Alosetron for irritable bowel syndrome

Sir—Michael Camilleri and colleagues (March 25, p 1035) report that alosetron is an effective treatment for irritable bowel syndrome (IBS). However, the US Food and Drug Administration (FDA) Medical Officer’s Review (now available at www.fda.gov/cder/approval/index.htm; accessed on Nov 12, 2000), which we originally obtained through the US Freedom of Information Act, has led us to question some of the analyses presented in the article.

The graphic techniques used by Camilleri and colleagues greatly exaggerate alosetron’s efficacy. Their figure 3 presents the relative difference in pain and discomfort scores from baseline on a 0–4 scale for the treated and placebo groups. Presented this way, the drug seems effective. However, when we plotted the absolute data contained in the Medical Officer’s Review, the data points are almost superimposable (figure). The exclusion of the baseline data from Camilleri and colleagues’ figure 3, unusual in a graph of this type, has the additional effect of enlarging the Y axis, and creating an apparent greater benefit for the drug.

The important finding that efficacy was confined to diarrhoea-predominant patients and was not evident among patients who alternated between diarrhoea and constipation (alternators) is relegated to a single sentence in the results. The FDA used this subgroup analysis as the basis for denying approval of the drug for use in alternators. Instead, Camilleri and colleagues concentrate overwhelmingly on the marginal benefits of the drug in the full study population, which they describe in their report’s title as IBS patients, obscuring the fact that they provide no evidence of benefit in the primary outcome variable in constipation-predominant patients (who were excluded) or alternators. This form of data presentation could lead to overprescribing.

Moreover, whether the diarrhoea-predominant patients even had diarrhoea is unclear. The medical officer reviewing the study stated: “Patients considered by investigators to fit the diarrhoea-predominant subtype had at baseline . . . stool consistency values that were neither loose nor watery”.

The Medical Officer’s Review is dated Nov 4, 1999, well before Camilleri and colleagues’ report went to press. Since five of the six investigators are employees of the pharmaceutical company that generated these data, the Medical Officer’s Review should have come to their attention in time to be incorporated into the final draft of the report. These discrepancies raise important questions about data presentation in studies sponsored by pharmaceutical companies.

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**Trend in absolute pain and discomfort scores**

![Graph showing trend in absolute pain and discomfort scores](image)

We clearly stated that benefit was seen in diarrhoea-predominant patients, but not in alternators, compared with placebo.

The new drug application for alosetron was submitted for women with diarrhoea-predominant IBS; this information is available. The assertion that over prescribing might occur based on our use of the term IBS in the title is without foundation.

We disagree that it is unclear whether the diarrhoea-predominant patients even had diarrhoea. Stratification of patients into IBS subtype was done independently by the enrolling physician on the basis of the patient’s predominant bowel pattern during at least 6 months before entry to the study, and this is clearly stated. This stratification was independent of stool-consistency scores collected in the 2-week screening period, which was too short to diagnose diarrhoea-predominant IBS according to the Rome criteria, but was useful to avoid inclusion of patients who were constipated at study entry. Additionally, there is no definition of diarrhoea that is widely accepted on the basis of stool consistency.
Thyroid disease classification

Sir—Although an open discussion about controversial medical issues is always useful for the scientific community, we think that D Poller and colleagues’ letter (Aug 19, p 679)¹ should be viewed carefully.

Poller and colleagues confirm that fine-needle aspiration (FNA) cytology should be used primarily to diagnose benign thyroid disease rather than as a means of diagnosis of malignant disease. In a previous report they propose the use of a five-point working system for thyroid FNA: THY1 inadequate; THY2 benign; THY3 indeterminate; THY4 suspicious; THY5 malignant. The practical importance of the use of an indeterminate classification (THY3) was stressed. With this apparently new approach to the preoperative characterisation of thyroid lesions, which is focused on the detection of true morphological features of benign thyroglobulins, they could exclude about the third of patients who had benign nodules from further assessment or treatment, with a low number of false-negative FNAs. The difficulty is knowing how the remaining two-thirds of lesions are classified and how these lesions will behave.

We believe that this approach to FNA cytology for nodular thyroid lesions does not represent a new and improved diagnostic method. To look at the cytological preparation from a different perspective cannot resolve the diagnostic limits of conventional cytology. The proposed THY3 and THY4 classifications seem an alternative and elegant method for masking diagnostic failure. Furthermore, we are perplexed by the clinical value of THY3 diagnostic category, especially if malignant lesions fall in this group.

Among 156 thyroid FNA, Poller and colleagues discovered six malignant thyroid lesions (five papillary carcinomas and one follicular carcinoma), five of which were included in non-malignant diagnostic categories (THY1, THY3, THY4). Among 50 multinodular hyperplasias, only 14 were classified as benign (THY2), whereas 12 were classified as indeterminate (THY3), 12 suspicious (THY4), one malignant (THY5), and 11 inadequate (THY1). Given the limited number of cases studied (sensitivity and positive predictive value for each of the diagnostic categories THY2, THY3, THY4, and THY5 were assessed on 17, 15, 24 and two cases, respectively)

we are sceptical that this approach can be comparable to any immuno- cytochemical method in which the morphological interpretation can be supported by immunodetection with a true marker of thyroglobulin transformation (ie, galectin-3) using a cheap and simple test.²

Moreover when thyroid FNA is used for a diagnosis of exclusion, the artificial expansion of the diagnostic categories including undefined and suspicious thyroid lesions will increase, rather than reduce, the number of unnecessary surgical treatments.

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Authors’ reply

Sir—We entirely agree with Armando Bartolazzi and Alessandra Gasbarri that our approach to FNA cytology still leaves the difficulty of how to manage two-thirds of patients who do not have a benign thyroid FNA. The point of our letter was to emphasise that, with strict adherence to cyto pathological and morphological criteria it is possible to accurately diagnose benign thyroid disease, which avoids the need for surgery in patients with benign (THY2) aspirates.

Our approach is not a new or improved diagnostic method but neither is it a means of masking our own diagnostic failure. Our system of thyroid FNA reporting is merely a different philosophical approach to that adopted by Bartolazzi and colleagues. If the principle is accepted that the purpose of thyroid FNA is to exclude benign disease, it does not matter that some FNA aspirates do not give a definitive answer as to whether a given lesion is benign or malignant. Patients with aspirates reported as indeterminate (THY3) or suspicious (THY4) can be managed according to agreed guidelines; generally reaspiration if indeterminate (THY3) or excision by lobectomy if (THY4).

Alopecia and cardiovascular events

Sir—Veikko Matilainen and colleagues (Sept 30, p 1165)¹ discuss the relation between androgenetic alopecia and serious cardiovascular events. We suppose that this type of metabolic disorder in men, including insulin resistance, hyperinsulinaemia, obesity, hypertension and dyslipidaemia, is equivalent to polycystic ovarian syndrome in women.²³

Androgenetic alopecia could be interpreted as a disorder of the same origin as hirsutism in women with polycystic ovarian disease. The metabolic disorders characteristic for this disorder also seems to be a risk factor for increased mortality from serious cardiovascular events.⁴ Genetic investigations would be necessary in the families of women who have polycystic ovaries syndrome and men presenting with androgenetic alopecia.

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1 Medical Team Leader Review 1999.
Physician Prescribing of Sterile Injection Equipment To Prevent HIV Infection: Time for Action

Scott Burris, JD; Peter Lurie, MD, MPH; Daniel Abrahamson, JD; and Josiah D. Rich, MD, MPH

Injection drug users, their sex partners, and their children are at high risk for acquiring HIV infection and other bloodborne diseases. The risk for disease transmission in the United States is partly the result of restricted access to sterile injection equipment. Physicians and pharmacists can play an important role in providing syringe access by prescribing and dispensing syringes to patients who use injection drugs and cannot or will not enter drug treatment. Prescribing and dispensing injection equipment are ethical, clinically appropriate, and fully consistent with current public health guidelines on disease prevention. An analysis of the laws of the 50 U.S. states, the District of Columbia, and Puerto Rico finds that physicians in nearly all these jurisdictions may legally prescribe sterile injection equipment to prevent disease transmission among drug-using patients and that pharmacists in most states have a clear or reasonable legal basis for filling the prescriptions. Given these medical and legal findings, physicians may wish to take a larger role in improving access to sterile injection equipment by prescribing this equipment for their patients where this practice is legal, and by joining efforts to change the law where it poses a barrier.

For author affiliations and current addresses, see end of text.

More new cases of HIV infections have been predicted to occur among injection drug users than among any other risk group in the United States (1). The sharing of syringes is the leading source of AIDS in women and children (2, 3) and is a leading cause of transmission of the hepatitis viruses (4, 5). The reuse of syringes is a known risk factor for acute bacterial endocarditis, subcutaneous abscesses, and cellulitis. Thus, addressing the sharing-and reuse of syringes by injection drug users and the scarcity of syringes that encourages these practices (6, 7) is a major public health priority.

A web of state rules on syringe prescription, drug paraphernalia, and pharmacy practice restricts the sale and possession of injection equipment and, in effect, makes physicians and pharmacists the gatekeepers to syringe access. A prescription is required to purchase a syringe under at least some circumstances in 14 states and can facilitate purchase in most states insofar as the pharmacist has legal responsibility for proper syringe sales. In light of the consensus among public health and medical authorities that injection drug users should use sterile injection equipment for every injection (8–10), we argue that physicians treating patients who use injection drugs should consider protecting their patients from bloodborne diseases by prescribing sterile injection equipment when appropriate.

In the past, physicians who wished to prescribe syringes have been deterred by the widespread perception that doing so would violate state and federal laws aimed at combating drug abuse (11–13). Today, medical evidence has established that providing safe injection equipment to injection drug users, although not a panacea, prevents HIV and other bloodborne infections and does not increase drug abuse (3, 14). This evidence compels a reassessment of the legality of providing injection equipment by prescription because the law that governs prescription and dispensing of injection equipment uses a standard of "medical necessity."

In an analysis of the legality of prescribing and dispensing syringes through the health care system (reported here), we found that both prescribing and dispensing sterile injection equipment are legal in most states. Where legality is in doubt, physicians and pharmacists should strongly consider advocating the elimination of legal barriers to safe injection.

Public Health, Clinical, and Ethical Dimensions of Syringe Prescribing

A recent HIV/AIDS Prevention Bulletin (8) from the U.S. Department of Health and Human Services establishes a standard of care for patients who use injection drugs (Table 1). The Department suggests that health care workers counsel injection drug users who continue using these drugs to use a new sterile syringe each time they prepare and inject drugs. This approach has been endorsed by leading medical and public health organizations (3, 9, 10). Strong evidence suggests that the organized provision of safe injection equipment reduces HIV transmission and
can facilitate entry into substance abuse treatment (3, 15–18). On the basis of this evidence, the Secretary of Health and Human Services certified to the U.S. Congress in April 1998 that needle exchange programs are effective in reducing HIV transmission and do not encourage drug use (19). Prescribing needles also falls within the accepted public health practice of eliminating the vector to reduce the transmission of vector-driven infectious disease (20).

For reasons that include federal funding restrictions and politicians’ reluctance to endorse controversial programs, the existing network of some 134 needle exchange programs cannot on its own satisfy the needs of injection drug users in the United States. Estimates of the annual number of syringes required to meet the single-use standard run in the range of 1 billion (21). The most recent estimate of the number of syringes distributed by needle exchange programs in the United States (1997) was 17.5 million (22). Although pharmacy sales of sterile syringes have increasingly been advocated as a method to supply sterile syringes (23), many pharmacists do not sell syringes to suspected injection drug users (24, 25), and some may demand a prescription even in states that do not legally require a prescription or proof of a legitimate medical purpose (24, 26–28). Furthermore, evidence indicates that some pharmacists are less willing to sell syringes to African-American prospective buyers (25). Some injection drug users may prefer the ready access to ancillary services offered at the needle exchange programs, others the anonymity of the pharmacy, and still others the access to medical care offered by physician prescribing of syringes.

Physician prescribing of syringes thus has the potential to complement existing public health efforts to prevent the transmission of HIV and other bloodborne pathogens among injection drug users, their sex partners, and their children. It has the added advantage of bringing injection drug users with substantial health care needs (29) into contact with the health care delivery system. This affords the opportunity to refer injection drug users to drug treatment and mental health services, to provide an array of preventive services ranging from tuberculosis screening to vaccinations, to counsel these patients about reducing drug- and sexual-risk behaviors, and to treat diagnosed existing conditions, such as HIV infection or hepatitis. Social workers can also attend to the nonmedical needs of injection drug users, such as food and housing. More broadly, physician prescribing of syringes could have considerable symbolic value by underscoring the public health importance of preventing HIV transmission among injection drug users and building professional and institutional support in an area that has, to date, been addressed primarily by public health specialists and lay advocates.

Prescribing sterile injection equipment is certainly appropriate from a clinical perspective. Many injection drug users cannot or will not abstain; others may be willing to try but cannot gain access to drug treatment services. Health care providers are well acquainted with the notion of setting intermediate goals in caring for patients. For example, a physician might suggest that a two-pack-a-day smoker reduce his or her daily tobacco consumption to a single pack because predictable benefits result from even a reduction in smoking.

Existing data suggest the potential effectiveness of prescribing sterile injection equipment. Injection drug users with diabetes in Baltimore, Maryland, were 2.5 times less likely to have HIV infection than other injection drug users, an effect that persisted even after controlling for confounding factors (30). The authors ascribed this finding to better access to sterile syringes among patients with diabetes.

Fundamental ethical principles also support physician prescribing of syringes. The ethical principle of beneficence requires efforts by physicians to maximize benefits and minimize harm to patients (31). Prescribing sterile syringes to injection drug users who continue to use these drugs is clearly consonant with this ethical principle. The absence of evidence that needle exchange programs increase levels of drug use (3, 19) provides reassurance that the principle of nonmaleficence will also be honored. To the extent that the provision of sterile syringes to injection drug users also reduces HIV transmission to injection drug users’ sex part-

Table 1. U.S. Department of Health and Human Services
Provisional Recommendations to Drug Users Who Continue To Inject

| Step using and injecting drugs |
| Enter and complete substance abuse treatment, including relapse prevention |
| Take the following steps to reduce personal and public health risks, if injection drug use persists: |
| Never reuse or "share" syringes, water, or drug preparation equipment |
| Use only syringes obtained from a reliable source (e.g., pharmacies) |
| Use a new, sterile syringe to prepare and inject drugs |
| If possible, use sterile water to prepare drugs; otherwise, use clean water from a reliable source (such as fresh tap water) |
| Use a new or disinfected container ("cooker") and a new filter ("cotton") to prepare drugs |
| Clean the injection site before injection with a new alcohol swab |
| Safely dispose of syringes after one use |
ners and children, the ethical principle of justice would also be fulfilled. In addition, the patient's autonomy would be respected because the prescribing clinician implicitly recognizes that not all injection drug users are ready to enter drug treatment and that some of those would choose a physician (rather than a pharmacy or needle exchange programs) as their preferred source for sterile syringes.

How might such a system of physician prescribing of syringes actually work? Clearly, the ideal situation is one in which the physician has or is entering into a long-standing relationship with a patient who uses injection drugs and has been encouraging the patient to enter drug treatment. Because the injection drug user has an interest in keeping appointments to secure a fresh supply of syringes, prescribing can also be the starting point for continuing medical care, perhaps eventually leading to abstinence. Anecdotal experience at needle exchange programs suggests that advice to injection drug users to enter treatment is most likely to be successful when the provider has a meaningful relationship with the injection drug user and if the optimal moment for such a referral is selected. In the interim, after an extensive drug use history has been obtained, prescribing of syringes is appropriate, with the understanding that abstinence is a future goal. We recommend that the syringe supply be frequent enough to encourage ongoing contact, with the health care system but not so frequent as to reduce the likelihood that the injection drug user will return. The patient should be encouraged to undergo hepatitis and HIV counseling and testing; if indicated, hepatitis A and B vaccines should be administered (32).

Evidence suggests that some physicians have provided sterile syringes to injection drug users since the earliest days of the HIV epidemic (14), but attitudinal barriers to widespread adoption of the practice could arise. Some physicians may, for example, be ambivalent about the appearance of facilitating behavior that they would prefer to see terminated (33) or believe that drug users in the waiting room will upset other patients. But not all health care providers in any given area need participate in order to improve the availability of sterile syringes, particularly in areas without needle exchange programs. The proper disposal of prescribed syringes after use is beyond the scope of this article, but creative methods of addressing this problem have been identified (34–36).

The Legality of Prescribing and Dispensing Injection Equipment: New Research

The prescribing and dispensing of sterile injection equipment are governed primarily by state law. Using standard legal research methods, we collected and analyzed the relevant statutes, regulations, and court decisions in the 50 states, the District of Columbia, and Puerto Rico. The results are presented in Table 2. Physician prescription of injection equipment to patients as a means of preventing the transmission of disease during drug use was clearly legal in 48 of the 52 jurisdictions, and dispensing the syringes in the pharmacy was clearly legal in 26. State law was considered to provide a reasonable claim to legality if it neither explicitly allowed nor forbade prescribing or dispensing, such that an attorney acting ethically and in good faith could argue that the practices were legal. Two states fell into this category with respect to prescribing, and 22 were in this category with respect to dispensing. Prescribing was clearly prohibited by law in only 2 jurisdictions; dispensing was clearly illegal in only 4. The legalities of needle distribution through the health care system are thus different from those associated with lay distribution through needle exchanges (37) or pharmacy sale without a prescription (38). A detailed analysis for each jurisdiction studied is

Table 2. The Legality of Prescribing andDispensing Sterile Injection Equipment to Injection Drug Users To Prevent Disease Transmission

<table>
<thead>
<tr>
<th>Physician Prescription of Sterile Injection Equipment</th>
<th>Pharmacy Sale of Prescribed Syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearly Legal</td>
<td>Reasonable Claim to Legality</td>
</tr>
<tr>
<td>AI, AK, AR, AZ, CA, CO, CT, DC, FL, GA, HI, ID, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY</td>
<td>OH, OK</td>
</tr>
</tbody>
</table>

Are Prescribing and Dispensing Injection Equipment to Injection Drug Users Authorized under Laws Governing Professional Practice?

Only a handful of state laws set out explicit criteria to govern a physician’s prescription of injection equipment. Our legal analysis assumed that, in the absence of specific rules, the prescription of syringes would be subject to the same general legal principles that apply to other prescriptions. Although there are important technical differences from state to state, physicians generally have broad discretion to prescribe drugs and devices that they believe will be medically beneficial for patients (39–41). A prescription is proper if it is written 1) in good faith, 2) in the course of normal professional practice, and 3) for a legitimate medical purpose in accordance with treatment principles accepted by a responsible segment of the medical profession (11, 42–48). For their part, pharmacists are authorized to dispense medications ordered by a valid prescription and are ordinarily expected to do so in the absence of a good reason to refuse (49). Physicians and pharmacists who fail to meet these standards are subject to discipline by their regulatory boards or to civil court suits alleging professional malpractice (39, 48).

The main legal issue, then, is whether prescribing or dispensing a syringe is medically legitimate. The medical evidence and public health guidelines reviewed above, combined with the support of major professional bodies, make a compelling case for the practitioner prescribing injection equipment as described in this article. Not all physicians will agree that prescribing injection equipment is within the bounds of good medical practice, but the support of a responsible segment of medical opinion is enough to satisfy the legal standard (50, 51).

The “good faith” and “normal course of professional practice” requirements assess whether the physician is practicing medicine within professional standards in the true best interest of the patient. Most physicians who have been subject to criminal conviction or professional discipline for abusing their prescribing powers have been reckless in their disregard for the patient’s welfare or minimum standards of care (47, 52, 53). Despite occasional accounts of physicians being prosecuted for legitimate prescribing of pain medication, courts are generally reluctant to interfere with physician discretion in the practice of medicine (54). Courts have consistently held that prescribing statutes were not meant to “invade the legitimate doctor-patient relationship when the doctor may dispense or prescribe . . . for medical reasons” (55, 56). Providing injection equipment to drug-injecting patients out of a sincere desire to prevent disease transmission, without pecuniary motive, easily satisfies these prongs of the standard.

Does Prescribing or Dispensing Injection Equipment Violate Laws Controlling Access to Syringes?

Our legal analysis then considered whether prescribing or dispensing of injection equipment that was within the ordinary discretion of physicians or pharmacists was nevertheless prohibited by another general state rule. The patchwork of laws, administrative regulations, and local ordinances that define the circumstances under which injection equipment may be sold or given away has been described in detail by Gostin and Lazzarini (38). The system includes drug paraphernalia laws, which prohibit the sale, distribution, or possession of any item that the seller or possessor knows will be used for the injection or preparation of an illegal drug; laws requiring a prescription for the sale or possession of injection equipment; and miscellaneous pharmacy practice regulations, which limit the discretion of pharmacists to sell syringes by, for example, requiring that they verify that a buyer has a valid medical or “lawful” purpose. Prescriptions are required by law in only a minority of states, but they may make it more likely that a pharmacist will sell injection equipment to the patient (especially when the buyer is required to show a legitimate medical need) (25–27) and may help protect the patient from arrest for possession of syringes (38).

Syringe prescription laws, which have often been seen as the greatest impediment to needle exchange programs, do not usually present a barrier to the provision of needles by physicians and pharmacists. Most prescription laws require just that—a prescription—and no more. Implicitly relying on medical licensure law, prescription laws typically do not themselves define the circumstances under which a prescription may be written or filled (57–60); thus, if the prescription meets the general standard for a valid prescrip-
tion, it is valid under the syringe prescription law. (Delaware's prescription law is the exception that illustrates the rule: It limits prescription of syringes to instances in which the device is "necessary for the treatment of an injury, deformity or disease then suffered" [61].)

All states except Alaska have drug paraphernalia laws. Paraphernalia laws make it illegal to transfer possession of any item knowing that it will be used for the ingestion of an illegal drug. Because writing a prescription does not entail the transfer of the physical possession of a syringe, the typical paraphernalia law simply does not apply to the physician who prescribes a needle.

The pharmacist may face more risk in filling the prescription because dispensing consists of the prohibited physical transfer of the needle. Moreover, although paraphernalia laws impose no affirmative obligation to inquire about the buyer's intentions, many pharmacists filling needle prescriptions will learn that they are to be used for illegal drug injection. Eight states' paraphernalia laws exclude syringes categorically (Georgia, Oregon, Wisconsin, and, as of 1 January 2001, New Hampshire) or when sold in amounts of 10 or fewer (Connecticut, Maine, Minnesota, and, as of 1 January 2001, New York). Six more provide some kind of exemption or immunity to pharmacists who would cover the filling of a valid syringe prescription (Colorado, Indiana, Louisiana, Montana, Ohio, and Tennessee). South Carolina's paraphernalia law omits any reference to syringes or injecting and does not apply to items used in the consumption of opiates. Prescription laws, in states that have them, will normally be construed by courts to supersede the more general paraphernalia provisions, so that a sale that is valid under the prescription law will not be deemed to violate the paraphernalia law. In the rest of the states, the paraphernalia laws remain the major source of uncertainty about the legality of filling a syringe prescription. Although it is reasonable to claim that these laws simply do not and were never intended to limit the discretion of health care professionals in preventing disease among their patients (38, 62, 63), the argument that they apply to prevent syringe sales is also reasonable.

Pharmacy regulations complete the legal quilt, and the specific language is critical. Provisions that require the pharmacist to establish that the buyer has a valid medical purpose can be satisfied by the available medical evidence regarding the value of sterile injection equipment in preventing the transmission of bloodborne pathogens. Regulations that forbid sales to someone with an "unlawful" purpose are different (64): Even if a paraphernalia law does not apply, illegal drug use could be found by a pharmacy board or court to be the sort of "unlawful purpose" to which the regulation refers. A prescription, even if not required, helps establish the medical legitimacy of the sale, and so may provide some reassurance and legal protection to the pharmacist trying to decide whether the buyer has a legitimate or lawful purpose.

Malpractice and Regulatory Concerns

Prescription distribution of syringes is a new clinical intervention that will be deployed in a politically charged climate. Some physicians and pharmacists may worry about malpractice liability should a patient or third party suffer injury from the syringe or the injected drugs or about the possibility of inquiries from federal drug enforcement authorities. Such risks can never be fully eliminated, and even winning a legal or regulatory battle can feel like a Pyrrhic victory to the professional forced to spend time, money, and energy defending himself or herself. These risks are more fully addressed in our legal research data, available on the Web at www.temple.edu/lawschool/aidspolicy/default.htm. In our view, the concern is valid but the risks are low.

A malpractice action would be difficult for a drug-injecting patient to sustain for both legal and practical reasons. Legally, the patient would have to prove that the injury (overdose or extended drug addiction, for example) would not have happened had the physician not provided the needle. The provision of the needle itself would have to be unreasonable in light of professional standards. The physician would have the strong additional defenses that the patient's injury was caused by the patient's own negligent decision to inject a dangerous drug and that any harm from prescribing the needle was offset by the demonstrable benefits of sterile equipment (65). A patient would also face practical barriers: A dedicated physician may be a more sympathetic figure under the circumstances than the plaintiff in the eyes of a jury, a consideration that may make it harder for the patient even to find an attorney. It is noteworthy that there have been no reported liability cases involving needle exchange programs.

A third party accidentally injured by the prescribed needle (because of improper disposal, for example) might have a more sympathetic case, but tracing the needle back to the prescriber or pharmacist would be difficult. As a
matter of law, courts in the few cases involving liability for improperly discarded needles have tended to impose liability, if at all, only on people responsible for the safety of the place where the stick occurred (Burris S. Liability for Accidental Injuries. Workshop on Safe Syringe and Needle Disposal. Baltimore, MD: Johns Hopkins School of Hygiene and Public Health/Kaiser Family Foundation/Centers for Disease Control and Prevention; 1996). We located no cases in which liability was based solely on having provided the needle. Making the physician liable for improper use or disposal of the needle by the patient would be a notable expansion of tort law. As in any other professional liability matter, it is important to factor into the risk assessment the data indicating that only a fraction of potential claims are ever formally filed in the legal system (66). Finally, a physician assessing malpractice risk should not ignore the possibility of a suit by a patient for whom the physician declined to provide sterile injection equipment.

Syringe prescription is only one area of health care that has recently become embroiled in federal efforts to combat drug abuse. The federal Drug Enforcement Administration has used threats of criminal prosecution to influence policy over the medical use of marijuana in California (67) and the practice of physician-assisted suicide in Oregon (68), despite state laws allowing both practices. Physicians and pharmacists may be concerned that prescribing syringes could make them a target of similar pressure, but close analysis suggests that the risk is slight.

Janet Reno, the attorney general of the United States, has subsequently made it clear that federal drug laws do not authorize the Drug Enforcement Administration to second-guess the professional judgments of physicians or usurp the states’ function of defining proper health care practice. In June 1998, Reno retracted the Administration’s threat to revoke or suspend the controlled substances prescription licenses of physicians who administered lethal doses of controlled substances pursuant to Oregon’s Death with Dignity Act. Reno explained that “there is no evidence that Congress, in the Controlled Substances Act, intended to displace the states as the primary regulators of the medical profession, or to override a state’s determination as to what constitutes legitimate medical practice . . .” (69). The only possible basis for federal action related to needles would be the Mail Order Drug Paraphernalia Law (70). Subsection (f) of the statute, however, explicitly exempts “any person authorized by local, State, or Federal law to . . . possess, or distribute such items.” The exemption reflects the focus of Congress on the commercial head-shop industry and its intention not to sweep within the paraphernalia law persons who have traditionally used covered items for legitimate purposes. In about half the states, physicians and pharmacists are explicitly authorized to possess, use, and distribute syringes; those in the remaining states have the implicit authorization of their professional status and long-standing practice. The exemption, moreover, applies to the person, not the specific transaction, so that even if it were claimed that a particular prescription or sale of a syringe was prohibited by state law, the fact that the provider is generally authorized to possess or distribute the item would be sufficient to trigger the immunity.

**Taking Action**

The decision to run a risk for a patient’s sake is one each physician and pharmacist must face on his or her own. On the basis of the ethical, clinical, and legal considerations we have set out here, some physicians and pharmacists may reasonably decide to make sterile injection equipment available to injections drug users when it is medically necessary. One of us (Dr. Rich) has begun to do so in his clinic, with the legal authorization of state health authorities. Preliminary experience with nearly 180 patients who have been prescribed more than 18,000 syringes reveals that this policy is well received by patients, physicians, and pharmacists. No major problems have occurred to date. Most patients engage in medical care, and many request substance abuse treatment referral. This intervention has a broad base of support, including that of the state’s medical society and pharmacists’ association, in a state with both paraphernalia and prescription laws. Providers introducing this care will face questions about the criteria for prescribing, the proper number of syringes, provisions for syringe recovery and disposal, and cooperation with local pharmacists. The risk for malpractice liability or allegations of unprofessional conduct may be minimized by observing a set of simple precautions in providing care, such as documenting a thorough assessment of the patient’s risk behaviors and barriers to drug treatment (Table 3). Some clinicians may wish to work with researchers to measure the impact of the intervention.

In some places, professionals faced with uncertainty about the applicable law may be unwilling to run the legal risk. This need not lead to inaction, however. Avenues exist
Table 3. Minimizing the Legal Risk of Prescribing Injection Equipment

| Action                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------|---|
| Choose the appropriate patient                                                                                                           |   |
| At risk for acquiring or transmitting bloodborne disease                                                                                |   |
| Unwilling or unable to stop injecting drugs                                                                                             |   |
| Participating in or able to enter ongoing care                                                                                           |   |
| Unwilling or unable to access drug treatment                                                                                             |   |
| Mentally competent                                                                                                                        |   |
| Conduct appropriate evaluation                                                                                                          |   |
| Take detailed history, including risk behavior                                                                                        |   |
| Coordinate with social service providers as necessary                                                                                   |   |
| Seek consultation as necessary (i.e., mental health, substance abuse)                                                                       |   |
| Assess drug treatment needs and motivation                                                                                                |   |
| Set short- and long-term goals for treatment                                                                                             |   |
| Monitor outcomes                                                                                                                          |   |
| Document the following:                                                                                                                 |   |
| Length and severity of drug use                                                                                                          |   |
| Frequency of syringe sharing                                                                                                            |   |
| Health status vis-à-vis bloodborne infection                                                                                             |   |
| Vaccination of those susceptible to hepatitis A or B                                                                                     |   |
| Frequent physician attempts to refer patient to drug treatment                                                                            |   |
| Counseling on harm reduction techniques at each visit                                                                                     |   |
| Number of syringes provided and retrieved at each visit                                                                                  |   |
| Other harm reduction services provided                                                                                                  |   |
| Educate the following groups:                                                                                                           |   |
| Patients about risks of ongoing injection                                                                                               |   |
| Patients concerning proper disposal of used syringes                                                                                      |   |
| Other physicians                                                                                                                         |   |
| Law enforcement officials                                                                                                                |   |
| Community                                                                                                                               |   |

for clarifying the law and minimizing the risks that a reasonable claim to legality will ever be challenged (37). Discussions with public health agencies, professional boards, and colleagues will be helpful in testing the local acceptance of the medical necessity of providing injection equipment to injection drug users. Contact with law enforcement officials can do much to clarify both the interpretation of the law and the willingness of authorities to prosecute. Physicians and pharmacists may be able to seek guidance in the form of an opinion from the state attorney general or to go to court for a declaratory judgment (a ruling on the law in advance of an arrest, prosecution, or dispute). In the few states where paraphernalia laws or pharmacy regulations appear to categorically prohibit the dispensing of syringes, physicians and pharmacists may add their considerable professional weight to efforts to change these rules.

Conclusions

Our analysis poses a challenge to physicians. If prescribing syringes is medically appropriate and ethically proper, physicians treating patients who use injection drugs are, at least in the absence of legal limits, obliged by their own professional standards to consider providing this care to patients who need it. And if the legal validity of prescribing syringes turns in significant part on its conformity with medical standards, “obeying the law” is no justification for failing to provide the care. It is, rather, within the power of the profession to help ensure that the law does not prohibit care that is medically justified. Pharmacists serve the health needs of the public and can become important sources of sterile injection equipment for injection drug users. This is not to say that there is no legal risk. It is axiomatic for lawyers that almost anyone can be sued or charged with a crime, although actually losing a case is far less random an occurrence. Yet even this risk does not justify the profession’s passively awaiting the final outcome of the political and legal struggle over access to sterile syringes.

Physicians and pharmacists, of course, cannot stem the epidemic of needle-borne infections on their own. Many injection drug users are not receiving regular care. Like needle exchange programs, prescription-based distribution of injection equipment is only a partial solution to the health crisis caused in significant part by a policy of restricting injection equipment and rationing access to drug treatment. A prescription will certainly help some patients obtain sterile injection equipment; even where it does not, however, writing a prescription has the legal and political value of establishing, by actual medical practice, the proposition that providing access to safe injection equipment is medically necessary and a “standard of care.” Only a thorough revision of drug policy will adequately address the epidemics of HIV infection and hepatitis among injection drug users (71). We suggest, however, that for physicians and pharmacists, this is a change that can begin with one prescription.

Note added in proof: On 14 June 2000, the House of Delegates of the American Medical Association (AMA) approved a resolution asking that “our AMA strongly support the ability of physicians to prescribe syringes and needles to patients with injection drug addiction, and in conjunction with addiction counseling, in order to help prevent the transmission of contagious diseases.” (Resolution 416, Physician Prescription of Needles to Addicted Patients.)

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Physician Prescribing of Sterile Injection Equipment

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