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Responsive Regulation of Internet Pharmacy Practice

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INTRODUCTION

The widespread and growing use of pharmaceutical products as a favored therapeutic modality in modern health care poses significant challenges for the pharmacy profession. Traditionally viewed as guardians of the nation's supply of medically useful drugs, the responsibilities of pharmacists are expanding because of the rapidly increasing volume of prescription orders,[1] and also because of the heightened demand for expanded pharmacist services in drug therapy monitoring.[2] Pharmacists are responsible for assuring absolute accuracy in their traditional dispensing role. This standard of perfection is an unreachable benchmark for any system of service or product provision, but pharmacists must nonetheless strive to achieve this ideal goal by initiating "sufficient institutional controls" over their order processing practices.[3] In addition, pharmacists have increasingly been held to have a "duty to warn" when the special circum-

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1. According to the National Association of Chain Drug Stores, the volume of prescriptions filled by the nation's pharmacists rose from 2.0 billion in 1992 to 3.15 billion in 2000. National Association of Chain Drug Stores, *Industry Facts, at* http://www.nacds.org/industry/industry_fr.html (last visited Mar. 21, 2001).

2. A report issued in December, 2000 by the United States Department of Health and Human Services indicates that the supply of pharmacists needed for the delivery of quality health care is being strained by the sharp demand for pharmacist services. Press Release, U.S Department of Health and Human Services, Health Resources and Services Administration, HHS Report Finds Emerging Shortage of Licensed Pharmacists (Dec. 12, 2000), *available at* www.hrsa.gov.newsroom/releases/2000Releases/pharmacistshortage.html. The report concludes that the number of unfilled pharmacist positions nationally rose sharply from about 2,700 in February of 1998 to nearly 7,000 in February of 2000, and that such vacancies are expected to continue to grow. *Id.*

3. Primary liability of pharmacies for failure to "initiate sufficient institutional controls" over the practice of their pharmacists was first recognized in *Harco Drugs, Inc. v. Holloway*, 699 So.2d 878, 881 (Ala. 1995). This new exposure to corporate liability, added to the traditional corporate exposure to secondary liability under *respondeat superior*, requires that pharmacies create practice sites that are conducive to successful pharmacy practice. Pharmacists can produce good results from their prac-

stances of a prescription suggest to a pharmacist that a patient may be at risk in a way that either the patient or the prescribing physician may not appreciate.[4] Pharmacists are being asked to do more for each patient, and there are more patients whose needs pharmacists are being asked to meet.

Owing to the increasing complexity of modern pharmacotherapy, and to the uniform adoption of the clinically-oriented Pharm.D. degree, contemporary pharmacists find themselves facing an unprecedented window of opportunity, during which the practice of "pharmaceutical care" could finally become a reality.[5] Conceived as a complement to medical care and nursing care, the purpose of pharmaceutical care is to address the well-documented problem of preventable drug-related morbidity.[6] The value of reliance on those pharmacists who practice pharmaceutical care to promote good outcomes for patients and to prevent adverse drug effects has been empirically established.[7]

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tices only if pharmacies provide a supportive place to practice, within which systems work well to enable pharmacists to meet societal expectations of them.

4. Although there continues to be controversy over a general duty for pharmacists to provide warnings to patients of all relevant potential adverse drug effects, it has become well settled that when a pharmacist has actual knowledge of an existing problem with drug therapy, and when harm to a patient is reasonably foreseeable, the pharmacist has a duty to inform the patient of actions that can be taken to eliminate or minimize the risk of harm. *See, e.g.*, Dora A. Gonzalez, *Prescription for Litigation: In Pursuit of the Pharmacist's "Duty to Warn" of Adverse Effects of Prescription Drugs*, 1 J. LEGAL ADVOC. & PRAC. 53 (1999); Roseann B. Termini, *The Pharmacist Duty to Warn Revisited: The Changing Role of Pharmacy in Health Care and the Resultant Impact on the Obligation of a Pharmacist to Warn*, 24 OHIO N. U. L. REV. 551 (1998).

5. *See, e.g.*, Charles D. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 AM. J. HOSP. PHARM. 533 (1990); L. M. Posey, *Pharmaceutical Care: Will Pharmacy Incorporate Its Philosophy Of Practice?*, 37 J. AM. PHARM. ASS'N. 145 (1997) (discussing the expanding role of pharmacists in patient care issues and how pharmacists can approach these issues).

6. Although some medication-related problems are simply tragic but unavoidable costs of therapeutic advances that bring previously unimaginable value to patient care, other medication-related problems are completely preventable by system changes that adapt to the increasing complexity of pharmacotherapy. S. Hennessy, *Potentially Remediable Features of the Medication-Use Environment in the United States*, 57 AM. J. HEALTH-SYS. PHARM. 543 (2000).

7. T-J Grainger-Rousseau et al., *Therapeutic Outcomes Monitoring: Application of Pharmaceutical Care Guidelines to Community Pharmacy*, 37 J. AM. PHARM. ASS'N. 647 (1997) (concluding that pharmacists can successfully implement drug therapy management in their practices, overcoming may obstacles to doing so); *see also* L. R. Borgsdorf et al., *Pharmacist-Managed Medication Review in a Managed Care System*, 51 AM. J. HOSP. PHARM. 772 (1994) (describing a pharmacist-managed medication review program that produced savings of $644 per patient per year due to reductions in the numbers of unscheduled physician visits, urgent care visits, emergency room visits, and hospital stays); V. M. Wilt et al., *Outcome Analysis of a Phar-*

Yet, despite obvious advantages over the traditional product-oriented focus of dispensing pharmacists, this new patient-centered approach to pharmacy practice has been slow to evolve. Time constraints faced by pharmacists, information deficits concerning specific patients and their unique needs, and the limits of the physical settings in which pharmacists practice, pose significant barriers to the maturation of pharmaceutical care from academic theory to practice reality.[8] There is a very real possibility that the logistics of traditional health care will prevent pharmacists from re-professionalizing to accept responsibility for the outcomes of drug therapy.

Internet pharmacy has the potential to overcome barriers that exist within traditional pharmacy practice, thereby enabling success with pharmaceutical care. Through alliances between local pharmacies and their Internet-based partners, prescription order processing can be moved offsite to "central fill" locations, reducing the volume of prescription orders to process at local pharmacies. Routine questions about medications can be answered by online pharmacists using email or other electronic (eventually real-time video) connections with patients, further addressing the current workload constraints that exist at most local pharmacies. Knowledge of a patient's diagnosis, results of laboratory tests, and established drug monitoring parameters, largely unavailable to pharmacists at present, can be made accessible to local pharmacists through the Internet. Pharmacies

macist-Managed Anticoagulation Service, 15 PHARMACOTHERAPY 732 (1995) (describing a potential cost avoidance of $4,072.68 per person per year in a family practice setting when pharmacists manage drug therapy for improved outcomes of patients receiving warfarin therapy). The focus of these reports has primarily been on economic cost savings for managed care plans, but the human cost savings are perhaps equally as dramatic, although far more difficult to quantify and report.

8. Although pharmacists in some practice settings have expanded their influence into areas beyond accuracy in order processing, there is a lack of congruence between the abilities of pharmacists and societal expectations of them. Paul G. Grussing, *A Comparison of Empirical Studies of Pharmacy Practice with Judicial Descriptions*, 44 DRAKE L. REV. 483, 485 (1996) (noting that barriers to practice frustrate the pharmacy profession's goal of serving society). Judicial perspectives on pharmacy practice have slowly evolved from concern for the limits of retail-oriented practice environments to optimism that pharmacists may be able to overcome environmental barriers to expanded practice. Scholarly discourse has encouraged a judicial view that expands expectations of pharmacists. *See* R. Paul Asbury, *Pharmacist Liability: The Doors of Litigation Are Opening*, 40 SANTA CLARA L. REV. 907 (2000) (concluding that traditional stereotypes of pharmacists are no longer accurate and that courts should abandon the limits of liability traditionally afforded pharmacists); Edward Casmere, *Rx for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule*, 33 J. MARSHALL L. REV. 425 (2000) (suggesting that a no duty to warn rule prevents pharmacists from achieving the professional recognition they deserve).

and pharmacists can use the Internet to integrate themselves with other care providers and institutions, opening up new opportunities for public service that simply cannot occur in the current disconnected system that locks pharmacists out of the mainstream of health care.[9]

This article suggests that pharmacy regulators could best protect and promote the public health through responsive Internet regulation that facilitates expanded pharmaceutical care practices. Regulation of Internet pharmacy should avoid restrictions that inhibit direct online care and product provision by pharmacists. Tough regulation directed toward Internet-based "rogue pharmacies" runs the risk of replicating the "war on drugs" that has for many years been fought by the Drug Enforcement Administration and other law enforcement agencies with only modest success. This crusade to protect the public from the scourge of drug addiction has prevented the diversion of many narcotic controlled substances, but it has also had the unintended, yet foreseeable effect of decreasing access to appropriate analgesic medications, leading to uncontrolled pain for many patients.[10] Tough regulation of Internet pharmacy could similarly restrict beneficial pharmaceutical care activities if regulations were so broad in scope and uncompromising in application as to have a "chilling" effect on even the most well intentioned of providers. Most pharmacists are highly risk averse. They adopt practices that steer them far clear of regulatory violations, and the threat of even an accusation of impropriety is often sufficient to alter practice patterns.[11] With regard to Internet pharmacy, the challenge pharmacy regulators must meet is to develop a regulatory

9. D. M. Angaran, *Telemedicine and Telepharmacy: Current Status and Future Implications*, 56 AM. J. HEALTH-SYS. PHARM. 1405 (1999) (suggesting that telepharmacy presents the pharmacy profession and individual pharmacists with great opportunities to become an even more integral part of the medication-use system).

10. *See* R. T. Angarola & S. D. Wray, *Legal Impediments to Cancer Pain Treatment*, 2 ADVANCES IN CANCER PAIN MANAGEMENT AND THERAPY 213 (1989) (noting that drug statutes and regulations often have a chilling effect on the prescribing and dispensing of opiates). The problems caused by underuse of opioid analgesics have been addressed through changes in policy that encourage appropriate pain management. *See* D. E. Joranson and A. M. Gilson, *State Intractable Pain Policy: Current Status*, APS BULLETIN 7 (Mar./Apr., 1997) (documenting a trend toward greater tolerance by regulators of opioid use in intractable pain). However, policy-on-paper has not necessarily changed policy-in-practice.

11. *See* R. Sean Morrison et al., *"We Don't Carry That"— Failure of Pharmacies in Predominantly Nonwhite Neighborhoods to Stock Opioid Analgesics*, 342 NEW ENG. J. MED. 1023 (2000) (reporting that of pharmacies surveyed in the New York City area, 51% did not have in stock a sufficient supply of opioid medications to provide adequate treatment for a patient with severe pain).

approach that is designed to prevent inappropriately risky medication use, while leaving unaffected the online innovations that can enhance the appropriate use of medications and improve a patient's quality of life.

Part I of this article describes established principles of drug regulation, and it explains how those principles can be applied to Internet pharmacy.[12] In Part II, the potential hazards of over-regulation are reviewed.[13] Outcomes-oriented responsive regulation is described as an emerging trend, and opportunities are noted for use of the Internet to improve outcomes for patients. Part III criticizes state paternalism, if it restricts informed patient choice of a provider of pharmaceutical products and services.[14] This article concludes that the most appropriate method for regulation of Internet pharmacy, in fact the only method that has a reasonable chance of success, is the Verified Internet Pharmacy Practice Site ("VIPPS") program of the National Association of Boards of Pharmacy ("NABP").[15]

I. State and Federal Regulation of Pharmacy

Pharmacists are required to comply with federal laws relating to the distribution of drug products.[16] Once a drug has enter interstate commerce, any person subsequently holding it for sale must be in compliance with both the Federal Food, Drug and Cosmetic Act ("FDCA")[17] and the Controlled Substances Act ("CSA").[18] Pharmacists must also comply with state laws regu-

12. *Infra* Part I (discussing the principles of drug regulation and how these principles can be applied to Internet pharmacy).

13. *Infra* Part II (reviewing the dangers of over regulation).

14. *Infra* Part III.A (criticizing state paternalism as a restriction on informed patient choice).

15. *Infra* Part III.C (concluding that the most appropriate method for regulation of Internet pharmacy is the VIPPS program of the NABP).

16. United States v. Sullivan, 332 U.S. 689, 696 (1948) (holding that the act of dispensing by a pharmacist is an act in interstate commerce and is subject to the misbranding provisions of the federal Food Drug and Cosmetic Act).

17. 21 U.S.C.A. §§ 301-397 (West 1999 and West Supp. 2000). The FDCA applies to all drug products, and it is administered by the federal Food and Drug Administration ("FDA"). Through its administration of the FDCA, the FDA assures the safety and efficacy of new drugs introduced into interstate commerce, it regulates the labeling and advertising of drugs, and it oversees the purity of drugs. FDA, *Overview of the Food and Drug Administration*, *at* http://www.fda.gov/opacom/hpview.html (last visited Feb. 23, 2001) [hereinafter *Overview of the Food and Drug Administration*].

18. 21 U.S.C.A. §§ 801-971 (West 1999 and West Supp. 2000). The CSA applies only to those drug products that have a potential for abuse, and it is administered by the federal Drug Enforcement Administration ("DEA"). Through its enforcement of the CSA, the DEA assures that abusable medications are restricted to a defined dis-

lating the practice of the profession of pharmacy. In most states, professional regulation of pharmacy is accomplished through a pharmacy act in which the legislature creates and empowers a board of pharmacy. The state board of pharmacy promulgates rules and regulations, which it enforces along with the provisions of the pharmacy act.

Internet pharmacy does not fit well into the standard regulatory scheme under which the federal government regulates the drug product, while state government regulates the pharmacy profession. Distinctions between product distribution and the provision of professional services become blurred, and the separate states or countries in which providers and recipients of services are located make it difficult to know who, if anyone, has jurisdiction over a transaction. Consider the following hypothetical example: Using the Internet, a Florida patient orders pharmaceutical products from an Internet site that purports to be located in Texas and promotes online availability of prescription-only medications without a prescription. In reality, the site is linked from a Texas site to another site in Nevada, and the patient never knows this. A questionnaire filled out by the patient is reviewed by a physician in Rhode Island, who receives the patient's electronically submitted information from the site in Nevada, and then authorizes the patient to receive the requested prescription-only medication. An email message is then sent to the patient by an Illinois pharmacy, offering to discuss the medication with the patient if the patient has any questions. This pharmacy includes in its message a hyperlink to a Louisiana site that describes in detail how to use the prescription-only medication, and the possible side effects of the medication. Several days later, a parcel with a return address of a North Carolina pharmacy arrives in Florida, and inside is a prescription vial containing the medication, labeled with the name and address of a different North Carolina pharmacy. If problems should arise for the patient, it would be difficult to know what regulatory authority has jurisdiction over the transaction. Even if substantive law is clear, the procedure of enforcement is certain to be time-consuming and unreliable.

The possible scenario described above is certainly not the only way for an Internet pharmacy to operate; nor it is necessarily typical of Internet pharmacies. There are some sites, many of

tribution system, and that those who divert controlled substances outside the system are punished for their wrongdoing.

them "offshore," that completely ignore the formality of requiring a physician's authorization to dispense, and they readily ship prescription-only medications to anyone who has the ability to pay for them, without even the pretense of a physician-reviewed questionnaire. On the other hand, the well-known dispensing-only sites, many of which have developed alliances with large community pharmacy chains, will meticulously follow all applicable legal requirements, and will not provide prescription-only products unless a patient has provided a valid prescription from the patient's own physician. These varied ways of conducting an Internet pharmacy business lead to differing needs of regulation to protect the public health.

A. Applying The Law To Internet Pharmacy

The outright sale of prescription-only pharmaceuticals without authorization from a licensed prescriber is the dispensing activity that most clearly violates the FDCA. Under the FDCA, a drug is classified as prescription-only for one of two reasons: (1) either it is deemed unsafe for use except under the supervision of a state-licensed prescriber, or (2) it is limited to prescription-only use by its approved New Drug Application.[19] The act of dispensing a drug contrary to this prescription requirement is an act that results in the drug being deemed misbranded while held for sale.[20] Misbranding is a serious violation of the FDCA that can result in seizure of a product, criminal prosecution of those who have distributed it, and an injunction to prevent further distribution.[21] Internet pharmacy sites that make no attempt to involve a physician in an authorization to dispense prescription-only medications are clearly in violation of the FDCA. They have misbranded the product.

When a prescription-only drug is dispensed pursuant to a physician's authorization that results from the review of an online questionnaire filled out by a patient, application of the FDCA is not so straightforward. It has been suggested that when a physician prescribes based solely on the review of an electronic message from a patient, there is legally not a "prescription," because there is no legitimate physician-patient relationship and/or because a legal prescription results only when a physician has

19. 21 U.S.C.A. §§ 353, 355 (West 1999 and West Supp. 2000).
20. 21 U.S.C.A. § 353(b)(1) (West 1999 and West Supp. 2000).
21. 21 U.S.C.A. §§ 331-337 (West 1999).

physically examined a patient.[22] If this interpretation is correct, then dispensing pursuant to an invalid physician's order would constitute a misbranding violation as described above. However, this legal approach presents potential difficulties, because in traditional prescribing there may not always be a physician-patient relationship that meets these narrow legal standards. Furthermore, problems might arise in the regulation of desirable innovative approaches to telemedicine, where physicians and patients may be remote from each other and not personally known to each other, if regulators were to adopt a very narrow construction of what physician behaviors are necessary to create a legally sufficient prescription. Developing strict standards to evaluate the conduct of physicians and patients, as a prerequisite to the recognition of a valid physician-patient relationship, might be an approach that creates more problems than it solves. Regulatory intrusion in the physician-patient relationship may put a stop to inappropriate Internet pharmacy practices, but it could also interfere with legitimate traditional health care or with valuable innovation in medical practice.

The FDCA offers an alternative to the potentially restrictive regulatory approach centered on defining the attributes of an acceptable physician-patient relationship. Rather than creating a new set of rules that requires an evaluation of the character of a prescriber-patient relationship (a perilous and potentially controversial activity), regulators could instead consider using existing statutory requirements that apply to those who dispense under prescriptive authority resulting from a diagnosis made through the mail. As is so often the case with the FDCA, this requirement depends heavily on the misbranding provisions of the Act. Under the FDCA, current misbranding provisions require extensive disclosure of information, at such a high level that dispensers could not possibly comply.[23] Yet, dispensers es-

22. Ross D. Silverman, *The Changing Face of Law and Medicine in the New Millennium*, 26 AM. J.L. & MED. 255, 267 (2000) (describing a view held by some medical groups that to prescribe a medication, the standard of medical care requires a physical examination of the patient, dialogue with the patient to discuss treatment alternatives, an attempt to establish a reliable medical history, information about the benefits and risks of a prescribed medication, and follow-up to assess the therapeutic outcome).

23. 21 U.S.C.A. § 352(f) (West 1999). The misbranding provisions of this statutory section require that the labeling of a drug bear "adequate directions for use," and "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health." *Id.* FDA regulations interpreting these requirements are summarized in 21 C.F.R. §§ 200-299 (2000). There is a strong argument that it would be impossible for a pharmacy to comply with the stringent pre-

cape what would otherwise be a misbranding violation, through a specific statutory exemption that relieves them of the need for compliance with exhaustive information disclosure requirements. As long as their prescription vial is properly labeled with the patient's name, prescriber's name and directions for use, according to information provided in the prescription being filled, they are eligible for the exemption. The FDCA states, however, that the exemption from the extensive disclosure requirement does not apply to "any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail."[24] Thus, an online pharmacy that conducts a business of dispensing pursuant to diagnosis by email would lose the exemption, be forced to comply with extensive misbranding provisions that cannot be met, and would therefore be in violation of the misbranding section of the FDCA. This statutory provision is, in effect, an exemption from an exemption. It does not apply simply to the act of prescribing by mail, or even to occasional acts of dispensing by mail. What is made illegal by the FDCA under this provision is the conduct of a business that promotes the availability of prescription-only drugs through diagnosis and prescribing by electronic mail, and then dispenses prescription drugs under such tenuous authority. Drugs dispensed in this way are misbranded under the FDCA. Thus, no intrusive evaluation of the physician-patient relationship is necessary. If email is considered mail (not a huge stretch of the imagination), then Internet pharmacies that conduct a business of dispensing medications prescribed through evaluation of electronic information have violated the law.

The only online pharmaceutical dispensing practice that clearly complies with the FDCA is the pharmacy practice that insists on a patient presenting, in some way, a prescription issued by the patient's local physician. In many ways, this pharmacy practice model is merely an advanced version of mail-service pharmacy. Over the Internet, such practices offer quicker, more consistent, and more comprehensive service than the service that can be provided through the mail. Although somewhat controversial when they were introduced several decades ago, quality concerns about mail-service pharmacies have

scription drug labeling regulations, because pharmacies dispense prescription drugs directly to patients, and prescription drugs are necessarily those drugs that are incapable of being labeled for safe and effective use by persons who are not health care professionals.

24. 21 U.S.C.A. § 353(b)(2) (West 1999 and West Supp. 2000).

been resolved.[25] This is an efficient and effective way to provide pharmaceutical products to those patients whose drug therapy monitoring services are furnished through another means. From a regulatory perspective, there are no critical FDCA issues for Internet pharmacies that function as mail-service pharmacies have. These are state-licensed businesses. They are required to be licensed in most states to which they ship dispensed pharmaceutical products, and they are subject to the same controls as any pharmacy within the state to which pharmaceutical products are dispensed. There is no evidence that these Internet pharmacies present threats to the public health that differ significantly from those of any other state regulated pharmacy practice.

B. Enforcing The Law With Internet Pharmacies

The enforcement of pharmacy laws by state boards of pharmacy and other state regulators faces obvious obstacles when an allegedly dangerous Internet pharmacy practice is located out-of-state. In the absence of evidence that an in-state pharmacy poses a risk of harm to in-state patients, state pharmacy regulators may have a difficult time justifying the use of resources for the enforcement of state laws. When a patient in one state is placed at risk of harm by a pharmacy in another state, regulators in both states must cooperate for them to be effective in their joint enforcement. Brick-and-mortar pharmacies can be investigated through cooperative efforts of regulators in two states, and problems with quality can be addressed in much the same way as is done with in-state pharmacies. However, in the time it takes to discover, investigate, and provide notice to an alleged Internet pharmacy violator, the fast-paced entrepreneur responsible for the original pharmacy site may very well have closed that site and moved to a different Internet location. The ability of businesses to link sites to each other makes it difficult for regulators to know against whom enforcement action should be initiated. Moving targets are hard to regulate, and the Internet facilitates frequent moving.

Despite these practical difficulties, there have been high-profile actions by attorneys general in several states to stop illegal Internet pharmacy practice. These actions usually charge that subject pharmacies have dispensed prescription drugs without a license in the state. They may also charge a violation of state

25. *See* Gregory S. Munro, *Regulation of Mail-Order Pharmacy*, 12 J. LEGAL MED. 1 (1991) (calling for state regulation of mail-order pharmacy).

consumer fraud laws.[26] As well-intended as these actions may be, it remains to be seen whether state attorneys general can maintain their level of commitment to this resource-intensive issue. The results of the recent state actions are not encouraging. One of the most active enforcers, Kansas Attorney General Carla Stovall, has estimated that of 400 online pharmacies believed to be selling drugs in the United States, only six were operating within the law, and only a fraction of the illegal operators were being investigated by a government agency.[27] Meanwhile, the chief investigator of unlicensed medical practice in Florida disclosed that he had only two people to investigate the entire health care industry.[28] Given the national scope and technical complexity of the problem, in the face of limited state resources, it is not surprising that state regulators have turned to federal authorities for help.

As the agency primarily responsible for regulating drug approval, production, distribution and marketing,[29] the FDA finds itself not particularly well situated to regulate professional practice. Yet, when the professional practice of pharmacy is used as a charade to protect large scale drug distributors from federal scrutiny, the FDA will not hesitate to weigh in with enforcement of federal laws usually applied only to manufacturers. For example, in the early 1990s, the FDA began to enforce federal laws against massive compounding by a small number of high-volume interstate distribution businesses that were masquerading as local pharmacies.[30] The federal enforcement action occurred only after state regulators were unable to protect the public from what had become an unregulated industry of clan-

26. *See Mail-Pharmacy Sues Michigan Over Attempt to Regulate Internet Drug Sales*, 5 MEALEY'S EMERGING DRUGS & DEVICES 6 (Feb. 17, 2000).

27. Sara Fritz, *In U.S. No Easy Rx for Online Pharmacies*, ST. PETERSBURG TIMES, Apr. 2, 2000, at 1A.

28. *Id.*

29. *Overview of the Food and Drug Administration*, *supra* note 17.

30. *See* United States v. Baxter Healthcare Corp., 901 F.2d 1401 (7th Cir. 1990) (concluding that the FDCA treats commercial manufacturers of drugs differently from pharmacies, because an improperly manufactured drug produced on a large scale will harm more patients than the same compounding mistake made on a smaller scale); *see also* United States v. Sene X Eleemosynary Corp., 479 F.Supp. 970 (S.D. Fla. 1979) (holding that the "practice of pharmacy defense" does not apply to a large interstate compounding operation that bears none of the characteristics of a traditional pharmacy practice).

destine drug manufacturers. An amendment to the FDCA was necessary to define FDA's regulatory authority in this area.[31]

The FDA has begun a similar enforcement campaign against Internet pharmacies, both foreign and domestic. However, the issues are more complex than they were with compounding pharmacies, and the targets of regulation are far more difficult to find. Federal enforcement activities directed at Internet pharmacy sites outside the United States have been of two types: (1) direct action against providers to put them out of business, in cooperation with local law enforcement authorities, and (2) distribution of an Import Alert to customs inspectors, designed to deny entry into the United States of illegal shipments from offshore Internet pharmacies.[32] Actions directed toward domestic sites have been equally as determined, but far less public. The agency has provided support for state enforcement activities, and it has stressed the need for more stringent self-regulation by the industry. Authority for federal enforcement has been based primarily on a conclusion that Internet sites are directed to the public, therefore strict rules for promotion of drugs directly to consumers apply.[33] Most Internet sites do not comply with the rigid requirements for advertising of prescription-only drugs directly to the public, thus they are considered in violation of the FDCA. This is an indirect approach to regulation that may be technically valid, but it uses statutory authority that was clearly intended to address public health threats other than those presented by Internet pharmacy. Meanwhile, the agency waits for Congress to provide more specific statutory direction.

Ultimately, no matter how tough state and federal regulators may be toward Internet pharmacies, their efforts will fall short of even the most modest goals. Just as illicit drug use has not been significantly curtailed, because enforcement authorities

31. 21 U.S.C.A. § 353a (West 1999) (codifying the amendment and carving out a safe harbor for pharmacies that compound small quantities of medications to meet special needs of individual patients, pursuant to a prescription issued by the patients' physicians), *held unconstitutional by* Western States Med. Ctr. v. Shalala, 2000 WL 33153172 (9th Cir.) (holding that § 353a is invalid in its entirety because § 353a(a) and § 353a(c)'s restrictions on commercial speech violate the First Amendment, but cannot be severed from the rest of the provisions of § 353a).

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

33. Marc J. Scheineson, *Ready to Regulate, FDA Goes Online: Agency Has Dropped Hands-Off Approach to Web Pharmacies*, LEGAL TIMES, June 19, 2000, at 25.

cannot be on every street corner, every hour, of every day, Internet pharmacy regulators will discover that they cannot monitor all web sites at all times. The decades-long failure of narcotic drug control authorities to prevent importation of illicit drugs into the country should instruct that the country's border cannot be made secure from anything but a small number of shipments made by offshore Internet sites to domestic medication users. And there is a terrible risk that strong regulation would stifle the Internet's growth and innovation, while doing little to prevent inappropriate medication use. Onerous Internet pharmacy regulation could have the unintended effect of deterring the development of novel approaches to care provision that reduce problems with drug therapy and enable alliances that improve the quality of care.

II. The Costs of Over Regulation

As noted above, there is clear evidence of a correlation between aggressive regulation of pharmacists and conservative pharmacy practices that do not consistently meet the needs of patients. Given the choice between a behavior that may raise a regulatory red flag but is clearly beneficial to a patient and an alternative behavior that is safe from a regulatory perspective but may not provide all available benefits to patients, many risk-averse pharmacists will adopt the latter strategy.[34] This is a sobering lesson learned through recognition of the barriers to effective pain management created by regulation of controlled substance medications. The under-treatment of pain is a serous problem in the American health care system, and one cause of the problem is a perception that regulators are intolerant of innovative pain management practices that challenge traditional notions of appropriate care.[35] Even though recent changes in policy-on-paper have clarified that restrictions on drug diversion should not play any role in restrictions on patient care, policy-in-practice has yet to reflect the more tolerant perspective of regulators. Once the fear of regulatory action becomes ingrained in the mind of a practitioner, it is difficult to dispel.

34. As recently as 1980, a DEA manual for pharmacists instructed that "[a] pharmacist who has any doubts, whatever, concerning the legitimacy of a prescription order presented to him should not dispense it." *See* Drug Enforcement Administration, The Pharmacist's Manual 34 (1980).

35. *See* Ann Alpers, *Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying*, 26 J. L. Med. & Ethics 308 (1998) (analyzing legal cases in which health care providers have been prosecuted for overuse of controlled substances).

Assertive and much-publicized enforcement directed against Internet pharmacy sites has the potential to deter innovative Internet pharmacy practices, in much the same way as aggressive regulation directed at diversion of narcotics has deterred innovative pain management practices. It is not always the reality of enforcement that matters as much as it is the perception that one is subject to enforcement action. Regulation is a powerful positive tool that can enable practitioners to meet their responsibilities to patients and improve outcomes for patients, but regulation can also prevent the development of new and valuable approaches to practice. Long viewed as being separate from the practice of health care and as a necessary evil to be tolerated but not welcomed, health care regulation has recently experienced a renaissance. Responsive regulation, as opposed to restrictive regulation, has the potential to bring health care regulators into the mainstream of health care. It is important that regulators of Internet pharmacy recognize the need to be specific in their enforcement activities and responsive to needs of the health care system. They must complement enforcement and discipline with at least equal emphasis on activities geared toward enabling productive change through regulation.

A. The Promise of Responsive Regulation

Responsive regulation promotes improvements in the quality of care. The quality improvement function of responsive regulation will be said to have succeeded when aggregated data measuring the professional performance of a group of licensed practitioners indicate that the mean for performance has changed for the better in response to regulatory activities. Most graphs illustrating the level of competence of a group of practitioners will show there are two opposing "tails" on either side of a bell-shaped curve plotting the number of practitioners versus the competence of each individual practitioner. The vast majority of practitioners will fall within the large body of the curve, near the mean and just barely below or above either side of it. The least competent practitioners will be represented in the low "tail," and the most competent practitioners will be represented in the high "tail" of the curve.

There are two types of regulatory actions that can significantly increase the mean for the group, thus showing an improvement in quality for the group. The first action is "culling." The elimination of truly incompetent practitioners from a group will raise

the mean of the competency for the group. Slicing off the lower "tail" of the curve shifts the curve in a positive direction, thus elevating the mean of competence for the group. This is the traditional role of the health care regulator. The second action, an alternative to the traditional enforcement function, is really an array of activities which emphasize removing systematic threats to quality and introducing systematic incentives to quality. Regulation geared toward those practitioners at or near the mean, and those at the higher "tail" of the curve can also shift the curve in a positive direction, just as can culling. These actions have a greater potential to improve the overall competence of the group, because there are far more individual practitioners near or above the mean than there are practitioners well below the mean. Yet, despite its potential for success, apple "polishing" has not be used by regulators nearly as frequently as has apple "picking." New theories of regulation suggest that cautious culling is necessary but far from sufficient to meet the regulatory challenge of public health protection.

Troyen Brennan and Donald Berwick have described a plan for the implementation of responsive regulation to enable success rather than punish failure. In their landmark book, *New Rules: Regulation, Markets, and the Quality of American Health Care*,[36] Brennan and Berwick propose a systematic approach to health care regulation, based on the principles of Continuous Quality Improvement ("CQI"). Their plan for responsive regulation encourages risk-taking as long as risks are monitored and controlled. They suggest that safe harbors from regulation should be carved out for major innovation, and that successful innovation should be rapidly spread throughout the health care system through the use of regulatory incentives.[37] They contend it is anachronistic to regulate fragments in an era when the primary goal is to reconnect the parts into a whole.

In a similar way, the much-publicized report of the Institute of Medicine, *To Err is Human*,[38] describes an unhealthy United States health care system. The report suggests regulation can play a more significant role in public health protection, and that problems with medication use are among the most significant threats to quality in health care. The report concludes that al-

36. TROYEN BRENNAN & DONALD BERWICK, NEW RULES: REGULATION, MARKETS AND THE QUALITY OF AMERICAN HEALTH CARE (1996).

37. *Id.* at 375-376.

38. *See* INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

most all accidents in health care result from human error, and these errors are usually induced by faulty systems that "set people up" to fail. In order to learn from error, health care regulators should require health care organizations to establish and maintain environments and systems for analyzing accidents and errors, so that redesign of processes is informed and productive.[39]

B. Pharmacy Systems and the Internet

The absence of explicit design, lack of shared goals, and the failure to use empirical evidence to correlate inputs with outputs, make it difficult to refer to medication use in the United States as a "system." Non-systematic medication use by physicians, pharmacists, and patients stands in stark contrast with the highly systematic drug development, production, and distribution by pharmaceutical manufacturers. It is the lack of a system that poses the greatest threat to quality in medication use, and the potential of the Internet to provide the framework of a medication use system is the greatest opportunity for responsive regulation of Internet pharmacy.

During new drug development, decisions about the safety and efficacy of recently discovered molecules are made based on randomized, controlled clinical trials that are evidence-based and protocol-driven.[40] Once approved for human use, the production and distribution of pharmaceuticals is restricted by a requirement for adherence to current Good Manufacturing Practices ("cGMP").[41] CGMPs mandate documentation, monitoring, and remediation when goals have not been met. The value of this highly organized system early in the drug therapy chain may be virtually nullified by the non-systematic last links of the drug therapy chain, when actual medication use is based on unguided, (and largely unevaluated) professional judgment, along with misplaced faith that patients use their medications appropriately and are satisfied with the results of their drug therapy.

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39. *Id.* at 155-201.

40. *See* 21 U.S.C.A. § 355(d) (West 1996) (mandating that sponsors of a new drug show the drug to be safe and effective by "substantial evidence," which is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified . . . to evaluate the effectiveness of the drug involved.").

41. 21 C.F.R. § 211.1 (2000).

Problems associated with drug therapy have been widely attributed to a need to re-engineer the system of medication use. With pharmacists as the focal point of system change, federal regulatory requirements have been initiated for Drug Regimen Review in nursing homes,[42] and for a comprehensive program of Drug Use Review aimed at outpatient pharmacy settings.[43] Courts of law have begun to recognize that pharmacists have a legal duty to evaluate drug therapy for every patient, and that technical accuracy in order processing is necessary but not sufficient to meet pharmacist professional responsibilities.[44] State boards of pharmacy have begun to shift their regulation from structure and process only, to an emphasis on outcomes that are linked to structure and process.[45] Mandatory CQI, as a component of administrative regulation of pharmacies, has been adopted by several states.[46] The pharmacy profession is emerging from its isolation on the street corners of the community and the basements of hospitals to accept responsibility for systematizing medication use. A key component, that is lacking in traditional medication use, is a means to facilitate communication among those who participate in medication use.

The Internet has the potential to be a key means of communication within a more systematic approach to drug therapy management. Two of the critical challenges to finding a solution to the problem of inappropriate medication use are the inaccessi-

42. 42 C.F.R. § 483.60(c) (2000) (stating that drug regimen review requires that a pharmacist examine all drugs being used by a nursing home resident at least once per month, and evaluate the appropriateness of these drugs).

43. 42 U.S.C. § 1396r-8(g)(2)(A)(i) (1994) (mandating that drug use review requires a pharmacist to screen each prescription for potential drug therapy problems, and that if a potential problem is detected, it be resolved prior to dispensing the medication).

44. Steven Huang, *The Omnibus Budget Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 24 AM. J. LAW & MED 417, 434 (1998) (noting the drug use review requirements codify a pharmacist's common law duty to check prescriptions for obvious errors, warn patients of known contraindications, and to warn patients or reactions between prescription and non-prescription medications).

45. The current emphasis on outcomes linked to structure and process, rather than structure and process by themselves, can be attributed to health services researcher Avedis Donabedian, who was among the first to suggest that the true measure of medical quality is the result of care. *See* Avedis Donabedian, *Evaluating the Quality of Medical Care*, 44 MILBANK MEMORIAL FUND Q. 166 (1966).

46. A recent move by health care regulators to require continuous quality improvement programs as proactive prevention of problems for patients, rather than using punishment of error as a reaction to problems for patients, has only begun to catch the attention of the mainstream of health care regulation. *See* Troyen A. Brennan, *The Role of Regulation in Quality Improvement*, 76 MILBANK Q. 709 (1998), *available at* 1998 WL 13685934.

bility of information describing the ideal for appropriate medication use and the deficiency of data defining the problems experienced in actual medication use.[47] Through the Internet, physicians, pharmacists, and patients can access criteria and standards for medication use, and they can develop strategies for improving therapy to reflect evidence-based, consensus-developed, clinical practice guidelines. The Internet can host real-time threaded discussions about therapy; some of which can be open to all Internet users, others of which can be password protected for access only by health care providers. Patients can report their symptoms, progress, and satisfaction with therapy on the Internet.

For example, assume that a patient who has been diagnosed with atrial fibrillation is treated with digoxin or another similar drug.[48] The patient is not prescribed an anticoagulant. Data from drug studies with many patients indicate that of patients diagnosed with atrial fibrillation, approximately 70% should be treated with an anticoagulant. However, data also show that only approximately 40% of the atrial fibrillation patients for whom anticoagulation therapy is indicated actually receive this beneficial therapy. By answering questions presented over the Internet, patients for whom the therapy is indicated but who are not receiving it can be identified and evaluated for anticoagulation therapy. This evaluation can be facilitated by online access to clinical practice guidelines. The questions asked of patients can be prompted by the dispensing of digoxin, a marker drug for atrial fibrillation. Once begun, anticoagulation therapy requires close monitoring. The results of laboratory tests and other observations by the patient can be reported on the Internet, and care providers can review this information to assure that standards for anticoagulation therapy are being met.

Not only can a health care provider use the Internet for the benefit of individual patients, aggregated data can be uploaded (with appropriate protection of patient confidentiality) to a cen-

47. *See* Jerry H. Gurwitz & Paula Rochon, *Considerations in Designing an Ideal Medication-Use System: Lessons from caring for the elderly*, 57 AM. J. HEALTH-SYS. PHARM. 548 (2000) (noting that information deficits are a key problem in medication use, and that organized data systems can greatly facilitate demonstration projects designed to improve the medication-use system).

48. Digoxin is frequently prescribed to improve the efficiency of the heartbeat. The data used in this example should be considered as illustrative only. While the example offered is a feasible one, constantly changing views of appropriate digoxin use make it impossible to use completely reliable figures.

tral location for analysis and use in generating new guidelines.[49] For example, experience with the use of anticoagulants by patients who have been diagnosed with atrial fibrillation can be reported to regulators and other reviewers for use as a performance database in the evaluation of a medication use system. These are not advantages that affect only the relatively few obvious beneficiaries in remote rural communities without adequate health care services, they are benefits for all users of medications, even those being treated at the most sophisticated urban medical centers. By facilitating communication from standards-setting groups, through health care professionals, to patients; and back from patients, through health care professionals, to standards-setting groups, a comprehensive program of medication use can be designed, with measurable goals and with correlated inputs and outputs. The Internet can be the tool through which medication use becomes a system.

The pharmacy is a logical focal point for an Internet-based medication use system. Every pharmacy has a computer, unlike other practice sites that may or may not be computerized, and Internet-access is readily available in pharmacies. Formal alliances between brick-and-mortar pharmacies and Internet pharmacies have been established so that seamless provision of pharmaceutical products and services between local and remote practice sites is possible. Patients, their caregivers, and health care providers can all log in to the pharmacy Internet site to share information. Patients do not always go to the same physician for all medical needs, but they usually go to the same pharmacy for their prescriptions. Thus, the pharmacy database is likely to be the most up-to-date record of a patient's medication use. When patients request refills of prescribed medications to continue therapy at times when a visit to the physician need not occur, valuable information about success or failure with drug therapy, and satisfaction with drug therapy, can be elicited if the appropriate questions are asked. Responses to these questions are valuable data that can be used to close the quality loop between the providers of care and the recipients of care. Individ-

49. *See* Jeff Goldsmith, *How Will the Internet Change Our Health System?; Powerful Though the Internet May Be, Its Impact on Health Care Will Continue to Be Tempered by Privacy Concerns and Professional Resistence,* 19 HEALTH AFF. 148 (2000) (noting that the Internet brings to health care managers and clinicians a flexible, external information architecture that can reach down into the dozens, even hundreds, of health care information "silos" and extract, analyze, aggregate, and redirect data, which clinicians and managers can use to make decisions).

ual patient responses that signal a need for medical attention can be queued up for evaluation by a pharmacist and then for referral to the patient's physician if necessary. Aggregated responses that indicate a common problem with many patients can be referred to standards-setting organizations for review and possible modification of practice guidelines.

III. Enabling Patient Responsibility for Drug Therapy

The Internet does not increase the possibilities for pharmaceutical care; it increases the practicality of pharmaceutical care. Any health-related activity that can be done electronically over the Internet can also be done physically, within the traditional medication use non-system. But the burdensomeness of physically looking up practice guidelines or interviewing patients about outcomes from drug therapy makes it unlikely that these activities will consistently be done without facilitation by the Internet. Use of the Internet not only opens up possibilities for enhanced communication up and down the chain of medication use, it shifts the balance of power from providers of care to recipients of care. The Internet changes the perspective of which end is "up" in the chain of medication use.

Other advances in technology have had significant effects on public participation in decisions about the use of products and services.[50] The printing press made it possible to widely disseminate information, as did radio and television. Yet the information disseminated through these media is controlled by the provider. The active provider of information chooses what to communicate to the passive recipient of information. The telephone is qualitatively different, because it is interactive for information exchange, although the number of participants in telephonic communication by voice is limited. By way of contrast, Internet users are active, their communication is interactive, and the number of participants is almost limitless. Through the Internet, the recipient of information has the opportunity to select whatever source of information she or he chooses from hundreds of thousands of possibilities. Internet users can interact with each other, either on a real-time basis, or with only a

50. *See* Alissa R. Spielberg, *Sociohistorical, Legal and Ethical Implications of E-mail for the Patient-Physician Relationship*, 280 JAMA 1353 (1998) (describing how innovations in communication and transportation have generally been greeted with initial concern, followed by relatively widespread acceptance).

short delay. Recipients of information now control the message they receive, due to Internet access. The Internet shifts the power over information exchange from the provider of it to the recipient of it.

A. Patient Autonomy and State Paternalism

A regulatory focus on providers of products and services makes perfect sense when the providers control the dissemination of information about their products and services and when providers can be readily located for enforcement activities. However, since the Internet shifts the control of information from providers to recipients, and since Internet providers are difficult to locate, it makes better sense to focus regulation on the recipients of Internet-based products and services. When the products and services are pharmaceuticals, a shift in regulatory focus from health care providers to patients requires reconsideration of deeply held beliefs about public health protection and about the need for centralized decision making about risk.

Within the traditional scheme of drug therapy regulation, most decisions about risk are made for patients, and not with patients. If a molecule has been discovered or synthesized, and there is evidence indicating that the molecule might be useful as a therapeutic agent, patients will nonetheless be denied the opportunity to use the molecule in their own therapy until years of testing and data analysis show the molecule to be relatively safe and effective for a population of users.[51] Even after safety and efficacy issues have been satisfactorily addressed and a new drug is approved for human use, the new drug will likely be restricted to "Rx Only" status. Only if a state-licensed prescriber then gives permission will a patient be authorized to use this new drug. While informed consent is a cornerstone of medical care and of health care regulation, the concept is rarely applied to drug therapy, and empirical data suggest patients are largely uninvolved in the choice of their drug therapy.[52] Physicians de-

51. Despite the millions of dollars spent to study the safety and efficacy of new drugs, approval does not in any way guarantee the adequacy of the pre-approval studies. *See* Barbara A. Noah & David B. Brushwood, *Adverse Drug Reactions in Elderly Patients: Alternative Approaches to Postmarket Surveillance*, 33 J. HEALTH L. 383 (2000). The FDA has withdrawn approval of numerous drugs that have been shown safe and effective with small numbers of subjects in controlled trials, yet have proven to be unsafe and/or ineffective when used by large numbers of patients in therapeutic use. *Id.*

52. Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367 (1986) (suggesting that patients' rights, normally

cide what drugs patients will use, and they prescribe how the drugs will be used. Patients are given the choice of either following doctor's orders or developing their own medication use behavior at the risk of being labeled as "noncompliant."[53]

Despite the emergence of a huge industry of alternative and/or complementary therapies that circumvent this costly and difficult-to-access traditional system, the appropriateness of state paternalism in drug therapy is seldom questioned. Drugs seem complex and mysterious. They are known to be both injury-reducing and injury-producing. It seems so sensible for government to protect citizens from the bad choices they might make in drug therapy, if given the opportunity to choose for themselves, even when only their own personal interests are at stake. The reality that adverse drug effects are rampant within the current paternalistic system of drug regulation is seldom considered by those who challenge the notion that autonomous individuals could make good drug therapy decisions for themselves if enabled to do so.

In theory, restrictive regulation of drug therapy serves several useful purposes: (1) it prevents overuse of drugs on which patients could become dependent, (2) it improves therapeutic outcomes by assuring that patients receive therapy that will make them better and not worse, (3) it brings patients back to physician offices on a consistent basis, so that necessary examinations and tests can be routinely performed, (4) it protects the financial resources of people who might otherwise squander their assets on useless nostrums, and (5) it protects the community from self-serving behaviors (i.e., antibiotic overuse) that are of limited value to individuals and are harmful to the population.[54] Each of these assertions is subject to challenge, particularly as

protected by the doctrine of informed consent, are not adequately protected when patients receive prescription drug therapy); *see also* Jeremy Sugarman et al., *Empirical Research on Informed Consent, An Annotated Bibliography*, 29 HASTINGS CENTER REP. S1 (1999) (listing and summarizing a long line of social science research that documents a tradition of physician silence when prescribing medications, as opposed to relatively well documented tradition of open disclosure by physicians when recommending surgery).

53. *See* Jenny L. Donovan & David R. Blake, *Patient Non-Compliance: Deviance or Reasoned Decision-Making?* 34 SOC. SCI. & MED. 507 (1992) (suggesting that patients who use medications differently from the way the medications have been prescribed may be engaging in risk-benefit decision making outside the physician-patient relationship).

54. *See* Chester N. Mitchell, *Deregulating Mandatory Medical Prescription*, 12 AM. J. L. & MED. 207 (1986) (arguing that public safety needs do not justify the mandatory prescription controls in place today).

applied to a relatively sophisticated group of individuals, such as those who use the Internet. It is not at all certain that users of Internet pharmacy would act against their own self interest, or against the interest of the community.

In response to those who paint a dire picture of potential widespread tragedy resulting from anything other than consistently aggressive and occasionally repressive regulation of Internet pharmacy, it is perhaps equally as plausible to assert that Internet users who are enabled to make good drug therapy decisions for themselves would do so. Responsive regulation, as opposed to restrictive regulation, has the potential to increase the availability of valid drug-related information and to facilitate assistance with medical decisions made by patients through access to online treatment algorithms.[55] Responsive Internet regulation could reduce health care costs and increase access to health care. This is not a claim that such benefits necessarily would result from responsive regulation of Internet pharmacy. The only way to know whether appropriately enabled Internet users could adequately protect themselves from harm caused by adverse drug effects and produce benefits from available therapies would be to compare outcomes in two populations: passive patients in the traditional system and active Internet users. In a sense, Internet pharmacy could be seen as an experiment in patient autonomy. This may be the time to find out whether technically sophisticated medication users really need government protection from themselves. This an opportunity for major innovation that should be taken seriously and empirically studied, as are other experiments. The question is not whether Internet pharmacy should be permitted; it is an unstoppable development that is certain to increase in popularity. Regulators should be asking how they can guide this inevitable technology through regulation that appropriately protects and promotes the public health.

B. Defining Relationships in Drug Therapy

The physician-patient relationship is one of the most highly respected bonds in our society. It is a covenental relationship of trust, which is based on an ideal of altruism and a reality of sci-

55. *See* Derek F. Meek, *Telemedicine: How an Apple (Or Another Computer) May Bring Your Doctor Closer*, 29 CUMB. L. REV. 173 (1998) (describing the use of technology to increase access to care for those patients who are not close to their care provider).

entific complexity.[56] There are special legal rules of confidentiality, privilege, and duty that apply to this most important of non-familial relationships. The medical profession has established standards of practice that reflect questions not only of technical expertise within the care provider role but also fundamental questions of role for the care provider. It is considered beneath the standard of care for a physician to provide incompetent services or to provide competent services in an uncaring way. The "what" and the "how" of medical care both matter. Patients must feel comfortable in their relationship with their physician, or else they will come to distrust the health care system and refuse to participate in it — all to the detriment of individuals and the population.

Threats to the physician-patient relationship have been seen in government oversight of the profession, as well as in corporate ownership of practice and in managed care.[57] Interference with the physician-patient relationship has even been used as justification for restricting legal recognition of emerging expanded responsibilities of pharmacists for drug therapy management.[58] Not unexpectedly, the Internet has been viewed with suspicion by the medical establishment, fearful that electronic communication could reduce the physician-patient relationship to a physician-patient interface.[59]

Within other contexts, the medical profession has struggled to define what activities of physicians comprise a satisfactory relationship with patients. For example, informed consent is now considered a necessary prerequisite to surgery, and the elements of a sufficient informed consent are generally well defined, although they remain somewhat controversial. But informed consent does not have a long history in medicine, and views persist among some physicians that patients are better off not being involved in complex medical decisions.[60] Drug therapy presents different challenges for relationship definition because, unlike

56. Ranney V. Weisemann, *On-Line or On-Call? Legal and Ethical Challenges Emerging in Cybermedicine*, 43 ST. LOUIS U. L. J. 1119 (1999) (noting that the essential feature of the physician-patient relationship is the exchange of a deep bond of trust between the parties).

57. *Id.* at 1151.

58. *See* Lauren Fleischer, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165 (1999) (arguing that pharmacist consultations with physicians and patients actually enhance the physician-patient relationship rather than threatening that relationship).

59. *See* Spielberg, *supra* note 50, at 1359.

60. *See* JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984).

surgery, there is no requirement that a "touching" occur for a physician to provide pharmaceutical treatment. The natural requirement for physical proximity in surgery need not logically lead to the human imposition of such a requirement in drug therapy. Physical proximity of physician and patient, of a type that will permit a hands-on examination prior to authorization to use any medication, seems unnecessary under all circumstances.

When a physician knows a patient already, or when a patient is known to another physician within a practice, and documentation of impressions from earlier care is readily available in a patient care record, it is not always necessary for the patient to physically visit a physician. Forcing a patient who is physically incapacitated or who has significant transportation barriers to visit a physician to secure permission to continue treatment of a recurrent or chronic condition seems wasteful of resources and unnecessarily inconvenient. On the other hand, a physician's brief review of a checklist submitted by a patient hundreds or thousands of miles away clearly cannot create a new physician-patient relationship within the model for practice that the medical establishment has developed. The difficult challenge is knowing how much physician-patient contact is enough for safe and effective treatment, and how much is too burdensome for patients who will forego all treatment when barriers to access are overwhelming. The inevitable conclusion is that one-size-fits-all descriptions of activities that comprise a sufficient physician-patient relationship, from a medical perspective, will fail to accommodate individual patient differences and varied personal circumstances.

The difficulty of using a medical model to define the character of a sufficient physician-patient relationship raises the possibility that other models might be more useful, including perhaps a patient-centered model. A sufficient physician-patient relationship might be one the patient believes to be sufficient, based on whatever criteria the patient chooses to apply. Deference to patients as the arbiters of the sufficiency of their relationship with physicians would require trusting patients to act responsibly on behalf of themselves and the community. Reliance on patients to make this determination could be based on respect for indi-

vidual autonomy, a basic principle of biomedical ethics.[61] The market failure of information asymmetry, which is often cited to justify state paternalism in drug therapy, may not be a persuasive rationale when applied to patients who are able to use the Internet and have access to virtually limitless information.[62] There is always the question of individual liberty and the challenge a free society must face in justifying any choice of the risks from which its members will be protected by government. It is difficult to understand why people can be allowed to eat snack foods with no nutritional value, participate in hazardous sporting events, and elect whomever they wish to govern them, but not be allowed to choose their own medicine. This observation is not intended to be an absolute claim that all patients could always appropriately define their relationship with a physician, but it is a suggestion that those who advocate strong regulation of Internet pharmacy in ways that perpetuate traditional physician-patient relationships should explain the basis of their advocacy. It may well be that harm resulting from a decision by a well-informed Internet user to acquire medication without medical authority should not be viewed as a regulatory failure.

C. Operationalizing Patient Responsibility

Conceptualizing and describing an ideal of informed and rational drug therapy choice by Internet pharmacy users is easier than is putting this laudable goal into practice. Responsible use of Internet pharmacy requires that users know the choices available to them and reflect on the consequences of their choices before they engage in potentially risky behaviors. Users of Internet pharmacies need to know significant therapeutic aspects of the medications they consider using. They also need to know the identity and qualifications of those from whom they acquire medications. If they choose to take risks with medications, or to acquire medications from unreliable or unidentified sources, then they must understand that protections ordinarily provided by regulatory agencies are being foregone.

The only means yet developed to enable Internet pharmacy users to protect themselves from risks that are unacceptable to

61. *See* Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 245 (2000) (discussing the close relationship between law and ethics).

62. *See* Eyal Zamir, *The Efficiency of Paternalism*, 84 VA. L. REV. 229 (1998) (containing an economic analysis of general legal paternalism).

them is the VIPPS program established and operated by NABP.[63] VIPPS is a voluntary program. Internet pharmacy sites that opt for VIPPS certification must apply to the NABP. The application is reviewed by NABP to assure that the Internet pharmacy is in compliance with relevant state and federal laws. VIPPS pharmacies must also maintain a quality assurance or quality improvement program. They must report to NABP any changes of information provided as part of the initial certification process. Once issued, certification is renewable annually following an update of the registration information and re-verification of licensure status.

VIPPS certified Internet pharmacies are granted authority to use the NABP/VIPPS hyperlink seal on their web sites. Visitors to the site may click on the seal to receive real-time verification that the site is certified. Any site that pirates the "click to verify" seal will soon discover the online, real-time verification process does not work for any site other than the certified site. "Rogue" sites are immediately exposed to the Internet user. Through the VIPPS program, Internet pharmacy users receive assurance that their certified provider has met exacting quality standards. They know who is providing their pharmaceutical products and services, and to whom to complain when things have not gone well. Although VIPPS is not a regulatory program, it provides assurance to Internet pharmacy users that certified sites are being overseen by pharmacy regulators.

The most significant drawback of VIPPS is that it is not well known to Internet pharmacy users. Even the best program is of little value if those who would benefit from it do not know about it. Pharmacy regulators should feel comforted that they have made significant strides toward adequately protecting the public health by endorsing and participating in the VIPPS program. However, until public knowledge of VIPPS increases to the level of, for example, the Good Housekeeping Seal of Approval or the Consumer Reports product ratings, there will continue to be significant regulatory challenges to meet in Internet pharmacy. Fortunately, there is a readily available medium to use in getting the word out about VIPPS to Internet pharmacy users; that medium is the Internet itself. By requiring search engines to provide streaming cautionary statements to any Internet user who enters a search term that suggests the intent to

63. A full description of the VIPPS program can be found at the VIPPS web site, *at* <www.nabp.net/vipps/intro.asp> (last visited Mar. 26, 2001).

acquire prescription-only drugs over the Internet, the user who is uninformed about VIPPS has the opportunity to discover the protections this program provides. It might be possible to require this same streaming cautionary statement be displayed any time an Internet user enters a Uniform Resource Locator ("URL") with similarly suggestive terms. The objective would not be to forbid use of the Internet, but to inform users that they may be going to a site where the presence or absence of the VIPPS seal would be a significant factor for them. Some Internet pharmacy users would continue to use sites not certified by the VIPPS program, but only after being informed of the VIPPS program and making a conscious choice to forego the protection it provides.

Conclusion

Traditional enforcement-oriented regulation will continue to have a role to play in government oversight of Internet pharmacy, when the pharmacy can be physically located, when resources necessary for enforcement are available, and when enforcement does not have a chilling effect on beneficial telehealth activities. However, it would seem sensible to steward scarce regulatory resources and devote them primarily to enforcement directed at those who distribute addictive controlled substances, or highly toxic drugs, to users who have ordered them over the Internet. Interfering with the acquisition of hair restoratives or drugs intended to enhance sexual function is an exercise of state paternalism that goes beyond what is necessary or expected under the circumstances. To be successful, any regulatory agency has to be credible with the public it serves, and the targeting of "lifestyle" drugs has the potential to adversely affect the credibility of pharmacy regulators. Mounting a taxpayer-funded crusade against bad choices that adversely affect nobody other than the person making the choice could have the appearance of economic protectionism, no matter how well intended as a public health measure.

Regulation of Internet pharmacy to protect the public health will be most effective when it empowers Internet users to protect themselves from risks the users believe to be unacceptable. Promotion of the VIPPS program is the best assurance regulators can provide to the public that individual Internet pharmacy users are being protected by the professionalism that state-licensed pharmacists offer through their oversight of the medica-

tion use process. Pharmaceutical care can be made more successful through Internet alliances within pharmacy; and between pharmacists, physicians and patients. In the end, this is simply a matter of trusting people to make good choices for themselves and providing them with the means to make their choices as good as they can be.