



SCHOOL OF LAW
CASE WESTERN RESERVE
UNIVERSITY

**Health Matrix: The Journal of Law-
Medicine**

Volume 11 | Issue 1

2001

An Analysis of Ethical Issues in Prescribing and Dispensing Syringes to Injection Drug Users

Zita Lazzarini

Follow this and additional works at: <https://scholarlycommons.law.case.edu/healthmatrix>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Zita Lazzarini, *An Analysis of Ethical Issues in Prescribing and Dispensing Syringes to Injection Drug Users*, 11 Health Matrix 85 (2001)
Available at: <https://scholarlycommons.law.case.edu/healthmatrix/vol11/iss1/7>

This Symposium is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Health Matrix: The Journal of Law-Medicine by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

AN ANALYSIS OF ETHICAL ISSUES IN PRESCRIBING AND DISPENSING SYRINGES TO INJECTION DRUG USERS

Zita Lazzarini, J.D., M.P.H.[†]

I. INTRODUCTION

PHYSICIANS CARING FOR PATIENTS at risk of HIV infection, or those already infected, face many complex decisions. Perhaps some of the most contentious are the physicians' and health agencies' roles in HIV prevention among active injection drug users (IDUs), and specifically whether health care providers or the government should endorse and support efforts to provide sterile syringes to drug users. Considerable attention, both public and scholarly, has focused on the appropriate use of syringe exchange programs (SEPs). Less debate has centered on efforts to deregulate syringes (remove prescription requirements or limits on possession) and the practice of physicians prescribing syringes to IDUs. This article considers two questions: whether it is ethical for physicians to prescribe, and pharmacists to dispense, syringes to IDUs, and whether physicians and pharmacists have an affirmative ethical duty to do so.

This article begins by describing the dilemma, and then discusses the ethical framework of the physician-patient and pharmacist-patient relationships. Next, this article considers several roles the law plays in relation to these questions. In conclusion, the article suggests that the weight of ethical rea-

[†] Director, Program in Medical Humanities, Health Law, and Ethics, University of Connecticut Health Center. The author would like to thank Scott Burris, who conceived this project and asked her to write the article, all the members of the Robert Wood Johnson Project who made helpful suggestions and comments on the manuscript, Jonathan Shapiro and Lorilyn Rosales for excellent research assistance during the course of writing the article, and Mitzi Ng for help in manuscript preparation.

soning supports physicians' choice to prescribe and pharmacists' to dispense syringes to IDUs.

The Problem

An estimated 1.1 to 1.5 million persons in the United States use injection drugs.¹ Injection drug users risk contracting viral diseases, such as hepatitis B and C, and HIV, parasitic infections, including malaria, and bacterial illnesses, such as endocarditis from using contaminated injection equipment. Injection drug use may cause as many as half of all new HIV infections nationwide.² Injection drug use has been the leading risk factor associated with new AIDS cases in the northeast since 1988.³ As a consequence, public health officials, clinicians, and policy makers have sought effective means to reduce injection drug use, get active IDUs into treatment, and reduce the risk that IDUs not in treatment will contract HIV or transmit it to their sexual partners, children, and other IDUs. Active IDUs can take relatively simple steps to avoid blood-borne infections by using a sterile syringe for each injection, not sharing drug preparation equipment with other IDUs, and not mixing drugs with other IDUs.

Structural impediments in most states (laws, regulations, and policies), however, make it dangerous or impossible for IDUs to obtain and carry sterile syringes,⁴ despite the fact that these syringes might save their lives. Many health officials and activists support syringe exchange programs as one means to provide sterile syringes to IDUs who cannot otherwise obtain

¹ See NATIONAL RESEARCH COUNCIL, COMM. ON AIDS RESEARCH & BEHAVIORAL, SOCIAL, & STATISTICAL SCIENCES, AIDS: SEXUAL BEHAVIOR AND INTRAVENOUS DRUG USE 225 (Charles F. Turner et al. eds., 1989); see also Timothy J. Dondero, Jr. et al., *Human Immunodeficiency Virus Infection in the United States: A Review of the Current Knowledge*, 36 MORBIDITY & MORTALITY WKLY. REP. 1 (Supp. 6 1987). See generally American Med. Ass'n, *JAMA HIV/AIDS Information Center* (visited Oct. 9, 2000) <<http://www.ama-assn.org/special/hiv/hivhome.htm>>.

² See Scott D. Holmberg, *The Estimated Prevalence and Incidence of HIV in 96 Large US Metropolitan Areas*, 86 AM. J. PUB. HEALTH 642, 642-54 (1996).

³ See Centers for Disease Control & Prevention, *Update: Syringe Exchange Programs—United States, 1997*, 47 MORBIDITY & MORTALITY WKLY. REP. 652, 652 (1998) (noting 1997 statistics of syringe exchange programs).

⁴ See Lawrence O. Gostin & Zita Lazzarini, *Prevention of HIV/AIDS Among Injection Drug Users: The Theory and Science of Public Health and Criminal Justice Approaches to Disease Prevention*, 46 EMORY L.J. 587, 595-642 (1997) (detailing the laws that limit syringe sales in the United States and American territories).

them legally.⁵ Some jurisdictions have modified existing laws to permit IDUs either to possess syringes (e.g., Oregon) or to purchase syringes without a prescription (e.g., Connecticut and Maine).⁶

Despite exhaustive empirical studies showing the overall beneficial impact of SEPs and syringe deregulation,⁷ heated public debate continues to focus on whether government should ever actively participate in providing syringes to IDUs. In the year 2000, after nearly twenty years of the AIDS epidemic, the U.S. remains without a national policy to support increased access to sterile syringes as part of a comprehensive HIV control policy, and with many state and local laws that continue to discourage safe injection behavior by IDUs.

Physicians caring for IDU patients have limited options for HIV prevention. They know their patients risk contracting HIV and other blood-borne diseases from contaminated injection equipment, in addition to the risk of transmitting these diseases to others once infected. Many also know that IDUs cannot legally obtain syringes on their own. Physicians have limited choices to protect their patients' and the public's health. They may be able to refer their patients to legal SEPs, or even, in a few states, to advise them to purchase syringes over the counter in local drug stores. But the majority of physicians caring for IDUs have no legal source of sterile syringes to offer IDUs, except the same source they would offer their diabetic patients, a prescription. Some physicians would like to be able to prescribe sterile syringes, but fear possible legal and professional consequences.⁸ Even where syringes may be purchased legally without a prescription, state law or regulation may demand that customers demonstrate a "legitimate medical purpose" for their use. Most pharmacists find a doctor's prescription *prima facie* evidence of medical legitimacy. Pharmacists may also be aware

⁵ See Centers for Disease Control & Prevention, *supra* note 3, at 652.

⁶ See *id.* at 654.

⁷ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, NAT'L RESEARCH COUNCIL & INST. OF MED., PREVENTING HIV TRANSMISSION: THE ROLE OF STERILE NEEDLES AND BLEACH 198-255 (Jacques Normand et al. eds., 1995) (providing empirical evidence and recommendations that needle exchange programs offer public health benefits for the prevention of HIV).

⁸ See Zita Lazzarini et al., *In New York City, Syringe Laws and Regulations Deter Physicians and Pharmacists from Prescribing and Selling Syringes to Persons Who May Be Injection Drug Users*, 18 J. ACQUIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY S141 (Supp. I 1998).

of, and feel constrained by drug paraphernalia laws that prohibit sales of paraphernalia, including syringes, where the seller knows that the user intends to use it to ingest or inject illegal drugs.⁹ In either case, pharmacists may demand customers produce a prescription even where laws actually do not require one.

In confronting this problem, physicians and pharmacists ought to ask: whether it is ethical for physicians to prescribe, and pharmacists to dispense, syringes to IDUs, and whether physicians and pharmacists have an affirmative ethical duty to do so. In considering this dilemma, three terms, "law," "ethics," and "morals," may cause confusion. For purposes of clarity, these terms are defined as follows: "law" consists of "norms formally promulgated by a political authority and more or less regularly enforced through a legal process based on adjudication;" "ethics," of "norms shared by a group on a basis of mutual and usually reciprocal recognition;" and "morals," of "notions of right and wrong that guide each of us individually and subjectively in our daily existence."¹⁰ Legal parameters are more easily defined than ethical parameters, since laws must be reduced to a single form for adoption and enforcement.

Ethics and law, however, are inextricably intertwined since widely held views of what is "right" and "wrong" (ethics) often drive formal policy formation (laws). By examining ethical approaches and related legal theories I hope to shed light on how professionals and policy makers might approach these issues. Necessarily, I will also consider the moral concerns that drive individuals. The debate over the "rightness" of providing sterile syringes to drug users may be founded on irreducible moral (as opposed to ethical) conflicts. The failure to reach perfect consensus should not, however, deter those interested in physicians' and pharmacists' obligations to their patients from seeking to make the most reasoned ethical evaluation of the problem. This article seeks to explore the contours of physicians' and pharmacists' obligations to their patients who are IDUs, in the context of the HIV epidemic, recognizing that law, ethics, and morals each play an important role in this debate.

⁹ See Gostin & Lazzarini, *supra* note 4, at 661-62 (describing pharmacist discretion in choosing to sell syringes to customers and the hurdles pharmacists face in making such sales).

¹⁰ Geoffrey C. Hazard, Jr., *Law, Morals, and Ethics*, 19 S. ILL U. L.J. 447, 448, 453, 451 (1995).

The article does not address the "whole picture" of HIV prevention. I take it as a given that increased access to syringes, through SEPs, deregulation, or prescription, cannot be effective alone and must be part of a comprehensive HIV prevention and treatment policy that includes integrated programs to prevent drug use and provides timely access to drug treatment for IDUs. Ultimately, physician prescriptions for syringes may reach only a small proportion of IDUs, and therefore, represent a small public health intervention. However, prescriptions can be a useful clinical tool for individual physicians and their patients. Prescribing also makes a powerful symbolic statement by physicians since it engages physicians directly in HIV prevention among active IDUs.

II. THE PHYSICIAN'S AND PHARMACIST'S RELATIONSHIP TO THE PATIENT

A. The Ethics of the Physician-Patient Relationship

1. Fundamental ethical duties and goals

The doctor-patient relationship may be defined as a fiduciary relationship characterized by unequal knowledge and power in which one party exercises special skills to benefit the other. As part of this special relationship, physicians have a fundamental duty to act in their patients' best interest, to avoid harming their patients, and to act as their patients' advocates when necessary.¹¹ A physician's duty traditionally arises during the first physician-patient encounter, concomitant with the beginning of the therapeutic relationship.¹² A duty may arise, however, without the physician ever meeting the patient face to face,¹³ as when a consultant gives advice on treatment of a patient based on a long-distance consultation.

¹¹ See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIO-MEDICAL ETHICS* 430-41 (4th ed. 1994).

¹² See, e.g., *Weaver v. University of Mich. Bd. of Regents*, 506 N.W.2d 264, 267 (Mich. Ct. App. 1993) (holding that a patient-physician relationship is not established when the patient does not receive advice or treatment from the doctor).

¹³ See *Johnson v. Padilla*, 433 N.E.2d 393, 396 (Ind. Ct. App. 1982) (granting summary judgment in favor of defendant physician who concurred in treating physician's plan to perform medical procedure when plaintiff did not allege the concurrence as negligence).

The content of that duty, what physicians can or ought to do, is more difficult to define. Professional codes, the common goals of the profession, and the application of ethical standards support certain broad principles of conduct, yet thoughtful professionals and ethicists can disagree about the details of specific cases.

Physicians, as professionals, commit themselves to professional codes of conduct and ethics which have their roots in the Hippocratic tradition of ancient Greece,¹⁴ but continue to be adapted to meet modern dilemmas.¹⁵ Professional codes are not usually binding as a matter of law, but they represent important current expressions of professional and societal norms.

Leading professional organizations define the goals of medicine broadly: to prevent disease, to restore or preserve health or function, and to alleviate suffering.¹⁶ Physicians may also work with patients to achieve other, patient-centered goals, which are compatible with the goals of medicine, including patients' social and spiritual goals as they cope with illness and death.¹⁷

2. Ethical theories

No single ethical theory or approach has achieved universal acceptance as the best or right way to resolve ethical dilemmas in medicine. Several approaches justify attention in this case: consequentialist (teleological), nonconsequentialist (deontological), and the principled approach. These theories, as well as the concept of "virtue," provide a theoretical basis for parts of the professional codes of ethics, and can be used

¹⁴ See TABER'S CYCLOPEDIA MEDICAL DICTIONARY 662 (14th ed. 1981).

¹⁵ See GEORGE M. BURNELL, FINAL CHOICES: TO LIVE OR TO DIE IN AN AGE OF MEDICAL TECHNOLOGY 63-64, 344-45 (1993) (discussing the tradition of the Hippocratic Oath); American College of Physicians, *Ethics Manual: Fourth Edition*, 128 ANNALS INTERNAL MED. 576 (1998) (examining emerging medical ethics including genetic testing, managed care, and organ donation).

¹⁶ See American College of Physicians, *supra* note 15, at 577.

¹⁷ See Kathy Faber-Langendoen, *Resuscitation of Patients with Metastatic Cancer: Is Transient Benefit Still Futile?*, 151 ARCHIVES INTERNAL MED. 235, 235-39 (1991) (describing the importance of knowing a patient's health care goals when making futility determinations); see also Rosamond Rhodes, *Futility and the Goals of Medicine*, 9 J. CLINICAL ETHICS 194, 198-99 (1998) (discussing decision-making values in relation to "futility" cases including patient autonomy and professional responsibility to promote the patient's "good").

both to describe how individuals actually behave (descriptive ethics) and how they should behave (normative ethics).

Consequentialism determines what is right based on what result an action brings. For example, in a utilitarian-consequentialist theory the proper action is the one that achieves the greatest benefit for the most people. Consequentialists need to know, or estimate, the outcomes of acts and must use some system to determine what is a "benefit" or which is the greater "benefit."¹⁸

By contrast, the deontological approach maintains that the correctness of an action must be determined independently of its results. According to deontologists, maintaining other universally important ideals, including truth telling, confidentiality, non-discrimination, and obedience to the law are more important than the actual outcomes of an act. Therefore, deontologists will not favor arguments based on the benefits or harms the action will bring about.¹⁹

Proponents of "virtue" ethics argue that physicians should embody the character, or virtues, of a good physician: truth, integrity, loyalty, courage, and compassion, among others. Also described as "character" ethics, this reasoning stresses the motivations of moral agents, both physicians and patients. Virtue ethics emphasizes that neither rules nor principles will guarantee ethical choices if the motivations of agents are improper. In determining the proper course of action, physicians should ask: (1) how would I act if I was motivated by truthfulness, loyalty, compassion, and integrity (or other professional virtues)? and (2) is my chosen action "appropriately gauged to bring about the desired [result] and [is it] morally justified in conformity with relevant principles?"²⁰

The principled approach to biomedical ethics, arguably the most common approach used in clinical ethics, holds that physicians must strive to respect four basic principles in making choices: respect for persons (or autonomy), beneficence, non-maleficence, and justice.²¹ Thus, the principled approach encompasses aspects of both consequentialism and non-consequentialism. The results of actions remain important

¹⁸ See BEAUCHAMP & CHILDRESS, *supra* note 11, at 47-53.

¹⁹ See *id.* at 56-62.

²⁰ *Id.* at 62-65, 66.

²¹ See *id.* at 100.

(helping rather than harming your patient), but the duty to respect individuals' autonomous choices relies more on the rightness of the action itself, often independent of its consequences. Ethical dilemmas arise when an action (or inaction) creates tension between principles. Critics of the principled approach note that it contains no formal means to resolve conflicts between principles.²²

Considering distinct ethical theories elucidates the different possible approaches to the questions: whether it is ethical for a physician to prescribe (or a pharmacist to dispense) syringes to IDUs to prevent blood-borne diseases; and whether the physician or pharmacist has an affirmative duty to do so. Key issues that reappear throughout the review of differing ethical approaches include: (1) the significance of empirical data on access to syringes and disease prevention; (2) defining the physician's role in caring for IDU patients; and (3) the symbolic import of providing syringes versus recommending treatment or abstinence.

3. Defining ethical duties in new situations: Should physicians prescribe syringes for IDUs?

Defining a physician's obligations to her IDU patient demands consideration of the nature of the physician's obligation, available alternatives, and often, practical implications such as the impact of illegal actions on the physician. IDU patients often experience a number of serious health and social risks. Continued use of illegal drugs poses risks of morbidity and mortality from many causes.²³ Use of injection drugs also places an IDU at high risk for blood-borne diseases (hepatitis B and C, HIV), infections caused by non-sterile injections (endocarditis, local abscesses), overdoses, dependence on other drugs, and many other infectious diseases related only indirectly to injection drug use (such as tuberculosis). IDUs are also disproportionately more likely to be homeless, mentally ill, unemployed, and have fragmented families. Thus

²² See *id.*

²³ See Lloyd N. Friedman et al., *Tuberculosis, AIDS, and Death Among Substance Abusers on Welfare in New York City*, 334 NEW ENG. J. MED. 828 (1996) (concluding that the incidence of tuberculosis, AIDS, and death is greater among indigent alcohol and drug users in New York City than the rates of these same outcomes in the age-matched general population of New York City).

IDU patients have substantial social service needs, as well as medical needs.

Ideally, the physician would like to help IDUs stop using drugs completely. However, not all IDUs will be able, or willing, to stop immediately. The demand for treatment often outstrips supply. Drug treatment programs may have waiting lists or prohibitive entry criteria.²⁴ The absence of childcare or treatment provision for pregnant women has curtailed access by female IDUs. Even after entering treatment, relapses are common, "[c]ycling one or more times from recovery back through relapse to dependence or abuse . . . is so common that it must be seen as an intrinsic feature of the natural history of individual drug behavior."²⁵ IDUs not in treatment, for whatever reason, risk deadly infections if they lack access to sterile syringes or do not practice safe injection practices.

From a practical perspective, physicians must grapple with the needs of their patients who lack access to treatment, have attempted treatment and relapsed, or who remain unready for treatment. Despite the government's war on drugs, including its efforts to restrict access to drugs and syringes, injection drug use has continued.²⁶ If physicians can take measures to protect patients from contracting a deadly disease in the short-term, their patients' long-term prospects for drug treatment, and eventual return to productive living, are much more significant.

The physician's basic ethical obligations—to help, not to harm, and to advocate for patients—support both protecting patients from blood-borne diseases and discouraging drug use. Providing competent and compassionate medical care for

²⁴ The Substance Abuse and Mental Health Services Administration (SAMHSA) website notes a "well documented substance abuse treatment capacity problem." *SAMHSA/CSAT Announces Grant Funding Opportunities* (visited Sept. 13, 2000) <<http://www.samhsa.gov/csatt1043098.htm>>.

SAMHSA has made substantial grants in recent years to try to fill that gap. *See Communities Expand Substance Abuse Treatment Efforts* (visited Sept. 13, 2000) <<http://www.samhsa.gov/press/99/991001nr.htm>> (describing 28.8 million dollars in new SAMHSA grants to combat emerging problems associated with the regional nature and shifting trends in illicit drug use).

²⁵ I INSTITUTE OF MEDICINE, *TREATING DRUG PROBLEMS* 73 (Dean R. Gerstein & Henrick J. Harwood, eds., 1990).

²⁶ *See* Jeff Stryker, *IV Drug Use and AIDS: Public Policy and Dirty Needles*, 14 J. HEALTH POL., POL'Y & LAW 719, 733 (1989).

IDU-patients²⁷ requires physicians to help their patients reduce the risk of blood-borne diseases and to stop using drugs or enter treatment. Physicians should also provide patients with timely and accurate scientific information regarding their conditions and treatments.²⁸

From a consequentialist perspective, the physician examines the effects of his/her action, including the harms and benefits associated with that action. Substantial scientific evidence suggests that increasing access to syringes can reduce HIV infections and does not increase drug use or related crime.²⁹ Also, legal restrictions on access to syringes have not been shown to reduce drug use or to have any direct public health benefit. Reliance on empirical data to "prove" the benefit of a policy practice appeals to scientists, physicians, and public health officials, but does not address the larger questions integral to the consequentialist approach: which is the highest good? and what if the "benefits" conflict?

From a deontological perspective, the physician looks to the norms of society "[b]ecause normative principles are integral to the kind of society that is desirable, [therefore] society may choose to forgo the benefits of a policy that is thought to undermine the moral values which the community holds dear."³⁰ Our society highly values an individual's freedom to control his or her life.³¹ Thus, one approach to evaluating the proper role of physicians in treating IDUs turns upon an evaluation of whether IDUs can exercise freedom of choice—whether they are "autonomous." If addiction or heavy drug use completely negates an IDU's free will, then physicians should not take any action that permits continued drug use, as that would be tantamount to facilitating slavery.³²

²⁷ See generally ETHICAL DILEMMAS IN HEALTH PROMOTION (Spyros Doxiadis ed., 1987) (discussing ethical issues in public health and preventive medicine).

²⁸ See *id.*

²⁹ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 251-53.

³⁰ Gostin & Lazzarini, *supra* note 4, at 645.

³¹ See Jeffrey Reiman, *Drug Addiction, Liberal Virtue, and Moral Responsibility*, in DRUGS, MORALITY, AND THE LAW 25, 26 (Stephen Luper-Foy & Curtis Brown eds., 1994).

³² See generally Jan Narveson, *Drugs and Responsibility*, in DRUGS, MORALITY, AND THE LAW 1, 11 (Steven Luper-Foy & Curtis Brown eds., 1994) (discussing John Stuart Mill's view on autonomy).

If, however, as I have argued, IDUs exercise autonomy, albeit a compromised autonomy, physicians can then work to "enhance" their patients' autonomy by not only offering them support for stopping drug use, but also by giving them the means to protect themselves from deadly diseases. Restricting access to syringes denies individuals the opportunity to take measures to protect their health and to make decisions affecting their bodies. By allowing individuals the opportunity to make choices that have significant public health benefits, prescribing syringes could prevent disease and preserve the health of individuals until they can stop using drugs.

Adopting a principled approach, whether or not to prescribe syringes to IDUs appears, at first, to bring the principles of *beneficence* and *respect for persons* into conflict. A physician might argue that continued drug use clearly harms the patient and therefore any action on the physician's part that is "beneficent," seeking to promote the good of the patient, should discourage and not promote drug use. In contrast, *respect for persons* suggests several important considerations. First, in the sense of "autonomy," *respect for persons* requires that the physician respect the autonomous choices of competent patients. If drug users continue to inject, yet want to use sterile syringes to reduce their risk of infection, then they should be able to exercise an independent choice to do so. Second, *respect for persons* suggests that physicians should strive to respect the humanity and dignity of each patient, and to refrain from demonizing patients for socially unacceptable or illegal behaviors, including drug use.

Most physicians would not think of refusing to treat or ignore the medical needs of their patients who smoke or drink alcohol, even to excess. By contrast, many doctors do not want IDUs as patients. Those who do treat IDUs and patients with a record of injection drug use may not treat their pain adequately, even when severe pain could be expected (cancer or other terminal condition), and may be reluctant to provide them with other interventions out of fear that it will increase their drug-using behavior.³³ When physicians focus exclusively on avoiding any action that could exacerbate IDU pa-

³³ See TROYEN BRENNAN, JUST DOCTORING: MEDICAL ETHICS IN THE LIBERAL STATE 148 (1991) (explaining why some care providers might refuse to pursue alternative methods of treatment out of fear that it could lead to greater use of illicit drugs); see also discussion *infra*, Part II.C.

tients' drug use, they may actually deny them necessary or useful care. For many patients who inject drugs, merely being engaged in the medical system in a positive way is a benefit. In this context, adopting and enforcing a government preference against any action that might appear to condone drug use, should not occur at the cost of exposing IDUs to HIV. The government should not inflict harm on an individual as a means of persuasion.³⁴

Upon closer examination, however, the apparent conflict between the principles of *beneficence* and *respect for persons* disappears in most cases. The physician's claim to *beneficence* can, and should, result in efforts to persuade IDUs to stop using drugs, enter treatment, or stop injecting. Given the scarcity of drug treatment and the reality that many patients will relapse before successfully ending their drug use, physicians inevitably will have patients who cannot or will not stop using drugs, successfully complete treatment, or stop injecting. Physicians owe a duty of *beneficence* to these patients too. For these patients, *beneficence* requires education about safer alternatives and access to sterile syringes. Prescribing syringes to patients who are IDUs provides access and permits patients to reduce the risk of contracting or transmitting HIV.

Finally, any discussion of HIV and drug use today must consider the principle of *justice*. African-Americans and Hispanics bear a disproportionate burden of both of these epidemics in the United States. Adding socio-economic status to the picture reveals a concentration of all three among society's most vulnerable communities. Consequently, the policies we, as a society, adopt to deal with drug use and HIV will disproportionately affect these communities.

Arguably, communities of color may already feel they have been ill-served by state and federal policies for HIV/AIDS prevention, education, medicines, drug treatment, and other social services.³⁵ Among the most important critiques of these communities has been the poor access many minority and impoverished people have to medical treatment

³⁴ See *Carey v. Population Serv. Int'l*, 431 U.S. 678, 715 (Stevens, J., concurring) (discussing contraceptive regulation and arguing that inflicting harm is an "unacceptable means of conveying a message that is otherwise legitimate").

³⁵ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 252.

for routine care, health promotion, and diagnosis and treatment of chronic conditions. A policy that promotes increased access by IDUs to regular medical care, that improves their chances of entering drug treatment and avoiding infection with HIV and other blood-borne diseases, would also promote the principle of *justice*.

Some would argue that despite its potential to prevent blood-borne diseases, providing IDUs with syringes, via any mechanism, but particularly from the prescription of a physician, violates the principle of *nonmaleficence*, the duty to do no harm. For example, by arguing that "but for" the physician's prescription for a needle, a drug user would not have overdosed and died, or would not have injured others in a motor vehicle accident. This argument fails because ample evidence has demonstrated that in the absence of sterile syringes, IDUs will use whatever is available. Denying IDUs access to syringes is unlikely to prevent specific harms such as those described above.

Also noteworthy in this context are the virtues of medicine. Compassionate physicians will recognize all their IDU patients' needs—both access to drug treatment, and to ways to prevent blood-borne infections while they remain addicted. Faithful physicians will not abandon their patient easily, even when that means facing the legal and ethical challenge of whether or not to prescribe syringes. Honest physicians will freely share with their IDU patients everything they know about ways to prevent blood-borne disease transmission, including safer injection practices and how and/or where to obtain sterile syringes. Courageous physicians will be willing to incur potential personal risks to promote their patients' best interests.

The physician has an ethical duty to care for his IDU patients. This can take several forms: education and counseling, referrals to drug treatment, or aiding patients in obtaining sterile syringes. If the physician fails to act and the patient contracts HIV, no future act can undo the harm. By taking action, the physician can help prevent further injury to the patient and preserve the chance to treat the patient for drug addiction at a later time. A variety of ethical approaches support a physician's option to prescribe syringes. Finding an affirmative duty, however, applicable to all situations, would be more difficult.

B. The Ethics of the Pharmacist-Patient Relationship

1. The pharmacist's duty and discretion

To varying degrees, pharmacists act independently of physicians. They may do so in order to fulfill their independent ethical obligations, to protect the health of "their" patients, or because they fear violating the law as they understand it. Increasingly, pharmacists strive to define pharmacy as a profession independent of medicine with its own national professional bodies, code of ethics, and often, professional practice guidelines.³⁶ Thus, some discussion of pharmacists' ethical duties is relevant to efforts promoting access to syringes through either over-the-counter sale or expanded prescribing.

Many factors affect pharmacists' decisions to fill prescriptions and to sell syringes over the counter.³⁷ Pharmacists are aware of, and feel constrained by, laws and regulations restricting the use, distribution, and sale of syringes.³⁸ In many states syringe prescription laws and regulations explicitly require pharmacists to sell syringes only upon proof of legitimate medical need. Other states have "voluntary" prescription requirements recognized by pharmacists (no legal provisions require a prescription, but pharmacists voluntarily

³⁶ See Mark A. Munger et al., *Professional Liability for Pharmacists: A Focus on Pharmacy Practice Acts*, 22 DRUG INTELLIGENCE & CLINICAL PHARMACY 886, 887 (1988) (indicating that it was only about ten years ago that twenty percent of states did not define pharmacy practice). See generally Stuart Anderson & Virginia Berridge, *Opium in 20th-century Britain: Pharmacists, Regulation and the People*, 95 ADDICTION 23 (2000) (discussing the historical development of pharmaceutical regulations for the sale and use of opiates in Great Britain and the resulting effects on community pharmacy practice).

³⁷ See Wilson M. Compton III et al., *Legal Needle Buying in St. Louis*, 82 AM. J. PUB. HEALTH 595 (1992) (reporting study considering pharmacists' decisions to make over-the-counter sales of syringes); see also Patricia Case et al., *Access to Sterile Syringes in Maine: Pharmacy Practice After the 1993 Repeal of the Syringe Prescription Law*, 18 J. ACQUIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY, S94 (Supp. I 1998).

³⁸ Legal provisions restricting access to syringes include syringe prescription laws (SP), drug paraphernalia laws (DP) and syringe regulations. See Gostin & Lazarini, *supra* note 4 (describing the distinct characteristics and distribution of these legal measures that restrict access to syringes); see also Case et al., *supra* note 37, at S94-95 (discussing pharmacist reluctance to sell syringes even after the change in the law).

choose to enforce one.) In other jurisdictions, pharmacists are expressly permitted to refuse to sell syringes that they believe may be intended for illegal use.³⁹ Even where sale is legal, the decision to sell syringes without a prescription is often left to the pharmacist's discretion. Pharmacists can refuse to sell syringes based on the idea of conscientious objection.⁴⁰ A pharmacist who is unsure if it is proper to sell to a specific individual may balk at selling syringes without a prescription.

Pharmacists exercise discretion even where customers present a prescription, perhaps by questioning the validity of the prescription. A pharmacist might also feel bound to report physicians, whom they know or whom they suspect of prescribing syringes to IDUs, to the Drug Enforcement Administration (DEA) or the local licensing and disciplinary authority. Pharmacists might, therefore, derail efforts by individual physicians to expand IDUs' access to syringes through prescriptions.

From an ethical standpoint, the American Pharmaceutical Association Code of Ethics states that "[a] pharmacist places concern for the well-being of the patient at the center of professional practice." It also states that "[a] pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner." Finally, while the pharmacist serves the individual, the Code states that "[a] pharmacist [also] serves . . . community, and societal needs."⁴¹

Pharmacists' precise role in promoting the good of the patient, however, has changed over time. Both the concept of pharmacists' duties and the definition of "practice" have grown in recent years.⁴² Cost control pressures continue to reduce physicians' time with patients and thus their ability to educate patients on the correct use of medications or devices.

³⁹ See Gostin & Lazzarini, *supra* note 4, at 631.

⁴⁰ See RICHARD R. ABOOD & DAVID B. BRUSHWOOD, *PHARMACY PRACTICE AND THE LAW* 306 (1994).

⁴¹ American Pharm. Ass'n, *Code of Ethics for Pharmacists*, 52 AM. J. HEALTH-SYS. PHARMACY 2131, 2131 (1995). Some have suggested that needle exchange programs give pharmacists an opportunity to engage in promoting public health. See Peter D. Hurd & Bruce Lubotsky Levin, *Public Health and Prevention*, in *INTRODUCTION TO HEALTH CARE DELIVERY: A PRIMER FOR PHARMACISTS* 171, 175-76 (Robert L. McCarthy ed., 1998) (describing how pharmacists serve both individuals and communities).

⁴² See Munger et al., *supra* note 36, at 888 (indicating that with the expansion of pharmacists' duties and practice, there is a need for standardized guidelines).

Expanded database collection by pharmacies often produce a "record" for individual patients that includes much of the information usually contained in the medical record. As a consequence, pharmacists have taken on some of the screening, counseling, and education duties previously performed by doctors.

Traditionally, the duty of the pharmacist was fairly simple. A pharmacist was required to correctly fill the prescriptions given by a doctor to his patients. The duty was limited primarily because of physicians' dominant position in health care during this century. Pharmacists questioning the prescribing practices of a physician might interfere with the physician-patient relationship. This approach relied on the "learned intermediary doctrine," in which a physician (the learned intermediary), not the pharmacist, had the duty to warn patients about the potential side effects of drugs.⁴³ The role of the pharmacist was little more than that of a dispenser.

The 1952 Code of Ethics went so far as to explicitly deter pharmacists from giving advice to a customer.⁴⁴ In this traditional setting, a pharmacist was only liable if he or she did not correctly fill the prescription that the doctor prescribed. Thus, a pharmacist was not responsible for advising customers regarding proper dosage (under this traditional view, the customer was not considered a patient of the pharmacist) or warning them of potential dangerous side-effects of drugs. These responsibilities remained with the physician.⁴⁵

Pharmacists' expanded role now encompasses greater practice, discretion, and duty. In addition to screening out

⁴³ See Lauren Fleischer, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 168 (1999).

⁴⁴ See *Code of Ethics of the American Pharmaceutical Association*, J. AM. PHARMACEUTICAL ASS'N: PRACTICAL PHARMACY EDITION 721, 722 (1952); see also Fleischer, *supra* note 43, at 168.

⁴⁵ See *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985) (holding that a pharmacist does not have a duty to warn a patient or inform a physician that a drug is prescribed in a dangerous amount or in an amount that might cause an adverse reaction in the patient); *Pysz v. Henry's Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984) (holding that pharmacist's duties include filling correct prescriptions with due care, not policing the individual using the medicine or deciding whether the individual is addicted); *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985) (holding that a pharmacist has no duty to refuse to fill prescriptions at amounts dangerous to the patient or to warn the physician of the danger).

"invalid" prescriptions, pharmacists are held responsible for either notifying a physician or directly warning a patient of an inadequate instruction in a prescription.⁴⁶ A pharmacist may also be held liable for failing to meet certain "minimum standards" of prescription review, including, on occasion, a duty to refuse to fill a valid prescription.⁴⁷ When interpreted most broadly, that is to hold a pharmacist liable even though she followed a valid prescription, it suggests a relationship, and therefore a duty between the pharmacist and customer, that is independent of the relationship between the physician and the patient.

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) expanded pharmacists' duties.⁴⁸ OBRA-90 requires pharmacists to screen prescriptions, to keep a history of patient records, and to make an offer to discuss proper drug use with Medicaid patients. Following the mandate of OBRA, many states applied those duties to all pharmacist-patient encounters.⁴⁹

The Commission to Implement Change in Pharmaceutical Education (CICPE) articulated pharmacists' increased responsibilities in the following terms: "the mission of pharmacy practice is to render pharmaceutical care. Pharmaceutical care focuses pharmacists' attitudes, behaviors, commitments, concerns, ethics, functions, knowledge, responsibilities and skills on the provision of drug therapy with a goal of achieving definite outcomes toward the improvement of a

⁴⁶ See *Riff v. Morgan Pharmacy*, 508 A.2d 1247 (Pa. Super. Ct. 1986) (finding that pharmacist has a duty to ensure safe prescription fills and refills, as well as providing safety information and notifying physician if problem perceived).

⁴⁷ See *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514 (Ind. 1994) (holding that, based on ordinary negligence principles, a pharmacist had a duty to refuse to fill a valid prescription for a dangerous, addictive drug when customer sought refills at an unreasonably fast rate). The court looked to a number of factors including foreseeability of injury, the nature of the relationship between the pharmacist and patient, public policy concerns, and any risk of an increase in cost. See *id.*

⁴⁸ See 42 U.S.C.A. § 1396r-8(g) (West Supp. 2000) (requiring states to establish drug use review programs). For a discussion of the pharmacist's duty under OBRA-90 standards, see Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 14 AM. J.L. & MED. 417, 433-40 (1998); see also David B. Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. LEGAL MED. 475, 476 (1997).

⁴⁹ See Fleischer, *supra* note 43, at 169-70.

patient's quality of life."⁵⁰ "Pharmaceutical care directs that this [achieving desired outcomes] responsibility is to be a shared obligation between the prescriber and the pharmacist."⁵¹

Pharmacists' duties exist in the context of the respective responsibilities of physicians and pharmacists. Legal interpretations have tended to divide these responsibilities into two broad categories, risk assessment and risk management. The responsibility for risk assessment falls primarily to the physician. Physicians must assess the risks and benefits in prescribing a drug to a patient during each visit and determine the most appropriate drug treatment. Pharmacists remain primarily responsible for risk management. "Risk management relates to the proper drug use rather than correct drug choice."⁵²

The difference between risk management and assessment is fairly simple. Risk assessment involves a decision by a doctor about the proper treatment for a patient based on that patient's individual needs and history. By contrast, risk management concerns the drug in general and the risks that the drug presents to any user. Generally, pharmacists are not responsible for an incorrect risk assessment.⁵³

The role of the pharmacist continues to change. Both the law (common law and statutory law) and pharmacy practice shape this change.⁵⁴ Although drug choice ultimately remains with the physician, the pharmacist plays a growing role. In-

⁵⁰ See American Ass'n of Colleges of Pharmacy, Comm'n to Implement Change in Pharmaceutical Educ., *What is the Mission of Pharmaceutical Education* (1993) at 376, available at <<http://www.farmacia.us.es/Decanato/Eurofarma/Euro%20Pharma%2021/AACP.htm>> (visited Sept. 12, 2000).

⁵¹ Robert L. McCarthy, *Health Care Ethics*, in INTRODUCTION TO HEALTH CARE DELIVERY: A PRIMER FOR PHARMACISTS 355, 361 (Robert L. McCarthy ed., 1998).

⁵² ABOOD & BRUSHWOOD, *supra* note 40, at 212.

⁵³ Although, it is even questionable whether a pharmacist was responsible for risk management under the traditional view of the pharmacist. Furthermore, others have contended that the pharmacist's responsibility has been misinterpreted by the courts in various situations. See David B. Brushwood & Larry M. Simonsmeier, *Drug Information for Patients: Duties of the Manufacturer, Pharmacist, Physician, and Hospital*, 7 J. LEGAL MED. 279, 282 (1986). For a good example illustrating the difference between risk management and risk assessment, see ABOOD & BRUSHWOOD, *supra* note 40, at 212-13.

⁵⁴ See Munger et al., *supra* note 36, at 888 (noting how courts examine both laws and pharmacy practice to determine an appropriate standard of care).

creasingly, clinical pharmacists help develop drug therapy programs for patients and act as therapeutic consultants.⁵⁵ Pharmacists counsel patients with diabetes, hypertension, and asthma.⁵⁶ They may instruct patients on the function and use of devices associated with their prescribed treatments. For example, pharmacists can review proper inhaler use for patients with asthma or syringe use and disposal for diabetics. As pharmacists take on greater responsibilities, the duty of the pharmacist will also continue to change. In this period of change, however, little consensus exists across geographic areas as to the scope of pharmacists' legal duties.

2. Defining ethical duties in new situations: Should pharmacists fill syringe prescriptions for IDUs?

Under the pharmacist's traditional role, a pharmacist would merely have to fill the prescription as given. As the role of the pharmacist has changed, so too have the ethical and legal obligations become more complex. Pharmacists exercise a greater degree of control and bear a greater responsibility than ever before. Yet, although the majority of pharmacists in various surveys have expressed support for over-the-counter sales of syringes in general, far fewer are enthusiastic about selling to IDUs.⁵⁷ In areas of first impression (such as syringe prescribing), where no clear definition exists as to the pharmacist's duty, an examination of the official statements of professional organizations, as well as existing codes of

⁵⁵ See generally Amy Broeseker & Kristin Kari Janke, *The Evolution and Revolution of Pharmaceutical Care*, in INTRODUCTION TO HEALTH CARE DELIVERY: A PRIMER FOR PHARMACISTS 393, 401-03 (Robert L. McCarthy ed., 1998).

⁵⁶ See Hurd & Levin, *supra* note 41, 175-76 (indicating that pharmacy can increase its public activity by counseling patients about diseases).

⁵⁷ See T. Stephen Jones & Jennifer Taussig, *Should Pharmacists Sell Sterile Syringes to Injection Drug Users?*, 39 J. AM. PHARMACEUTICAL ASS'N 8 (1999) (reporting that pharmacists are divided in their support of the sale of syringes to intravenous drug users); see also Thomas A. Farley et al., *Attitudes and Practices of Pharmacy Managers Regarding Needle Sales to Injection Drug Users*, 39 J. AM. PHARMACEUTICAL ASS'N 23, 23-26 (1999); Alice A. Gleghorn et al., *Pharmacists' Attitudes About Pharmacy Sale of Needles/Syringes and Needle Exchange Programs in a City Without Needle/Syringe Prescription Laws*, 18 J. ACQUIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY S89 (Supp. I 1998); Linda Wright-De Agüero et al., *Impact of the Change in Connecticut Syringe Prescription Laws on Pharmacy Sales and Pharmacy Managers' Practices*, 18 J. ACQUIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY S102, S108-09 (Supp. I 1998) (explaining the reasons why pharmacists are unwilling to sell to IDUs).

ethics and legal concepts of duty and liability, helps define the pharmacists' ethical and legal duties.

In late 1999, leaders of the American Medical Association (AMA), the American Pharmaceutical Association (APhA), the Association of State and Territorial Health Officials (ASTHO), and the National Alliance of State and Territorial AIDS Directors (NASTAD) issued a joint statement calling for the coordinated efforts of state leaders in pharmacy, public health, and medicine to address access to sterile syringes as a means of preventing further transmission of blood-borne infections. For instance, the "APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to permit the unrestricted sale or distribution of sterile syringes and needles by or with the knowledge of a pharmacist in an effort to decrease the transmission of blood-borne diseases."⁵⁸ Where the law permits sales of syringes without a prescription, or can be interpreted to allow sales to IDUs with prescriptions, APhA's position supports pharmacists dispensing syringes.

The pharmacists' professional code also provides relevant guidance. This code obliges pharmacists to put the health needs of their patients first.⁵⁹ Medical decisions, including the potential benefits of access to sterile syringes, should be made based on objective scientific criteria. Thus, if the preponderance of the evidence from well-designed scientific studies indicates probable health benefits and low risks, pharmacists ought to honor prescriptions for syringes.

The risk assessment/risk management model is somewhat outdated in the era of expanding pharmaceutical practice and duties. Using it, however, would not contradict the result suggested by either of these approaches. Applying the risk assessment/risk management model, the pharmacists' role would be limited to complete and accurate instruction in how to use the prescribed treatment, in this case, syringes. Pharmacists could provide information on safe injection practices, disposal of needles, and means to access drug treatment. The risk assessment/risk management approach also suggests

⁵⁸ *Report of the APhA House of Delegates: Actions of the Official Legislative Body of the American Pharmaceutical Association*, 39 J. AM. PHARMACEUTICAL ASS'N 447, 447 (1999).

⁵⁹ See American Pharm. Ass'n, *supra* note 41.

pharmacists should sell syringes. Where syringes are validly prescribed, and there are no absolute risk management contraindications to their use, the pharmacist would assume that a physician has already assessed the situation and determined that the benefits of prescribing syringes in this situation outweigh the risks. In this context, the pharmacist's duty is to sell the syringes, and to manage their proper use through patient education.

Even where legislatures have modified laws to permit over-the-counter sale of syringes, pharmacies (and pharmacists) still have the option of whether to sell syringes without a prescription. After Connecticut changed its law to permit the limited sale of syringes over-the-counter, a questionnaire to 15 pharmacies in New Haven found that four had policies against the sale of syringes without a prescription.⁶⁰ Thirteen of 18 pharmacies in Hartford allowed the sale of syringes without a prescription.⁶¹ By contrast, in pharmacies on the periphery of Hartford, only five of nine pharmacies allowed the sale of syringes without a prescription.⁶² One pharmacist responded that he suspected that most, if not all of the pharmacists that work the day shift, only sell syringes with a prescription.⁶³ Thus, deregulation alone does not necessarily guarantee that IDUs will have access to syringes without a physician's prescription. Conversely, even where the law does not require a prescription, pharmacists may be more willing to sell an IDU syringes with a prescription (which implies a physician's endorsement of a legitimate medical purpose) than to sell syringes over-the-counter.

Pharmacists dispensing syringes based on prescriptions have ample support for their actions in the position statements of their national professional body, ethical codes, and even a relatively conservative interpretation of the pharmacist's role. Some might even suggest these materials create an obligation to dispense syringes to prescription-holding IDUs in the absence of specific reasons to believe that the prescription would be harmful.

⁶⁰ See Merrill Singer et al., *Pharmacy Access to Syringes Among Injecting Drug Users: Follow-up Findings from Hartford, CT*, 113 PUB. HEALTH REP. 81, 82 (Supp. I 1998).

⁶¹ See *id.* at 84.

⁶² See *id.*

⁶³ See *id.* at 85.

C. Why Some Physicians and Pharmacists Might Refuse to Treat IDUs

Physicians may feel ill-prepared for treating IDUs and perceive few positive reasons for involvement with them. IDU patients can be difficult and demanding. Their medical problems are complicated by their need for social services, that may include drug treatment, housing, counseling, assistance with parenting, child care, and ultimately job training. Most regular physicians' offices are not equipped to provide this level of intensive intervention and support, so IDUs who are patients may not ever get the support they need to quit using injection drugs. Additionally IDU patients present interpersonal challenges.⁶⁴

When physicians do treat IDUs, they may be so wary of encouraging drug use that they may not provide the care the patient needs to treat an underlying illness. Physicians are particularly hesitant to prescribe narcotics to IDUs, or former IDUs, even when such treatment is warranted by conditions known to cause pain. Physicians may also refuse to provide other forms of treatment due to fears that the treatment will facilitate continued drug use.⁶⁵

Pharmacists may avoid selling syringes to IDUs for reasons of safety, or fear of harming their businesses. Common concerns expressed by pharmacists are that having IDUs as customers will drive away other customers, that IDUs will commit crimes in and around the pharmacy, or that they will discard their used needles and syringes nearby.⁶⁶ The reluctance of physicians and pharmacists to interact with IDUs results in reduced access to health care and pharmacy services for IDUs, who already receive less care than the majority population.⁶⁷

Additionally, physicians and pharmacists may morally oppose an IDU's drug use or other illegal activities, or be personally repelled by the IDU's affect or daily life. Sepa-

⁶⁴ See generally PETER A. SELWYN, *SURVIVING THE FALL: THE PERSONAL JOURNEY OF AN AIDS DOCTOR* (1998).

⁶⁵ See Brennan, *supra* note 33, at 148 (illustrating how physicians treating an IDU patient declined to use a "central line," fearing that it would provide an easy port for injecting illegal drugs).

⁶⁶ See Wright-De Agüero et al., *supra* note 57, at S105-09; see also Gleghorn et al., *supra* note 57, at S92.

⁶⁷ See discussion *infra* Parts II.A.3 and II.B.2.

rating professional ethical duties from personal responses may be necessary for some professionals to care for IDUs regularly.

III. THE ROLES OF LAW IN THE DEBATE OVER PRESCRIBING/DISPENSING SYRINGES

A. The Relationship Between Law and Ethics

Ethical values and legal principles are usually closely related, but ethical obligations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations.⁶⁸

The law influences ethical analysis in at least two ways. First, in many situations, legal analysis of physician liability establishes the physician's legal duty in a particular case.⁶⁹ Although legal duties are not always dispositive of ethical duties in a particular situation, the law usually establishes the minimum quality of action acceptable to society. In these cases, the law may provide the floor, while ethics describe the normative goal or ideal.

Second, however, the law may pose a structural barrier to ethical conduct. In these cases the tension between law and ethics may create an ethical dilemma for physicians, whether to fulfill their duties to patients and break the law, or to obey

⁶⁸ AMERICAN MED. ASS'N, COUNCIL ON ETHICAL & JUD. AFFAIRS, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, § 1.02 (1998).

⁶⁹ The law has defined a physician's general duty towards his patients as a "duty to use reasonable care and diligence in the exercise of his skill and the application of his learning . . . to use his best judgment in exercising his skill and applying his knowledge." TOM CHRISTOFFEL, *HEALTH AND THE LAW: A HANDBOOK FOR HEALTH PROFESSIONALS* 309 (1982) (citing *Pike v. Honsinger*, 49 N.E. 760, 762 (N.Y. 1898)). *But see Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 342 (Cal. 1976) (stating that "legal duties are not discoverable of nature, but merely conclusory expressions that, in cases of a particular type, liability should be imposed for damage done"). In determining whether a legal duty existed in *Tarasoff*, the justices stated that "[a] physician may not reveal the confidence entrusted to him in the course of medical attendance . . . unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community." *Id.* at 347 (quoting the AMERICAN MED. ASS'N, *PRINCIPLES OF MEDICAL ETHICS* § 9 (1957)).

the law and leave some obligations unfulfilled. Both of these issues, the standard of care and the physician's options, when faced with legal barriers, will be covered below.

Law plays a significant role in discussions of duty, which also occupies much of the dialogue about ethics. This section reviews three ways in which the law affects determinations of physicians' and pharmacists' ethical duty, establishment of a standard of care, and duty to third parties, in addition to the law as a barrier to actions which physicians or pharmacists feel are ethically justified.

B. The Standard of Care

A legal determination of the standard of care often frames the discussion about the physician's and pharmacist's obligation with respect to his or her patients, and provides a minimum threshold for ethical duties. Yet, because the standard of care continuously evolves, it may be difficult to determine in new situations. Ultimately, only a court or a jury can determine whether physicians' and pharmacists' actions comply with the standard of care. Nonetheless, we can examine factors that are used in establishing the standard of care in order to determine how a court might analyze a situation. These factors include: the reasonable practitioner standard, customary practice, practice guidelines, a respectable minority position, new developments in the field (scientific, medical, technical), the limitations of self-regulation, and whether a professional or ordinary standard of care applies.

1. A professional standard of care

As a general rule, physicians must exercise reasonable care comparable to that expected of other physicians of similar skill, training, and education.⁷⁰ Expert witnesses testify in court as to what a reasonable physician would do. Although community standards have historically played an important role in establishing the applicable standard of care, increasingly, courts rely on a national standard.⁷¹ Ultimately, a jury determines the standard of care based on the evidence introduced.

⁷⁰ See CHRISTOFFEL, *supra* note 69.

⁷¹ See generally DAVID M. HARNEY, *MEDICAL MALPRACTICE* ch. 21 (3d ed. 1993 & Supp. 1998) (discussing standards of care for conduct of medical practitioners).

Health care professionals make decisions everyday based on multiple factors, including the facts of the particular case, the caregiver's perceived duties, and the patient's perceived needs, personal preferences for treatment, knowledge of new scientific evidence, and willingness to act. In much of medical care, when there are different treatments available, "the choice between them is usually based on value judgments, not medical judgments."⁷² Some patterns of choices become codified as part of "customary practice," which helps establish the standard of care.⁷³ While the customary practice is not determinative, it plays an important role in establishing the reasonableness of the physician's actions.

Physicians have a duty to keep up to date with progress in their fields and to use their "best judgment" in making decisions. This duty includes knowing the latest research regarding drugs, techniques, and procedures in their specialty.⁷⁴ In these cases, custom does not protect a physician from liability.

Practice guidelines also play a role in the formation of the standard of care. The admission of a guideline into evidence, however, does not compel the court to accept the guideline as

⁷² Alexander M. Capron & Vicki Michel, *Law and Bioethics*, 27 LOY. L.A. L. REV. 25, 36 (1993).

⁷³ This deference to the profession is partly due to the courts' "reluctance to overburden [the medical profession] with liability based on uneducated judgment." W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 32, at 189 (5th ed. 1984). It is also suggested that courts may want to avoid a legal standard of care "because of the potential physical and economic harm to patients caused by legally-defensible but inferior or unsafe medicine" (specifically, there is concern that medical progress would slow), see Margaret Lent, Note, *The Medical and Legal Risks of the Electronic Fetal Monitor*, 51 STAN. L. REV. 807, 827 (1999).

⁷⁴ In fact, courts have recognized this duty. See, e.g., *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879-80 (1982) (finding physician liable for malpractice for failing to consider recent studies questioning accepted medical practice); *Toth v. Community Hosp. at Glen Cove*, 239 N.E.2d 368, 373 (N.Y. 1968) (holding that physicians are required to use their best judgment irrespective of contrary custom or practice); *Morgan v. Sheppard*, 188 N.E.2d 808 (Ohio Ct. App. 1963) (ruling on multiple assignments of error and holding that a physician who performed a surgical procedure must exercise the same degree of care that an ordinarily prudent person in the same profession would have exercised under similar circumstances); *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971) (holding the standard in a malpractice action, that physician did not possess or employ the required skill and knowledge, is qualified by the advanced state of the profession at the time of the treatment), *vacated on other grounds*, 421 A.2d 1027 (Pa. 1980) (abandoning the *Incollingo* determination for damages).

the appropriate standard of care.⁷⁵ Courts still depend on expert testimony to establish the relevance of the practice guidelines.⁷⁶ Ultimately, courts may find other evidence more persuasive of the standard of care.⁷⁷

However, even where customary practice or practice guidelines exist, there are times when a physician could utilize more than one treatment option. Courts allow for a "respectable minority" rule which permits physicians to choose between acceptable treatments without fear of facing liability if the chosen treatment does not work.⁷⁸

Leaving aside for now how courts might consider criminal provisions as they conflict with a possible standard of care, we can apply these various determinants of a professional standard of care to the issue of physicians prescribing syringes to IDUs. The most problematic aspect of an argument for prescribing syringes as the standard of care is customary practice. The vast majority of physicians currently caring for IDUs do not prescribe syringes. These physicians may not know their patients use injection drugs, or be unaware of HIV risk, or assume that such a prescription would be invalid or violate medical practice acts.

⁷⁵ See Paul D. Rheingold & Thomas P. Valet, *Practice Parameters: New Standards for Medical Care?*, TRIAL, May 1993, at 56, 57.

⁷⁶ See Gary W. Kuc, Comment, *Practice Parameters as a Shield Against Physician Liability*, 10 J. CONTEMP. HEALTH L. & POL'Y 439, 463 (1994) (discussing how statements made by medical experts and recorded in learned treatises are an exception to the hearsay rule).

⁷⁷ See Edward B. Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886 (1991) (noting evidence contrary to medical practice parameters may be considered if the court finds the other evidence more persuasive as to the standard of care).

⁷⁸ See, e.g., *Sprowl v. Ward*, 441 So.2d 898 (Alaska 1983) (holding evidence of alternative treatments admissible if both commonly accepted modes of treatment); *Roberts v. Tardif*, 417 A.2d 444, 451-52 (Me. 1980) (requiring physicians to be held to a national standard of care); *Downer v. Veilleux*, 322 A.2d 82 (Me. 1974). There are a couple of variations to the respectable minority rule that courts have utilized. Compare *Fritz v. Parke Davis & Co.*, 152 N.W.2d 129 (Minn. 1967), and *Gresham v. Ford*, 241 S.W.2d 408 (Tenn. 1951) (expressing approval of a variation of the "respectable minority" rule by finding that a treatment approved by a considerable number of physicians is acceptable), with *Rickett v. Hayes*, 511 S.W.2d 187 (Ark. 1974) (holding that when reasonable physicians merely disagree as to proper treatment, negligence is not proven) and *Haase v. Garfinkel*, 418 S.W.2d 108 (Mo. 1967) (finding that when reasonable physicians disagree as to a proper course of treatment, a physician may choose to use one type of treatment over another without liability).

Existing law provides little guidance here. Courts have interpreted medical practice acts to invalidate prescriptions for narcotics to IDUs for the purpose of maintaining their habits.⁷⁹ Although no court has addressed whether similar reasoning should be applied to the prescription of syringes, decisions related to prescribing controlled substances have been used (perhaps erroneously) to suggest that a prescription for syringes for an IDU to prevent blood-borne diseases would be invalid. Although customary practice does not support prescribing, it should not be determinative in light of the substantial evidence regarding public health guidelines, new developments, and the views of the respectable minority which support a new or evolving standard of care.

Practice guidelines, the practices of a respectable minority, and new developments in the field provide the strongest evidence for prescribing syringes as the standard of care. Public health and clinical authorities endorse physicians recommending that IDUs use sterile syringes for each injection.⁸⁰ Where no legal access to syringes exists, these recommendations would seem to support physician prescribing to IDUs who fit all other criteria (who have been counseled to stop using, enter treatment, or stop injecting, but cannot or will not currently.)

Some physicians experienced in treating IDUs and persons with HIV want to prescribe syringes but fear legal consequences.⁸¹ Others have actually begun pilot programs for IDUs in states with syringe prescription laws.⁸² A respectable

⁷⁹ See *People v. Goldberg*, 369 N.Y.S.2d 989 (N.Y. Sup. Ct. 1975). "It is clear that a doctor who issues a prescription or dispenses controlled substances for non-medical purposes is not acting 'in the course of his professional practice only.'" *Id.* at 991.

⁸⁰ See HELENE D. GAYLE ET AL., HIV PREVENTION BULLETIN: MEDICAL ADVICE FOR PERSONS WHO INJECT ILLICIT DRUGS (U.S. Dep't of Health & Hum. Serv., May 9, 1997); American Med. Ass'n, *A Physician Guide to HIV Prevention* (1996), available at <<http://www.ama-assn.org/special/hiv/treatmnt/guide/hivguide/hivguide.htm>> (visited Sept. 27, 2000); REPORT OF THE U.S. PREVENTIVE SERVICES TASK FORCE, GUIDE TO CLINICAL PREVENTIVE SERVICES 591(2d ed. 1996); PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 253-54; REPORT: THE TWIN EPIDEMICS OF SUBSTANCE USE AND HIV (Nat'l Comm'n on AIDS, Wash. D.C.), July 1991, at 10 (recommending that legal barriers placed on IDU's access to sterile syringes be removed).

⁸¹ See Lazzarini et al., *supra* note 8.

⁸² See Scott Burris et al., *Physician Prescribing of Sterile Injection Equipment to Prevent HIV Infection: Time for Action*, 133 ANNALS INTERNAL MED. 218, 223 (2000).

minority view arguably already supports physician prescribing. Additionally, the overwhelming weight of empirical evidence collected and analyzed in recent years suggests a potential public health benefit from access to sterile syringes for IDUs to protect against HIV infection.⁸³

Given that public health and clinical authorities endorse the idea that IDUs use sterile syringes for each injection (for clinical and public health reasons), an evolving standard of care that includes physicians prescribing syringes is a reasonable option that comports with scientific evidence.

2. An ordinary standard of care

Despite the courts' marked deference to professional opinions regarding the standard of care, professional self-regulation cannot be completely unfettered. Complete professional discretion for setting the standard of care gives a profession the opportunity to shield itself (perhaps unfairly) from liability:

[A] whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.⁸⁴

Courts will also consider professional responsibility in the context of an ordinary standard of care. A professional standard is not absolute, nor does it exist in a vacuum. The foundation of the ordinary standard of care is the duty to adopt reasonable behaviors and precautions that minimize resulting perils and dangers.⁸⁵ Ordinary care mandates that persons of ordinary prudence utilize care to prevent injury to themselves or others under circumstances similar to those at

⁸³ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 253; *see also* 1 SCHOOL OF PUB. HEALTH, UNIV. OF CAL., BERKELEY & INST. FOR HEALTH POL'Y STUD., UNIV. OF CAL., SAN FRANCISCO, THE PUBLIC HEALTH IMPACT OF NEEDLE EXCHANGE PROGRAMS IN THE UNITED STATES AND ABROAD 20-21 (1993).

⁸⁴ The T.J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932) (finding tugboat company liable for loss of cargo, regardless of industry standards, for not having their tugs equipped with radio receivers).

⁸⁵ See *Adams v. Bullock*, 125 N.E. 93 (N.Y. 1919).

issue.⁸⁶ Defining the ordinary standard of care in any situation requires two steps: (1) calculating the risk, and (2) establishing what a reasonably prudent person would do.⁸⁷

To calculate risk, courts often turn to Judge Learned Hand's formula for an economic theory of negligence. Using this formula, $B < pL$ formula,⁸⁸ the burden (B) of taking the necessary precautions is weighed against the injury (L) multiplied by the probability (p) that the injury will occur.⁸⁹ Where the cost of preventing the risk is less than the product of the cost of the injury and its probability, the defendant is liable.⁹⁰ Although Hand's formula functions well in theory, applying it to real world situations may be more problematic. Difficulties arise when courts or juries attempt to set monetary values on personal injuries and the costs of prevention.⁹¹ Juries may make judgments founded on reasonableness rather than by balancing costs.

The ordinary standard of care also demands the evaluation of what a "reasonably prudent person" would do in like circumstances. This legal fiction compares the defendant's behavior with that of a reasonably prudent person in order to determine negligence. A reasonable person is defined as one who adheres to the general standard of behavior in the community, or who possesses the average level of moral judgment in the community.

⁸⁶ See MARK A. FRANKLIN & ROBERT L. RABIN, TORT LAW AND ALTERNATIVES 34 (6th ed. 1996).

⁸⁷ See generally *id.* (describing method of conveying concept of "reasonable care" to a jury).

⁸⁸ See *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d. Cir. 1947) (discussing the formula to determine an individual's duty to protect against injury when assessing negligent conduct).

⁸⁹ See Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 32-33 (1972) (explaining Judge Learned Hand's formula for calculating risk and the economic theory of negligence).

⁹⁰ See *Helling v. Carey*, 519 P.2d 981 (Wash. 1974), *reaff'd*, *Gates v. Jensen*, 595 P.2d 919 (Wash. 1979) (holding the decision not superceded by state statute). In *Helling*, a woman lost part of her vision due to glaucoma and sued her ophthalmologist for malpractice. At the time, the professional standard provided that patients under the age of 40 were not tested for glaucoma. This standard was challenged and the Supreme Court of Washington found in *Helling's* favor, since the test was very simple and inexpensive to administer whereas the disease was potentially blinding. Thus, the benefits of the test clearly outweighed the costs of administering it.

⁹¹ See generally *McCarty v. Pheasant Run, Inc.*, 826 F.2d 1554 (7th Cir. 1987) (explaining the difficulty in determining monetary value of personal injuries).

In determining the standard of care for physicians treating IDUs at risk for contracting HIV and other blood-borne diseases, we can apply an ordinary negligence standard utilizing a cost-benefit analysis. Different variables contribute to this analysis: (1) the nature of the injury, (2) the probability of the injury, and (3) the costs of preventing the injury. The nature of the injury, when IDUs are infected with blood-borne diseases, remains serious. Although recent advances in anti-retroviral therapy have lengthened survival, HIV infection remains incurable, and finally fatal. Infections with hepatitis B or C, though less deadly, are more common and cause substantial illness and death in a proportion of patients.

The probability of injury—in this case, the probability that an IDU will contract HIV or another blood-borne infection by sharing needles—can be derived from national AIDS data. At the end of June 1999, 36% of the 711,344 AIDS cases reported from July 1998 to June 1999 were directly or indirectly associated with injection drug use.⁹² Furthermore, estimates indicate that up to 90% of IDUs are infected with hepatitis C.⁹³ These numbers show that IDUs are at great risk of blood-borne diseases, and represent a significant proportion of those who contract HIV. Finally, a cost-benefit analysis must determine the burden of taking the necessary precautions to prevent the injury. Recommendations state that people who inject drugs should use sterile syringes to prevent the transmission of HIV and other blood-borne diseases.⁹⁴

From an economic perspective, it costs approximately \$195,188 to treat an HIV-infected person for a lifetime. In

⁹² See Centers for Disease Control & Prevention, *HIV/AIDS Surveillance Report: Midyear Edition*, Vol. 11, No. 1, Table 5 (1999). Available at <www.cdc.gov/hiv/stats/hasrlink.htm> (visited Sept. 12, 2000) (citing AIDS cases by age, exposure category, and sex).

⁹³ See Miriam J. Alter & Linda A. Moyer, *The Importance of Preventing Hepatitis C Virus Infection Among Injection Drug Users in the United States*, 18 J. ACQIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY S6 (Supp. I 1998).

⁹⁴ See *Report of the APhA*, *supra* note 58 (stating the APhA's formal position encouraging the revision of state laws to permit the unrestricted sale or distribution of sterile syringes); see also George D. Lundberg, *New Winds Blowing for American Drug Policies*, 278 JAMA 946 (1997) (indicating the AMA recommends the use of sterile syringe programs for prevention of HIV infection); GAYLE ET AL., *supra* note 80, at 3; American Med. Ass'n, *supra* note 80; REPORT OF THE U.S. PREVENTIVE SERVICES TASK FORCE, *supra* note 80, at 727; PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 251-53; REPORT: THE TWIN EPIDEMICS OF SUBSTANCE USE AND AIDS, *supra* note 80, at 10.

1992, the median annual budget for running a SEP was \$169,000. Using these data, it costs approximately \$9,400 to prevent each new case of HIV infection among SEP clients, their sex partners, and children (where the government or private organization bears the cost of the SEP).⁹⁵ Studies indicate that IDUs could bear much of the cost of this type of "prevention," as most were willing to pay ten times the wholesale cost of syringes and none were unwilling to pay at all.⁹⁶

Providing IDUs access to syringes costs relatively little compared with the cost of treating patients with HIV infection. Syringe exchange programs cost the most, but considerably less than the lifetime cost for HIV infection. Over-the-counter sales or prescription sales of syringes cost even less. The most direct means to prevent HIV among IDUs is to get them to stop using drugs. Persuading IDUs to stop using drugs may not always be possible,⁹⁷ even when treatment is available.⁹⁸ As a consequence, physicians may justifiably seek reasonable alternatives to protect IDUs and the public health.

Thus, considering the B<pL formula (using the data on addiction, drug treatment, and the probable benefits of access to

⁹⁵ See SCHOOL OF PUB. HEALTH, UNIV. OF CAL., BERKELEY & INST. FOR HEALTH POLICY STUDIES, UNIV. OF CAL., SAN FRANCISCO, *supra* note 83, at 21 (estimating that prevention of HIV costs \$9,400 per HIV infection avoided).

⁹⁶ See Benjamin Junge et al., *Pharmacy Access to Sterile Syringes for Injection Drug Users: Attitudes of Participants in a Syringe Exchange Program*, 39 J. AM. PHARMACEUTICAL ASS'N 17, 21 (1999). In this study examining pharmacy access to sterile syringes, respondents said they would pay a mean sum of \$0.80 per syringe at a pharmacy (including a range from \$0.10 to \$4.00) and no one said that they would not pay anything for syringes at the pharmacy. See generally Alice A. Gleghorn et al., *Acquisition and Use of Needles and Syringes by Injecting Drug Users in Baltimore, Maryland*, 10 J. ACQUIR. IMMUNE DEFIC. SYNDR. & HUM. RETROVIROLOGY 97 (1995).

⁹⁷ See John K. Watters, *A Street-based Outreach Model of AIDS Prevention for Intravenous Drug Users: Preliminary Evaluation*, 14 CONTEMP. DRUG PROBS. 411, 422 (1987) (discussing how 15 years of increased treatment options have not abated drug use); see also Joyce F. Jackson et al., *A Coupon Program - Drug Treatment and AIDS Education*, 24 INT'L J. ADDICTIONS 1035 (1989) (finding treatment program location, age, sex, and origin to be significant predictors for continuation in heroin treatment program).

⁹⁸ See James A. Wiley & Michael C. Samuel, *Prevalence of HIV Infection in the USA*, 3 AIDS S71, S72 (Supp. I 1989) (discussing that there are often not enough adequate drug treatment centers available to those who want to seek such services). Treatment centers often have long waiting lists making access difficult. At any given time, less than 15% of IDUs are in treatment on a given day. See *id.*

sterile syringes), the ordinary standard of care analysis suggests that a relatively low burden intervention, such as prescribing syringes to IDUs under specific circumstances, ought to be an option, if not an obligation, of physicians.

3. Conclusions from a standard of care analysis

In summary, both ordinary and professional standards of care support prescribing syringes to IDUs to prevent blood-borne infections. Substantial evidence supports the argument that the standard of care should include educating patients on safe injection and access to syringes through either SEPs or prescription.⁹⁹ Where the law provides no other legal access to syringes (syringe prescription and/or drug paraphernalia laws in force, and no SEPs), expert medical testimony could show that the proper standard of care is to prescribe needles to known IDUs. As discussed, practice guidelines are not dispositive, but can be introduced as evidence as to the proper standard of care. The AMA, the Centers for Disease Control and Prevention, and the National Commission on AIDS have recommend the use of clean needles and syringes for IDUs.¹⁰⁰ Some physicians may already participate in SEPs or even supply needles to their patients.

C. Duty to Third Parties

Issues of legal duty may extend to others beyond the doctor-patient or pharmacist-patient relationship. Important questions about the physician's (or pharmacist's) potential duty include:¹⁰¹ (1) Does the physician have a duty to protect those who share injection equipment with their IDU patients?, (2) If so, how can the physician satisfy this duty (by educating patients on the correct use of sterile syringes, by providing prescriptions for sterile syringes, or by directly warning the third party of the potential risk)?, and (3) Does the physician have a duty to protect third parties by not providing syringes, and thus not providing the instrumentality that could cause harm to others if used incorrectly?

⁹⁹ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 251-53.

¹⁰⁰ See *supra* note 94.

¹⁰¹ This section will focus on the application to physicians, although similar reasoning, if not law, may be applied to pharmacists.

Generally, an individual has no duty to control the conduct of another or to warn third parties who are in danger as a result of such conduct. Aside from a possible moral obligation, there is no legal duty to help another in danger.¹⁰² A duty to prevent harm or to warn of the risk of harm, however, may arise out of a special relationship, such as the physician-patient or therapist-patient-relationship described in *Tarasoff v. Regents of the University of California*.¹⁰³

In *Tarasoff*, the court held that when a therapist is aware that a patient poses a danger to a foreseeable third party, she must take reasonable measures to warn or protect that third party.¹⁰⁴ Preventing the danger the patient poses to others justifies the resulting breach of the confidential relationship between the therapist and patient. *Tarasoff* reaffirmed that the physician-patient relationship can create positive duties to third parties, and established a common law duty to take steps to protect (to warn or to warn others who might protect)

¹⁰² See *Cairl v. State*, 323 N.W.2d 20 (Minn. 1982) (holding that there is only a duty to warn when specific threats are made against specific victims); *Williams v. Sun Valley Hosp.*, 723 S.W.2d 783 (Tex. Ct. App. 1987) (holding that a hospital does not have a blanket responsibility over its patients and has no duty to protect third parties from unpredictable behavior); see also KEETON ET AL., *supra* note 73, § 30, at 375 (discussing the expert swimmer who sees another person drowning has no duty to help the person).

¹⁰³ See *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 343-45 (Cal. 1976) (finding psychotherapist liable to warn others of dangers posed by a patient). The *Tarasoff* court relied on the comments to section 319 of the Restatement (Second) of Torts. *Id.* at 343 (referencing RESTATEMENT (SECOND) OF TORTS §§ 315-19 (1965)). The first illustration of section 319 describes a hospital that negligently fails to diagnose or treat properly a patient with a communicable disease. See RESTATEMENT (SECOND) OF TORTS § 319 cmt. a, illus. 1 (1965). The second illustration describes a hospital that negligently allows a delirious smallpox patient to escape. See *id.*, cmt. a, illus. 2. Since the hospital failed in its duty to its patient, the consequences of that failure extended the risk to foreseeable others.

¹⁰⁴ Most jurisdictions have adopted this doctrine in some form. Some courts limit a *Tarasoff*-type duty to situations in which the victim is readily identifiable. See *Higgins v. Salt Lake County*, 855 P.2d 231 (Utah 1993) (holding a therapist owes a duty to third parties when a patient is a likely danger to an individual or a distinct group of individuals). In fact, in most cases that follow *Tarasoff*, the tendency is to limit the duty to a third party to those who are readily identifiable. California has a statute that limits liability of therapists to only identifiable and foreseeable third parties; see also Cal. Civ. Code § 43.92(a) (West 2000). But see *Hamman v. County of Maricopa*, 775 P.2d 1122 (Ariz. 1989) (finding that a psychiatrist's duty to warn third persons is not limited to those third persons who have been targets of direct threats, but also includes foreseeable victims who are subject to risk as a result of a patient's conduct; vacating Court of Appeal's opinion in part and remanding for further proceedings).

an identifiable third party of dangers that a physician knew or should have known were posed by a particular patient. A duty to third parties may require disclosure of otherwise confidential information to third parties, or it may merely mandate the disclosure of information, about the risks, directly to the patient.

In the context of communicable diseases, some cases have imposed a positive duty on physicians to protect third parties from a patient's communicable disease, particularly when the physician failed to warn the patient or the regular sex partner of the patient.¹⁰⁵ A physician may breach this duty by failing to inform the patient of exposure to or diagnosis of a communicable disease, by failing to warn the patient of the dangers associated with the communicable disease, or by giving erroneous advice to the patient.¹⁰⁶ Inadequate care of the patient amounts to a breach of duty and causes a danger to third parties.¹⁰⁷

No cases have imposed a similar duty on physicians in relation to syringe-sharing partners of IDUs. Current public preventive care guidelines recommend that physicians should

¹⁰⁵ See *DiMarco v. Lynch Homes-Chester County, Inc.*, 559 A.2d 530, 534 (Pa. 1989). But see Lawrence O. Gostin, et al., *Legislative Survey of State Confidentiality Laws, with Specific Emphasis on HIV and Immunization* (Final Report presented to the U.S. Centers for Disease Control & Prevention, the Council of State & Territorial Epidemiologists, and the Task Force for Child Survival—Carter Presidential Center, 1997). Most state statutes governing HIV-related information do not impose a duty to warn third parties of potential exposure. Instead, HIV-statutes usually shield physicians or health departments from liability for failure to warn and permit them to warn sex or needle-sharing partners only when certain conditions are met. See *id.*

¹⁰⁶ See *DiMarco*, 559 A.2d at 534; see also *Myers v. Quesenberry*, 144 Cal. App. 3d 888 (1983) (holding that a physician has a duty to take reasonable steps to protect foreseeable victims of patient's dangerous contact). This has occurred in at least one AIDS related case, see *Reisner v. Regents of Univ. of Cal.*, 37 Cal. Rptr. 2d 518, 522 (Ct. App. 1995) (finding physician liable for not warning the third party victim to take precautionary measures). In this case, a young girl contracted HIV through a blood transfusion, and her physician did not inform her that she had been infected with HIV. A few years later, her boyfriend became infected and sued.

¹⁰⁷ In these situations, the existence of a third party is presumed. See *Gooden v. Tips*, 651 S.W.2d 364 (Tex. App. 1983) (commenting that jurisdictions outside of Texas have allowed third parties to bring causes of action against a physician for the physician's negligent treatment of a patient and holding that it was inappropriate to grant the defendant's motion for summary judgment). Thus, the physician has a duty to provide reasonable care in order to protect family members. See *Shepard v. Redford Community Hosp.*, 390 N.W.2d 239 (Mich. Ct. App. 1986) (holding that although a medical specialist is held to a "national standard of care," lack of supplies and equipment locally may justify differences in treatment).

counsel IDU patients to stop using drugs or adopt safe injection practices. These guidelines suggest that the standard of care may soon include a duty to adequately inform IDU patients of the risk of transmission via contaminated syringes, and to counsel IDUs on how to avoid infection through safe injection practices. The guidelines present a weaker argument for an affirmative duty to assist IDUs to obtain sterile syringes. The guidelines provide no support for the proposition that physicians have a duty to protect third parties *by refusing to prescribe*. Physician refusal to prescribe is neither necessary nor sufficient to protect IDUs' partners and may actually increase their risk of harm by increasing the risk that IDUs will use contaminated syringes.

When caring for IDUs, physicians may satisfy any duty to third parties by informing the patient of the risk of transmission and a reasonable means to avoid transmission (i.e., use of sterile syringes and condoms.) When IDUs have no legal access to syringes, physicians could ethically choose to prescribe syringes, in part, to protect the patient's sexual and needle-sharing partners and children from possible future infection.

D. Responses to Otherwise Prohibited Acts: Civil Disobedience and Medical Necessity

"A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."¹⁰⁸ A physician's duty extends beyond providing care for his or her patient. Physicians should work to change laws that are contrary to the best interests of their patients.¹⁰⁹ "Professional ethical responsibilities exist beyond statute and may require defiance of the statute."¹¹⁰ Thus, not only should a physician assist IDUs in accessing sterile syringes, but they should also work to change the laws that restrict access.

When faced with an apparently unjust law or one that conflicts with their ethical obligations, public health goals, or personal morals, physicians may quietly comply with the law, work

¹⁰⁸ AM. MED. ASS'N, COUNCIL ON ETHICAL & JUD. AFFAIRS, *supra* note 68, at xiv.

¹⁰⁹ *See id.*

¹¹⁰ ROBERT HUNT SPRINKLE, PROFESSION OF CONSCIENCE: THE MAKING AND MEANING OF LIFE-SCIENCES LIBERALISM 115 (1994).

to change it, or break the law in order to achieve some higher goal. When physicians opt to break the law and perform some legally prohibited act (e.g., providing syringes to IDU patients in some settings) they may characterize their actions as civil disobedience or claim the defense of medical necessity.

1. Civil disobedience

The concept of civil disobedience has deep roots in American political, social, and cultural history.¹¹¹ Acts of civil disobedience highlight injustices in society. Civil disobedience is one means of taking action to bring about change.¹¹² One hundred fifty years ago, Henry David Thoreau argued that people should refuse to follow laws that they believe are unjust:

[I]f it [the injustice] is of such a nature that it requires you to be the agent of injustice to another, then, I say, break the law...What I have to do is to see, at any rate, that I do not lend myself to the wrong which I condemn.¹¹³

Thoreau's words speak directly to the issue at hand. Physicians may face a conflict between their moral and ethical obligations to their patients and their legal obligations as a member of society. Medical evidence demonstrates the importance of sterile syringes for IDUs. In this context, physicians and pharmacists may conclude that the legal and structural obstacles are unjust.¹¹⁴ When a physician or pharmacist believes her moral obligations outweigh her legal obligations, civil disobedience may result.¹¹⁵

¹¹¹ For a general review of civil disobedience in American history, see Bruce Ledewitz, *Civil Disobedience, Injunctions, and the First Amendment*, 19 HOFSTRA L. REV. 67, 71-80 (1990). See also Martin C. Loesch, *Motive Testimony and a Civil Disobedience Justification*, 5 NOTRE DAME J.L. ETHICS & PUB. POL'Y 1069, 1072-88 (1991).

¹¹² See E.R. Shipp, *Errors of Omission*, WASH. POST, June 3, 1999, at B6 (discussing anti-war protests); see also Laura Brown, *By His Own Hand*, BOSTON HERALD, Nov. 30, 1996, at 8 (discussing anti-abortion protests).

¹¹³ HENRY DAVID THOREAU, *WALDEN AND CIVIL DISOBEDIENCE* 243 (Sherman Paul ed., Houghton Mifflin Co. 1960) (1854 & 1849).

¹¹⁴ See discussion *infra* Part III.B.1.

¹¹⁵ See Loesch, *supra* note 111, at 1087-90. See generally Mark E. DeForrest, Comment, *Civil Disobedience: Its Nature and Role in the American Legal Land-*

In order for an action to legally constitute civil disobedience, there are four elements that need to be met: (1) the act must be illegal, (2) the act must be "predominantly nonviolent," (3) the act must be intended to rouse the notice of the community to the illegal action, and (4) the actor must be willing to accept punishment for his action.¹¹⁶ Acting within this framework, physicians and pharmacists can use civil disobedience as a vehicle for social and political change. Two areas of medical practice illustrate instances in which some physicians have refused to obey what they perceive to be unjust laws.

Before *Roe v. Wade*¹¹⁷ was decided in 1973, establishing a woman's right to choose to have an abortion, many physicians challenged state and federal abortion statutes. Some brought suits challenging the laws on their construction or their impact on patient care.¹¹⁸ Others chose to act in their patient's best interests, independent of legal constraints. For example, California's Therapeutic Abortion Act of 1967 permitted physicians to perform abortions only in cases where the procedure was necessary to preserve the life of his or her patient.¹¹⁹ This vague language allowed physicians to exercise discretion in determining when to perform an abortion. Although this resulted in more patients obtaining abor-

scape, 33 GONZ. L. REV. 653, 660-63 (1997) (discussing the interplay between moral order and enacted law in regard to civil disobedience).

¹¹⁶ See DeForrest, *supra* note 115, at 655-60; see also Loesch, *supra* note 111, at 1092-94 (enumerating and discussing some of the constituent elements of civil disobedience).

¹¹⁷ 410 U.S. 113 (1973) (holding that a woman has Ninth and Fourteenth Amendment protection over reproductive choices including abortion).

¹¹⁸ See, e.g., *Doe v. Dunbar*, 320 F. Supp. 1297 (D. Colo. 1970) (determining standing under Colorado's therapeutic abortion act); *Poe v. Menghini*, 339 F. Supp. 986 (D. Kan. 1972) (holding that objectionable provisions of Kansas abortion statutes may be severed without perverting ultimate purpose of therapeutic abortions); *Kenan v. Warren*, 328 F. Supp. 525 (W.D. Wis. 1971) (granting motion to temporarily enjoin proceedings against physician performing abortions upon unquickened embryos based on the finding that both physician and women had constitutional right to perform or seek abortions, respectively); *Planned Parenthood Ctr. of Tucson, Inc. v. Marks*, 497 P.2d 534 (Ariz. Ct. App. 1972) (holding state abortion statutes are ambiguous, and as applied, are invalid since they deprive petitioners of liberty without due process of law); *People v. Barksdale*, 503 P.2d 257 (Cal. 1972) (holding that abortion statute did not give adequate notice to physician of the prohibited conduct or of procedures constituting compliance); *Beecham v. Leahy*, 287 A.2d 836 (Vt. 1972) (challenging Vermont law prohibited abortion except where mother's life in danger).

¹¹⁹ Therapeutic Abortion Act, ch. 327, § 1, 1967 CAL. STATS. 1535 (codified as amended at CAL. HEALTH & SAFETY CODE §§ 25950-25955.3 (1995)).

tions, courts did not always endorse physicians' judgments.¹²⁰ As a result, patients were able to obtain abortions through the help of their physicians acting in the best interests of their patients.¹²¹ Ultimately, the Supreme Court established the assumption that physicians had acted in the patient's best interest unless proven otherwise.¹²²

In a more recent example, many physicians and professional associations emphatically signaled their intention to disobey the law after California adopted Proposition 187 in 1994. This proposition required doctors, nurses, social workers, and teachers to report any patient, client, or student that they might suspect to be an illegal immigrant to authorities.¹²³ Because physicians' ethics, medical care, and patient confidentiality were endangered by the proposition, the AMA's policy-making body condemned Proposition 187.¹²⁴ The AMA voted to oppose any federal regulations that required physicians to determine the immigration status of their patients before treating them.¹²⁵ In addition, the 298,000 member AMA reaffirmed its position requesting Congress to provide adequate funds for existing healthcare programs for ille-

¹²⁰ Compare, e.g., *People v. Belous*, 458 P.2d 194, 198-206 (Cal. 1969) (holding that physician's convictions of abortion and conspiracy could not stand when the term "necessary to preserve" was not susceptible to a construction that could satisfy due process), and *People v. Abarbanel*, 239 Cal. App. 2d 31, 33 (Dist. Ct. App. 1975) (holding that there was no showing that the physician performed the abortion for a purpose other than to save the mother's life), with *People v. Wellman*, 149 N.W.2d 908 (Mich. App. 1967).

¹²¹ See, e.g., *Belous*, 458 P.2d at 206; *Abarbanel*, 239 Cal. App. 2d. at 34-35.

¹²² See *United States v. Vuitich*, 402 U.S. 62, 71 (1971) (explaining that medical standards, malpractice law, and societal expectations provide physicians with motivation to properly care for their patients).

¹²³ See Vincent Iacopino & Thomas Crane, *Prop. 187: A Prescription for Disaster*, S.F. CHRON., Oct. 31, 1994, at A22 (condemning Proposition 187 as "a prescription for a medical ethics, public health and human rights disaster").

¹²⁴ See *Nation In Brief—AMA: Proposition 187 is Bad Medicine*, ATLANTA J. & CONST., Dec. 8, 1994, at C6 (reporting AMA's vote to oppose Proposition 187 because it poses substantial health risks to California residents and presents a "breach of physician ethics and patient confidentiality"); see also Sandra Jacobs, *Immigration Policy Blamed for TB's Comeback: Tracking Infected People Essential*, TIMES-PICAYUNE, Apr. 23, 1995, at A27 (noting the belief of some physicians that Proposition 187 would hurt efforts to control tuberculosis).

¹²⁵ See *AMA Condemns Proposition 187*, DES MOINES REG., Dec. 8, 1994, at 7 (announcing AMA's reaction to California's proposal to deny all state benefits except emergency care to illegal immigrants).

gal aliens.¹²⁶ The AMA's president-elect, Dr. Lonnie Bristow, said that the California measure poses "a breach of physician ethics and patient confidentiality."¹²⁷

In both these cases, pre-*Roe v. Wade* abortion laws and Proposition 187, physicians also protested government intrusion into the doctor patient relationship.¹²⁸ This theme of seeking to preserve areas of medical decision-making from government interference could also be raised by physicians willing to prescribe syringes. Physicians have broken the law in other contexts as well. Studies indicate that many physicians have lied to insurers and other third-party payors to ensure their patients receive the proper care and coverage.¹²⁹ Others have lobbied for the use of illegal drugs for medicinal purposes,¹³⁰ while some have prescribed fatal doses of medication for terminally ill patients who seek help in ending their own lives.¹³¹

Presently, the existing laws in most states make it risky for health care providers such as physicians and pharmacists to provide sterile syringes for IDUs.¹³² Therefore, the actions taken by physicians and pharmacists to actively provide access for IDUs to sterile syringes would constitute an illegal action that satisfies the first requirement for civil disobedience. Physicians' and pharmacists' actions of prescribing or dispensing syringes

¹²⁶ See *AMA Board Votes to Oppose Proposition 187*, THE RECORD, Dec. 8, 1994, at A27.

¹²⁷ *AMA Condemns Proposition 187*, *supra* note 125.

¹²⁸ See, e.g., *Abele v. Markle*, 452 F.2d 1121 (2d Cir. 1971) (arguing that Connecticut abortion laws violate the constitutional rights of female physicians); *Doe v. Bolton*, 319 F. Supp. 1048 (N.D. Ga. 1970) (challenging validity of state statute that interfered with physicians' ability to adequately counsel women seeking abortions); *Walsingham v. State*, 250 So.2d 857, 862 (Fla. 1971) (stating that the government should not hinder physician's ability to decide how to best care for patients); *Iacopino & Crane*, *supra* note 123; *AMA Board Votes to Oppose Proposition 187*, *supra* note 126.

¹²⁹ See Victor G. Freeman et al., *Lying for Patients: Physician Deception of Third-Party Payers*, 159 ARCHIVES INTERNAL MED. 2263 (1999) (ascertaining situations in which physicians would deliberately deceive third-party payers in order to get the payers' approval for care that was medically indicated).

¹³⁰ See generally Abbie Crites-Leoni, *Medicinal Use of Marijuana: Is the Debate a Smoke Screen for Movement Toward Legalization?*, 19 J. LEGAL MED. 273 (1998); Matthew W. Grey, Comment, *Medical Use of Marijuana: Legal and Ethical Conflicts in the Patient/Physician Relationship*, 30 U. RICH. L. REV. 249 (1996).

¹³¹ See Derrick A. Carter, *Knight in the Duel with Death: Physician Assisted Suicide and the Medical Necessity Defense*, 41 VILL. L. REV. 663 (1996).

¹³² See Gostin & Lazzarini, *supra* note 4.

are acts that take place everyday in physicians' offices and pharmacies without any threat to the peace. In fact, their actions "demonstrate that they assume the responsibility of community membership and act with the best interests of the community in mind."¹³³

By prescribing in the regular course of medical practice or dispensing during the course of pharmacy business, physicians and pharmacists make a conscious and public statement about the injustice of the status quo. The degree of attention society gives to such acts may vary, but one purpose of civil disobedience is to demonstrate to society, and the governing bodies that oversee it, that the existing laws are unjust.¹³⁴ Where physicians and other health care providers pursue civil disobedience, they must be willing to accept the consequences associated with their actions.¹³⁵ For professionals such as physicians and pharmacists, who may face loss or suspension of licensure or even criminal penalties, this represents a serious factor.

2. Medical necessity

Breaking the law, however, need not result in punishment if physicians successfully claim a defense such as medical necessity. The defense of necessity, generally, is that there are times when individuals should be free from legal restraints in order to prevent imminent harm, or to provide services that preserve life and health.¹³⁶

For a physician to invoke the medical necessity defense, in general, he or she must demonstrate four elements: (1) he or she acted to avoid or prevent an imminent harm, (2) there were no reasonable legal alternatives to violating the law, (3) the harm of the act was not disproportionate to the harm avoided, and (4) there was a reasonably anticipated causal relationship between

¹³³ Loesch, *supra* note 111, at 1093.

¹³⁴ See DeForrest, *supra* note 115, at 658 (citing Paul J. Weber, *Toward a Theory of Civil Disobedience*, 13 CATH. LAW 198, 202 (1967)).

¹³⁵ See *id.* at 659.

¹³⁶ See Steven M. Bauer & Peter J. Eckerstrom, *The State Made Me Do It: The Applicability of the Necessity Defense to Civil Disobedience*, 39 STAN. L. REV. 1173, 1174 (1987) (citing *United States v. Bailey*, 444 U.S. 394, 409-11 (1980)); *Doe v. Busbee*, 471 F. Supp. 1326, 1328 (N.D. Ga. 1979) (discussing Medicaid reimbursement for abortion and other medically necessary services). For a general discussion of the necessity defense, see *State v. Marley*, 509 P.2d 1095, 1109 (Haw. 1973).

the act and the harm avoided.¹³⁷ It should be noted, however, that the defense of medical necessity has been raised in a number of cases where state laws were violated by providing syringes to IDUs and has produced mixed results.¹³⁸

A physician relying on the medical necessity defense needs to show that he or she was acting under a reasonable belief, supported by medical testimony and evidence, and that it was necessary to break the law in order to avoid imminent injury. Ample medical and public health evidence demonstrates that giving IDUs access to sterile syringes to reduce HIV transmission does not increase drug use or crime.¹³⁹ Given the rising numbers of IDU-patients at risk for new infection or transmission of HIV to others,¹⁴⁰ physicians can convincingly argue that providing sterile syringes will avoid imminent infections.

In addition to acting against an imminent harm, a physician should demonstrate that there was no reasonable legal alternative to prevent the spread of HIV besides providing sterile syringes. Although physicians have other options, when examined

¹³⁷ See Bauer & Eckerstrom, *supra* note 136, at 1175; James L. Cavallaro, Jr., Case Note, *The Demise of the Political Necessity Defense: Indirect Civil Disobedience and United States v. Schoon*, 81 CAL. L. REV. 351, 356 n.31 (1993) (citing WAYNE R. LAFAVE & AUSTIN W. SCOTT, JR., CRIMINAL LAW § 5.4(d) (2d ed. 1986)); see also *United States v. Cassidy*, 616 F.2d 101, 102 (4th Cir. 1979) (discussing how reasonable belief alone, without other defense elements, is not sufficient to prove the defense of necessity). Cf. *Jenks v. State*, 582 So. 2d 676, 679 (Fla. Dist. Ct. App. 1991) (holding that the elements of medical necessity are (a) that the defendant did not intentionally bring about the circumstances precipitating the unlawful act, (b) that the defendant could not accomplish the same objective using a less offensive alternative, and (c) the evil sought to be avoided was more heinous than the unlawful act perpetrated to avoid it).

¹³⁸ Compare *Commonwealth v. Leno*, 616 N.E.2d 453 (Mass. 1993) (holding physician was not entitled to necessity defense since harm was not imminent), *State v. McCague* 714 A.2d 937, 942-43 (N.J. Super. Ct. App. Div. 1998) (holding the defense inapplicable since the danger was not imminent) and *State v. Sorge*, 591 A.2d 1382 (N.J. Super. Ct. Law Div. 1991) (refusing to dismiss action against defendant activists on the grounds that their actions were not such an extraordinary and unanticipated mitigation that it clearly would have been exempt by the legislature had the idea occurred to the legislature), with *People v. Bordowitz*, 588 N.Y.S.2d 507 (N.Y. Crim. Ct. 1991) (allowing use of the medical necessity defense) and *People v. Monroe*, 593 N.Y.S.2d 742 (N.Y. Crim. Ct. 1992) (holding that defendant was not exempt from the ban on possession of hypodermic needles because he was a participant in Dept. of Health's needle exchange program).

¹³⁹ See PANEL ON NEEDLE EXCH. & BLEACH DISTRIB. PROGRAMS, *supra* note 7, at 251-53.

¹⁴⁰ See discussion *infra* Part III.B.2 (discussing the rising numbers of AIDS cases directly or indirectly related to injection drug use).

closely, they are neither as effective nor reasonable solutions.¹⁴¹ Physicians could counsel IDU-patients to stop using drugs, stop injecting, or enter treatment. Unequivocally these options, if successful, would benefit the patient and reduce their HIV risk. Physicians should attempt to persuade IDUs to take one of these steps. However, many IDUs are unready to stop or unable to enter treatment when they are ready. Additionally, physicians could counsel patients to use only sterile equipment obtained in pharmacies or SEPs. As demonstrated, however, the legal climate does not always permit IDUs to obtain syringes this way, and thus, this is not a viable option. Therefore, the only reasonable and effective means of preventing the transmission of deadly blood-borne diseases by injection drug use, for patients who are unable or unwilling to quit, is to ensure that the patients use sterile syringes when injecting drugs.

Coupled with the lack of reasonable legal alternatives, the action taken should not be disproportionate to the harm avoided.¹⁴² Specifically, the physician should show that his or her breaking of the law produces less harm than that resulting from the spread of HIV and other blood borne diseases. Beyond the arguments based on economic costs, compassion argues that IDUs should be permitted to avoid deadly infections where simple means of prevention exist. Additionally, protecting IDUs from HIV and hepatitis will also benefit the public health, both directly through fewer cases of disease among IDUs and indirectly through fewer cases among their sex partners and children.

Finally, the physician needs to show that there was a direct causal relationship between his or her action and the imminent harm avoided. While some courts have recognized availability of sterile syringes as a means to prevent imminent harm, others have not.¹⁴³ Arguably, physicians providing IDUs access to sterile syringes fulfill this test. The problem of transmission and spread of HIV, as well as other blood borne diseases, is directly related to the use of contaminated syringes by IDUs. Substantial

¹⁴¹ See Bauer & Eckerstrom, *supra* note 136, at 1180 (discussing fact that legal alternatives must not simply be available, but effective alternatives to problem).

¹⁴² See *United States v. Bailey*, 444 U.S. 394, 409-10 (1980) (describing how actors can make the defense of necessity when the actor is forced to choose the lesser of two evils).

¹⁴³ For a listing of cases where courts have and have not recognized sterile syringes as legal means to prevent imminent harm, see *supra* note 138.

evidence suggests that providing IDUs with sterile syringes will reduce the risk of disease transmission.

Official state action to consider, accept, or reject various public health measures also may pose problems for those claiming medical necessity as a defense or seeking to challenge existing laws in other ways. Where defendants have violated the law, arguing medical necessity as a defense, courts have often looked at whether the legislature has already considered the health threat in question. Where the legislature has already acted, courts have tended to defer to its determinations. For example, in one case, the court rejected arguments of medical necessity where the legislature had defeated a proposal to liberalize access to syringes.¹⁴⁴

IV. CONCLUSION

Although the topic of drug use and the correct stance of the government and private practitioners in dealing with IDUs continues to excite emotions and raise substantial debate, a careful analysis of ethical and legal duties suggests a more active and positive role for physicians and pharmacists in preventing HIV infection among IDUs than has often been described. Physicians' primary responsibility to help their patients extends to protecting the health of their drug-addicted patients who cannot, or will not, stop injecting drugs. Where no legal means exist for IDUs to access sterile syringes, and therefore, practice safe injection, physicians can easily argue that ethical imperatives support providing prescriptions to IDUs as part of a comprehensive HIV prevention and care strategy. Pharmacists, also ethically bound to put "the well-being of [their] patient[s] at the center of [their] professional practice[s],"¹⁴⁵ can argue that similar imperatives support their filling of such prescriptions.

From a legal perspective, physicians could argue that prescribing syringes fits easily within an evolving standard of care based on new empirical evidence, practice guidelines, and the views of a respectable and qualified minority. Pharmacists can argue that the legal standard of risk management supports their filling prescriptions for syringes for IDUs and their active role in counseling IDUs on safe injection practices and disposal of

¹⁴⁴ See *Commonwealth v. Leno*, 616 N.E.2d 453, 455 (Mass. 1993).

¹⁴⁵ American Pharm. Ass'n, *supra* note 41.

syringes. The weight of arguments in this analysis of ethical and legal approaches to the question of prescribing syringes to IDUs suggests that prescribing and/or dispensing syringes is ethically permissible. Less evidence supports a general affirmative obligation to prescribe or dispense.

Laws do exist that might be invoked against physicians, pharmacists, or IDUs. The approach of the courts to such cases remains difficult to predict. At least theoretically, the defense of medical necessity provides an option for any of these parties, should criminal charges be brought against them.