other forty-nine states. Kansas can argue that it should not have to shoulder the responsibility of what is in essence a national threat to public health. In fact, the Texas Board of Pharmacy has made that very argument: "We just don't have the personnel to spend a long time on the Internet searching for [rogue pharmacies]," said Gay Dodson, executive director of the Texas Board of Pharmacy. She continued, "we… could go out and look every day to see what's out there, but sites pop up just overnight."[131] Her ten investigators handled 1500 complaints in 1998,

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[128]Reza, *supra* note 126.

[129]Noah, *supra* note 124, at 155.

[130]Federal Food, Drug, and Cosmetic Act § 9, 21 U.S.C. § 372(a) (1999).

[131]Andrew Park, *FDA May Help States Regulate Web-based Pharmacies*, KNIGHT-RIDDER TRIB. BUS. NEWS, Dec. 29, 1999, *available at* 1999 WL 28721498.

and another five employees were responsible for inspecting the state's 5000 pharmacies.[132]

Aside from lower prices, foreign online pharmacies hold another advantage over online pharmacies in the United States. At the height of the AIDS scare in the late 1980's, AIDS activists demanded immediate access to potential treatments that were available overseas but not in the United States.[133] A July 20, 1988, FDA memo opened the door to these imports.[134] Importing drugs unapproved by the FDA was (and still is) flatly prohibited by law, but the FDA used its enforcement discretion to allow U.S. consumers to import up to ninety days' worth of drugs for personal use.[135] The policy is designed to allow U.S. residents to purchase drugs not approved by the FDA if (1) the patient is using the drug under the care of a physician and (2) the drug is not available in the United States.[136] The latter stipulation is more significant than it may appear – according to the policy, patients cannot purchase a drug that *is* available in the United States, e.g. a U.S. patient could not purchase Prozac from a foreign pharmacy because Prozac is available in the United States.[137] In practical terms, this policy prevents U.S. customers from bypassing the U.S. retail drug market in favor of much lower retail prices in other countries.

However, there are exceptions to the exception. A U.S. resident *can* purchase a drug from a foreign pharmacy even if that drug is available from U.S. pharmacies, but only if the FDA has certified and approved the manufacturing source (a single drug such as Prozac may be manufactured in different locations for different markets).[138] And there is an exception to the limitation of the exception: even if the FDA has not approved the manufacturing source, FDA enforcement standards allow the drug to be delivered to the U.S. customer with a simple warning that the FDA cannot vouch for the safety of the product.[139] In other words, it is possible to buy almost any drug from a foreign pharmacy, regardless of whether it is available in the U.S. and regardless of whether the FDA approved the manufacturing source, so long as the enforcement agent is willing to exercise his or her discretion. And FDA guidelines encourage enforcement agents to do just that: "We must remember the

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[132] *Id.*

[133] Memorandum from Ronald G. Chesemore, Director of Regional Operations, Food and Drug Administration, to Regional Food and Drug Directors, *Pilot Guidance for Release of Mail Importations* (July 20, 1988).

[134] *Id.*

[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] Marvin A. Blumberg, FDA, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, Apr. 3, 1998, *at* <http://www.fda.gov/ora/import/pipinfo.htm>.

[139] "Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified." FOOD AND DRUG ADMINISTRATION REGULATIONS AND POLICY MANUAL § 9, *available at* <http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html>.

consumer protection provided by unlimited, extensive coverage of mail imports is not commensurate with the resources that are expended,"[140] and "[g]enerally, little time should be spent on the coverage of mail importations."[141]

However popular the end result may be with AIDS activists, this discretionary enforcement strategy presents the same problems as any other discretionary enforcement strategy. First and foremost, discretionary enforcement creates legal and regulatory uncertainty and is ripe for favoritism or abuse. Though there is no evidence of favoritism or abuse in enforcing drug import laws, the evidence of legal and regulatory uncertainty is compelling. By its own admission, the extent to which drug import laws had been enforced by the FDA varied widely between the different regions and field offices.[142] One memo suggests some Customs enforcement districts detain all imported prescription drugs, while other districts detain none: "Surveys have shown a significant variance among the districts in the area. A typical example is the district's coverage of mail importations which varies from 0% to 100%. Such unequal enforcement is unfair to both the consuming public and the trade."[143] If the FDA's own regulators and enforcement officials could not agree on what should and should not be cleared for delivery, one can hardly expect patients and suppliers to know what can or cannot be shipped. Though the FDA memo was intended to clear up this confusion, it is not clear whether the memorandum made the level of enforcement any more uniform among the different FDA regions and field offices.

VIII. POSSIBLE SOLUTIONS

While states have traditionally resisted federal incursion into professional licensing, online pharmacies could force the federalization (at least partially) of both medical and pharmaceutical licensing. NAFTA alone could force the federal government to expand its role because states will be largely powerless to enforce their own laws against Canadian and Mexican pharmacies.

Expanding federal regulation into an area traditionally overseen by the states certainly is not without precedent, and expansion of the federal role hasn't necessarily meant the federal government occupied the field or even assumed direct control over licensing. A relevant example is the Commercial Motor Vehicle Safety Act of 1986, which set minimum standards for commercial tractor-trailer and bus drivers.[144] Prior to the Act, state licensing standards varied widely, and commercial drivers frequently obtained licenses from more than one state.[145] Drivers could hide or spread convictions among several driving records and continue driving.[146] The CMVSA allowed states to continue issuing drivers licenses, but it required them to

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[140]§ 9-71-10.

[141]§ 9-71-30.

[142]§ 9-70-00.

[143]*Id.*

[144]COMMERCIAL DRIVER'S LICENSE PROGRAM, FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION, *available at* <http://www.mcs.dot.gov/safetyprogs/cdl.htm>.

[145]*Id.*

[146]*Id.*

observe minimum national standards when licensing commercial drivers, and it forbade drivers from having a license in more than one state.[147]

Likewise, federal regulation of medical practice may not be too far a leap from the current scheme. The federal government is already involved in monitoring medical practitioners, even though states still license all healthcare professionals.[148] The U.S. Department of Health and Human Services maintains the National Practitioner Data Bank to keep track of complaints against physicians, and some members of Congress want to open the database to the public.[149]

According to the American Telemedicine Association [hereinafter "ATA"], three basic approaches have been offered for regulating telemedicine:[150]

1) Full and Unrestricted Licensure: Each telemedicine practitioner would need a license in any state in which he/she consulted a patient via the Internet. States would decide issues of reciprocity in a way similar to the drivers license compact between the states, if they chose to allow reciprocity at all.
2) Limited Licensure: Practitioners would be licensed in the states in which they treat patients face-to-face, and a secondary or limited license would be granted for practice via telemedicine. The secondary license could be granted by the states individually or by the federal government.
3) National Licensure: The federal government would assume control over all practitioner licensing.[151]

The ATA supports limited licensure, as does the Federation of State Medical Boards [hereinafter "FSMB"].[152] The FSMB produced "A Model Act to Regulate Practice of Telemedicine or Medicine by Other Means Across State Lines," which would establish the secondary license state-by-state.[153] As of May 21, 1999, only three states (Alabama, Tennessee, and Texas) had adopted legislation consistent with the Model Act.[154] Conversely, fourteen states had adopted legislation requiring full and unrestricted licensure in the previous four years.[155]

Regardless of lawmakers' wishes, prescription drug regulation will most likely move from a licensing model to a certification model. Practical considerations make this inevitable because, aside from expanding the "war on drugs" to prescription pharmaceuticals, there is little the federal government can do to prevent U.S.

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[147] *Id.*

[148] *See generally* Correspondence and Hearings of the Commerce Committee, U.S. House of Representatives, *available at* <http://com-notes.house.gov/cchear/hearings106.nsf/actionkey?OpenView&StartKey=National+Practitioner+Data+Bank>.

[149] *Id.*

[150] AMERICAN TELEMEDICINE ASS'N, *supra* note 97.

[151] *Id*

[152] *Id.*

[153] FEDERATION OF STATE MEDICAL BOARDS, REPORT OF THE AD HOC COMMITTEE ON TELEMEDICINE (1996), *available at* <http://www.fsmb.org/telemed.htm>.

[154] AMERICAN TELEMEDICINE ASS'N, *supra* note 97.

[155] *Id.*

consumers from ordering the drugs they want from a foreign pharmacy.[156] To some extent, federal officials have acknowledged as much.[157]

Yet concerns about consumer protection and public health and safety are not diminished with the advent of online pharmacies. On the contrary, one might argue that these concerns are magnified. As previously discussed, enforcing regulations in cyberspace can be difficult under the best of circumstances; online pharmacies can appear and disappear overnight. Tort recovery is highly unlikely if the pharmacy is located in another country. Accordingly, regulators are forced to rely on professional certification rather than licensure. Programs like VIPPS could be, perhaps, expanded to an international scale. Moreover, national certifications would acquire brand name value. Most U.S. consumers probably wouldn't purchase an unknown cancer treatment manufactured and sold in Nigeria, but U.S. consumers already have already demonstrated their willingness to buy pharmaceuticals from European sources.[158] That can most likely be attributed to confidence in European drug regulation.

IX. BENEFITS TO CONSUMERS

At the least, one can argue that the result of imports from foreign online pharmacies is egalitarian – no longer must a U.S. resident live near the border or fly to Europe for drugs that are unavailable in the U.S. The competitive pressures of international retail drug trade could lower drug costs for consumers worldwide. In fact, the competition is already under way. The National Community Pharmacists Association is pressing Congress to allow retailers to buy drugs overseas – where prices are a fraction of the amount charged in the U.S. – for reimport into the United States.[159] If the FDA maintains a fairly liberal import policy, the "brand name" value of each nation's certification could result in a sort of competition between regulatory agencies. For example, if U.S. consumers decide the FDA's drug approval process takes too long and is unnecessarily stringent, they may decide instead to trust the somewhat less-stringent approval process of a European country and purchase a drug that is already approved in Europe but not in the U.S. In fact, the growing business of importing drugs not available in U.S. pharmacies seems to indicate consumers have done just that. Thus regulatory drug approval might become more like an Underwriter's Laboratories listing: consumers would decide for themselves whether FDA approval was worth the wait (and manufacturers might debate whether it was worth the cost) when another country has already approved the drug. Critics might argue the option to purchase desired drugs from foreign pharmacies could result in competitive pressures on the FDA, which in turn might shortcut its evaluation

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[156]Actually, some federal officials appear inclined toward the "war on drugs" strategy. In March, U.S. Customs Service Commissioner Raymond Kelly announced the arrest of twenty-two people in Thailand in a joint operation between his agency and the Thai government. The defendants were accused of operating an online pharmacy that sold drugs without a prescription. Associated Press, *Internet Drug Sales Bring 22 Arrests*, DES MOINES REGISTER, Mar. 22, 2000, at A8, *available at* 2000 WL 4951512.

[157]Foss, *supra* note 116.

[158]*See, e.g.*, Associated Press, *Seniors Shop Canada for Low-Priced Drugs*, BANGOR (Maine) DAILY NEWS, Sept. 13, 1999.

[159]Conlan, *supra* note 119.

process to keep pace with European agencies. On the other hand, manufacturers might argue that the competitive pressure could force the FDA to strike a better balance between consumer protection and consumer demand. Understandably, the FDA may not wish to throw the borders open to just any pharmaceutical import, but the emergence of international manufacturing standards should give the FDA a better idea of which countries provide reasonable guarantees of safety and which do not.

X. AN UNKNOWN

As stated before, one would presume that the practice of medicine – including the aspects that relate to prescription drugs – should be the same regardless of the state. However, this presumption is not completely true. Oregon, for example, licenses naturopathic[160] doctors to prescribe under the FDC, a practice that has produced considerable criticism from other practitioners.[161] Other states might object that they do not consider naturopaths adequately trained to prescribe drugs, and that under no circumstances would they want an out-of-state naturopath prescribing drugs to an in-state resident. Presumably, a state could authorize chiropractors or even pharmacists to prescribe drugs. In fact, some twenty-eight U.S. states allow pharmacists limited authority to consult with patients, write prescriptions, and fill the prescriptions they write.[162] But powerful physician's associations such as the American Medical Association almost certainly would fight any attempt to give full prescribing powers to pharmacists (or chiropractors), and it is unlikely that any state government would extend such authority to pharmacists.

However, the issue may not be so straightforward with American Indian tribes. Courts are increasingly recognizing tribal sovereignty to include almost all areas of civil regulation.[163] Tribal governments exert authority over wildlife,[164] environmental affairs,[165] and family law,[166] and now some tribes are expanding their reach into gambling,[167] corporation law,[168] and even automobile licensing.[169]

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[160]Naturopathic physicians are awarded an "N.D." rather than an "M.D." *See* Website of American Naturopathic Med. Ass'n, *at* <http://www.anma.com>.

[161]*See*, *e.g.*, Website of American Naturopathic Medical Ass'n, *at* <http://www.anma.com/cnme.htm>. This site, maintained by a naturopathic medical organization, is sharply critical of some naturopaths who claim to be able to perform all the functions of medical doctors. *See id*.

[162]Judy Chi, *Power of Pen: Pharmacist Prescribing is Advancing Slowly But Surely Throughout the Country*, 144 DRUG TOPICS (2000).

[163]*Id*.

[164]*See*, *e.g.*, Michael R. Anderson, *Law and the Protection of Cultural Communities: The Case of Native American Fishing Rights*, 9 L. & POL. 125 (1987).

[165]*See*, *e.g.*, Steffani A. Cochran, Comment, *Treating Tribes as States under the Federal Clean Air Act: Congressional Grant of Authority—Federal Preemption—Inherent Tribal Authority*, 26 N.M. L. REV. 323 (1996).

[166]Manuel P. Guerrero, *Indian Child Welfare Act of 1978*, 7 AM. INDIAN L. REV. 51 (1979).

[167]William Claiborne, *Indian Casino Plan Forges Odd Alliances Pro and Con*, WASH. POST, Mar. 12, 2000, at A3.

Medical practice is hardly booming on Indian lands. Physicians generally are provided by the U.S. Indian Health Service,[170] so the adoption of professional medical/pharmaceutical regulation is unlikely to be guided by a politically prominent organization tantamount to a state or national medical association. On the other hand, health care could become a major industry on tribal lands if online pharmacies move there to take advantage of more favorable regulations. A tribe might, for example, permit pharmacists to write prescriptions themselves and to do it on the basis of an online form or interview. While it is clear that the FDC gives states substantial latitude to determine who is or is not qualified to write prescriptions, the FDC makes no mention of tribal governments, much less whether they can license professionals to act within the FDC.[171]

Tribal pharmacy regulation has not been an issue because most pharmacists who work on Indian lands are federal employees, and those who are not federal employees (as well as those who are federal employees) are licensed by a state pharmaceutical board (even if it is not the state in which the tribal lands are located).[172] The states can exert some authority over the pharmacists they license, even when those pharmacists practice on Indian land.[173] However, the states have no authority to regulate or inspect the facilities of pharmacies on Indian land.[174]

The unanswered question is what rights – if any – the pharmacies and pharmacists licensed by a tribe would have beyond tribal lands. As previously noted, the courts haven't yet resolved the impact of the Dormant Commerce Clause on state regulation of online pharmacies. The FDC makes no mention of tribal governments, but since Congress maintains sole authority to regulate commerce with Indian tribes, one could argue that tribal drug regulations would be subject to the same analysis as state drug regulations. Internet commerce in general presents promising opportunities for economic growth on reservations, many of which are isolated from major population centers. Because of the unique legal authority of tribal governments and the near irrelevance of geography in Internet commerce, Indian territory may prove to be a popular location for online pharmacies. If so, Congress will be faced with yet another challenge to traditional drug regulation.

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[168]*See*, *e.g.*, Website of Native American Constitution and Law Digitization Project, *at* <http://thorpe.ou.edu/codes/absshaw/Corporations.html>.

[169]Curtis Killman, *Playing Tag*, TULSA WORLD, Nov. 24, 1998, *available at* <http://search.tulsaworld.com/archivesearch/default.asp?WCI=DisplayStory&ID=981124_Ne_a1playi>.

[170]*See* Website of Indian Health Service, *at* <http://www.ihs.gov/AboutIHS/IHSintro.asp>.

[171]For a general discussion of state-federal-tribal jurisdiction, see Fred L. Ragsdale, Jr., *Problems in the Application of Full Faith and Credit for Indian Tribes*, 7 N.M. L. REV. 133 (1977); Stanley G. Feldman & David L. Withey, *Resolving State-Tribal Jurisdictional Dilemmas*, 79 JUDICATURE 154 (1995).

[172]E-mail correspondence from David Denoyer, Executive Director, New Mexico State Board of Pharmacy, to Ty Clevenger (Feb. 10, 2000).

[173]*Id.*

[174]*Id.*