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The Law (and Politics) of Safe Injection Facilities in the United States

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Addressing the Health Consequences of Injection Drug Use

Injection drug use has been a public health problem in the United States for many decades. ^{1,2} It accounts for a third of this country's cumulative AIDS cases. ³ Injection drug users (IDUs) are at high risk of acquiring hepatitis and HIV. ^{4–7} Skin abscesses and endocarditis can result from unsterile injection. ⁸ A recent wave of fentanyl-related overdose deaths has called attention to the high number of fatal overdoses among IDUs. ^{9–11}

Many of the harms associated with injection drug use stem from the scarcity of sterile injection equipment and users' fear of the criminal justice system. ^{12–15} Anxiety about social rejection and arrest deter use of health and preventative services and force IDUs into hidden locations that are poorly suited for hygienic injection. ^{14,16–20} The likelihood that IDUs will contract a blood-borne disease increases significantly when they inject in public spaces or "shooting galleries." ^{18,21} Although opiate overdose is typically reversible through the administration of naloxone (an opiate antagonist), witnesses often hesitate to summon first responders out of fear of legal consequences. ^{22,23} Lack of proper syringe disposal facilities and legal disincentives to safe disposal increase the risk that used syringes will be improperly discarded, creating public anxiety and some risk of accidental disease transmission. ²⁴

Syringe access and disposal, outreach, and drug treatment programs help reduce these risks. ^{25–28} These interventions do not address the lack of a safe and hygienic setting for injection, nor are they sufficient to overcome the behavioral influence of relationships and other factors present in informal injecting milieus. ^{29,30} Recognizing this unmet need, some 40 cities worldwide have introduced safe injection facilities (SIFs) as one way to address unsafe drug consumption environments. ^{31,32}

An SIF is a place supervised by licensed health personnel where IDUs inject drugs they obtain elsewhere. Facility staff do not directly assist in injection, but rather provide sterile injection supplies, answer questions on vein care and safer injection methods, administer first aid, and monitor for overdose. 33,34 SIF staff also offer general medical advice and referrals to drug treatment and other social programs. Some SIFs extend services to drug users who do not inject. In addition to reducing the health risks of drug use and serving as a bridge to other services, SIFs are intended to reduce the externalities of public drug use in the communities they serve. They generally target high-risk, socially marginalized IDUs who would otherwise inject in public spaces or shooting galleries. SIFs

Laws and law enforcement practices have chronically complicated the implementation and limited the impact of harm reduction programs in the United States. 40–42 Without at least a reasonable claim to legality, an SIF would be vulnerable to police interference and could have difficulty obtaining funding. Clients could be arrested for drug possession, and staff members might fear arrest or discipline by professional licensing authorities. Following the example of syringe exchange, health activists might open "underground" SIFs to meet IDU needs and push the policy agenda. 43,44 Over time.

however, official authorization and public funding would be needed to allow SIFs to be properly evaluated, let alone to operate effectively and at scale.

State legislation authorizing politically controversial harm reduction interventions is not unprecedented: since the beginning of the HIV epidemic, 19 states have passed laws authorizing syringe exchange programs (SEPs), pharmacy syringe sales, or both, and SEPs have been authorized by city or county governments in 2 additional states. 45 Unlike an SEP or pharmacy, however, an SIF openly provides a place for consumption of controlled substances. Federal law enforcement agencies may view this as a direct challenge to national drug laws. An SIF authorized by a state or local government therefore has the potential to trigger a complicated legal and political conflict between state health powers and federal leadership in the "War on Drugs." We offer an initial assessment of the main legal issues and place them in the context of other drug policy conflicts.

The Public Health Case for Safe Injection Facilities

The mechanisms through which an SIF prevents infections and overdoses among clients are straightforward. Studies of existing facilities have generally reported beneficial results for clients and positive or neutral results for the site neighborhood. Whether, or at what level of use, an SIF can have a measurable impact on overall population health is a matter for continuing research. We base our analysis on the proposition that the SIF is a potentially useful public health intervention that should be available for evaluation and adaptation in the United States. We briefly summarize the evidence.

SIFs have been operating in Europe since the 1980s. Reviews report that SIFs have consistently led to less risky injection behavior and fewer overdose deaths among clients, increased client enrollment in drug treatment services, reduced nuisances associated with public injection, and saved public resources. 31,46,47 Demonstrating a community-level impact has been difficult, however, because many programs have been "pilots" with limited coverage, operating under sometimes counterproductive regulations. 32,48 In 2001, after several years of public deliberation and the closure of a short-lived illegal facility, a pilot SIF opened in Sydney, Australia, under a license issued by the New South Wales (state) government. 41 In 2003, the Canadian federal government waived its drug laws to allow a pilot SIF in Vancouver. 49 Here, too, there had been considerable debate about harm reduction strategies, and health activists had for a time operated an unauthorized SIF. 44

Both facilities have been extensively evaluated.^{50,51} In multivariate analyses of an IDU cohort in Vancouver, SIF use was negatively associated with needle sharing (adjusted odds ratio [AOR]|=|0.30) and positively associated with less frequent reuse of syringes (AOR|=|2.04), less outdoor injecting (AOR|=|2.7), using clean water for injection (AOR|=|2.99), cooking or filtering drugs prior to injecting (AOR|=|2.76) and injecting in a clean location (AOR|=|2.85).^{50,52,53} In Sydney, both SIF clients and nonclient injectors in the same neighborhood reported high rates of sterile syringe use and low rates of sharing even before the SIF opened, but 41% of SIF clients reported adopting at least one safer injection technique since using the facility. A series of 3 annual neighborhood surveys found that SIF users were more likely to use new syringes

than nonusers and less likely to share injection equipment other than syringes, although these differences were not statistically significant.⁵¹

Both the Sydney and Vancouver facilities were effective gateways for addiction treatment, counseling, and other services. ^{51,54} By the third annual survey, Sydney SIF clients were significantly more likely to report starting drug treatment in the previous year than nonclients (38% vs 21%). In Vancouver, SIF attendance and contact with its addiction counselor were each associated with a more rapid uptake of detoxification services. ⁵⁵ Overdoses do occur in SIFs—in Vancouver, the rate was 1.3 per 1000 injections ⁵⁰—but the more relaxed environment and the presence of medical assistance likely account for the lack of any reported overdose deaths in an SIF. ^{35,38,48,51,56}

Both the Vancouver and Sydney evaluations found some positive and no negative effects on the surrounding community. In both cities, there was a significant reduction in observed instances of public injection in the neighborhood. The numbers of discarded syringes and the amount of injection-related litter in the vicinity also declined substantially. In neither instance was there an increase in crime or drug dealing in the vicinity 50,51,57 (although in Sydney there was a slight increase in the negligible level of loitering around the SIF⁵⁸). A series of surveys in Sydney found that area residents and business owners had experienced a sustained decline in exposure to public injection and discarded syringes following the opening of the SIF. Evaluators sought, but did not find, any evidence that the SIFs had encouraged new drug use or discouraged its cessation. S0,51,60

In theory, SIFs can save public funds by preventing death, disease, and crime, but analysis of costs and benefits has been limited. Fiscal benefits in the form of lower

ambulance and hospital utilization have yet to be documented, but may be significant given the evidence that SIFs prevent wound infections and successfully treat large numbers of overdoses on-site. ^{31,51} In spite of their positive results, both the Sydney and Vancouver SIFs are currently threatened with closure because of changes in government leadership. ^{49,50,61}

International evidence supports efforts to implement SIFs in the United States, where momentum to evaluate the feasibility of this public health intervention is increasing (A. Kral, RTI International, written communication, September 29, 2007). 32,36,62 No laws explicitly authorize or forbid SIFs. To the extent that they provide clean syringes, SIFs would be required to comply with state laws governing SEPs. 41 Beyond that, assessing the legality of an SIF requires a prediction about how local, state, and federal officials will interpret varying state and federal laws on drug possession and the maintenance of premises for illegal drug use. 63 Whether the legality of an SIF would be challenged in the first place is a function of how law enforcement officials exercise their prosecutorial discretion. Much would depend on the political climate, both in the local community and in Washington, DC.

The least politically and legally obtrusive way to launch an SIF would be to cast it as an incremental extension of an SEP already authorized by state law—the only change would be that clients could stay in the facility to inject and receive medical advice and assistance. The program could avoid the "SIF" label and instead portray itself as a response to community concerns about public injecting and discarded syringes, or as a

way to reduce emergency response costs to overdose. This approach would avoid state legislation directly challenging federal drug policies. The acknowledged possession and consumption of drugs on the premises is, however, the crucial legal difference between an SEP and an SIF. Syringe exchange laws do not authorize possession of drugs at the SEP, but police are expected to turn a blind eye to possession insofar as they do not treat SEP attendance or syringe possession as justification for a drug search. Overlooking open possession and consumption would be asking for a more substantial degree of self-restraint than many police would exercise, especially if the state also had a law prohibiting the operation of premises for drug consumption. In the absence of local political support and at least tacit police acquiescence, the clients and perhaps even the staff of such an "SEP with chairs" would be vulnerable to arrest and prosecution. It may be that some activities of this sort are already going on, but because of its limitations, we do not dwell on this "soft" approach.

In the analysis that follows, we aim to frame future legal debate and action by addressing the 2 key legal issues arising from the explicit authorization and open operation of SIFs in the United States: (1) Would the creation of an SIF be within the authority of a legislature, state health commissioner, or local government? If so, (2) how would such an SIF be treated under federal law? We do not address the claims that an SIF is either required by international human rights treaties or forbidden by international drug control treaties. These claims will have little bearing on domestic legal decisions and have been canvassed elsewhere.³⁴

State vs Local Authorization

State legislatures certainly have the authority to sanction the operation of SIFs, including the use and possession of illegal drugs on the premises. States and municipalities have the duty to protect and preserve the welfare of their citizens. The legal authority to fulfill this duty, called the "police power," has been recognized as a basic attribute of the state since the founding of the nation. 66 Disagreements about the effectiveness of SIFs do not diminish legislatures' discretion to pass health laws based on their independent assessment of the facts.

Explicit authorization by a state legislature is the optimal course, for several reasons. It eliminates uncertainty about the legality of an SIF in light of other state laws. It legitimizes the operation in the eyes of subordinate governmental agencies, greatly decreasing the chance that a local police department or prosecutor would take formal action against it and providing the SIF operators and clients with protection against informal police pressure or interference. The legislative process affords an opportunity to address the concerns of the community and other stakeholders in the creation of such a facility. Finally, state legislative authorization puts the SIF on its strongest footing against a challenge from the federal government, as discussed in the next section.

A state government might also authorize an SIF through administrative action by the executive branch. Health agencies in all states have rule-making authority to protect public health, although the scope of this power varies. ^{67,68} In New York, for example, statutes authorize the state health commissioner to promulgate regulations exempting classes of persons from the needle prescription laws, ⁶⁹ a power the commissioner used to authorize SEPs. ⁷⁰ Additionally, many governors have the authority to issue executive orders authorizing activities that do not conflict with existing law. ⁷¹ Executive authority

to alter controlled substances rules is generally narrow, however, so any executive order or administrative regulation purporting to authorize the use or possession of controlled substances could be challenged as exceeding the executive's authority. (Such an objection was raised in 2004 when the governor of New Jersey attempted to authorize SEPs through an executive order. ⁷²) If unchallenged or upheld, the effect of an executive authorization on implementation would be much the same as state legislative authorization.

Most local governments have some police power to protect public health, and they have the discretion to implement programs that are supported by reasonable evidence of effectiveness in combating existing health threats. SEPs authorized by local governments have successfully operated in several cities in Pennsylvania, California, and Ohio without state authorization. Hollowing that model, an SIF could be authorized by a mayor, local health commissioner, county agency, or city council, depending on local government design. However, a locally authorized SIF would be on the weakest footing in relation to a federal challenge, and might also be attacked as conflicting with state law. For example, the attempt by Atlantic City, NJ to implement an SEP was successfully challenged in court by the local prosecutor, who argued that it was prohibited by state drug law. A locally authorized SIF would have relatively less protection against police interference. While legal arguments are important, the durability of a local authorization would also depend on an explicit or implicit agreement among stakeholders to avoid arrests and other legal challenges.

The Impact of Federal Drug Laws

States have clear legal authority to authorize SIFs, just as they can legalize the cultivation, distribution, and possession of marijuana for medical purposes. ⁷⁶ State authorization could make an SIF legal under state law and prevent state law enforcement officials from taking action against it. It is equally clear, however, that state authorization cannot nullify federal drug laws, and so does not immunize an SIF against being shut down by federal law enforcement agencies through raids, arrests, or other legal proceedings.

There are at least 2 sections of the federal Controlled Substances Act that could be interpreted to bar an SIF. Section 844 prohibits drug possession, and so is violated by every client who appears at the clinic with drugs.⁷⁷ Although federal law enforcement officials rarely if ever target simple possession by individuals,⁷⁸ the law would allow them to do so if they wished to interfere with the operation of an SIF.

An SIF authorized at the state or local level could also be deemed to violate

Section 856, known as the Crack House Statute. This law makes it illegal to "knowingly open or maintain ... [or] manage or control any place ... for the purpose of unlawfully ... using a controlled substance." There are reasonable legal arguments for the proposition that the law should not be read to cover an SIF. Aside from technical arguments about the way the law is written, defenders of an SIF could point to the legislative history: the law was a response to the proliferation of "crack houses" where users congregated to purchase and consume drugs during the height of the crack epidemic, and later amendments addressed the emergence of "rave" parties whose sponsors were deemed to be profiting from Ecstasy use. It was never intended to interfere with a legally authorized public health intervention. It should not be interpreted to infringe upon states'

traditional authority in public health, absent a "clear statement" of Congress's intention to do so. 80,81 These arguments are reasonable, but are by no means certain to convince federal judges.

Defenders of an SIF could also contend that federal interference with an SIF oversteps the bounds of federal regulatory authority. Congress gets its power over controlled substances from its broader power under the Constitution to regulate interstate commerce. Occasionally, and unpredictably, the Supreme Court decides that Congress has gone too far, trying to regulate a matter with too tenuous a connection to commerce. This argument was, however, rejected under similar facts in a recent California medical marijuana case. In the 6–3 ruling, the 3 dissenting justices protested against the interference with state policy, writing that "[t]his case exemplifies the role of States as laboratories. The States' core police powers have always included authority to define criminal law and to protect the health, safety, and welfare of their citizens." While these views may resonate with many judges in an SIF case, it is worth noting that the composition of the Supreme Court has changed since that decision. Two of the 3 justices expressing their support for the states' right to experiment in drug policy have left the court, replaced by justices that may well take a different view.

The most conservative prediction is that courts would uphold federal action against an SIF under either the drug possession or Crack House law, or both. Thus, the most important legal question is really a political one: would federal lawmakers or law enforcement officials support, or at least ignore, a state-authorized SIF? The possible forms of authorization parallel those at the state level. Congress could pass a law authorizing SIFs. The attorney general could promulgate a regulation under the

Controlled Substances Act, which would be open to legal challenge but would be interpreted deferentially by courts. The secretary of the Department of Health and Human Services and the attorney general could approve pilot SIFs under the provision of the Controlled Substances Act authorizing research.⁸³

The political opposition to such moves could well be fierce, but federal *inaction* would be enough to allow a state SIF to proceed. The attorney general could simply instruct federal law enforcement personnel to ignore the SIF, either because he or she interprets the Controlled Substances Act to allow SIFs or in the exercise of "prosecutorial discretion." Given limited resources, legal uncertainty, and higher priorities, law enforcement personnel routinely decide not to pursue cases they deem less important.

The case of Oregon's physician-assisted suicide law shows how this approach might unfold. After Oregon voters approved the measure in 1994, Attorney General Janet Reno determined that the Controlled Substances Act did not authorize her 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." On her orders, no federal arrests or prosecutions took place. When the administration changed in 2000, Reno's successor, John Ashcroft, repeated the analysis and arrived at the opposite conclusion, threatening legal action against doctors who prescribed lethal doses of controlled substances under the Oregon law. (The matter ultimately reached the Supreme Court, which agreed with Reno. (S)

Congress might also act, as it did in the case of syringe exchange, by using its power of the purse. It might put limitations on the use of federal funding for safe injection facilities, or even use money as a threat to prevent cities from operating an SIF

even with their own funds. One legislator responded to an October, 2007, meeting to consider an SIF in San Francisco by attempting (unsuccessfully) to amend a 2007-08 appropriations bill to bar any federal funds to "to cities that provide safe haven to illegal drug users through the use of illegal drug injection facilities." (110th CONGRESS, 1st Session, HR 3043, Engrossed Amendment Senate, October 25, 2007.)

Conclusions and Recommendations

We have mapped a rocky legal path for SIFs. There is enough evidence of effectiveness to justify state and local health officials implementing SIFs on a pilot basis. A period of careful evaluation and adjustment of protocols would be required to determine how to operate an SIF to optimal effect and, ultimately, whether SIFs represent a good investment of public health resources in any particular community.

If SIFs are to be tested here, state authorization is desirable if not absolutely necessary, and would itself be a political challenge. Once approved by a state or local government, there would still be the question of winning federal support or at least tacit acceptance. Implementation of SIFs in this country will therefore require careful planning and a sustained political effort. The US experience with SEPs—as well as the SIF experience in Australia and Canada—suggests that progress will be slow and will depend on "activists willing to push the agenda, public officials willing to exercise leadership, researchers able to present authoritative findings, and proponents who effectively mobilized resources and worked to build community coalitions, using persistent but nonadversarial advocacy." Nationally, professional organizations could help by endorsing the intervention. From a scientific point of view, it would be reasonable to

expect the Centers for Disease Control and Prevention or even the National Institutes of Health to support research on the efficacy of SIFs. In fact, federal research funding will likely be another occasion for political dispute, and so funding might have to come initially from other sources.

The first step would be a decision by local or, ideally, state-level health authorities to pursue the intervention. The planning phase should include assembling the evidence of need and negotiating with stakeholders. Besult and emergence in other cities, planners should not assume that law enforcement and emergency services providers will oppose the idea. Planning also requires an assessment of the alternative forms of legal authorization available under state or local laws, and a thorough analysis of state criminal code and state regulations governing the conduct of medical professionals. Proponents may also consider less obtrusive methods than formally establishing an SIF, such as the simple addition of a medically supervised seating area to an existing SEP or the use of a mobile van. These choices will depend heavily on the degree of support among stakeholders and the strength of any opposition.

Once an SIF is authorized, events could unfold in a number of ways. As was most often the case with locally authorized SEPs, it might be that no law enforcement agency challenges the legality of the program. Under this scenario, the possible conflict between the SIF and federal law would remain a hypothetical legal question. Another possible avenue for action would be for the state or locality itself to seek a "declaratory judgment," an official judicial interpretation of the applicability of the Controlled Substances Act to an SIF. This has the advantage of offering legal certainty to the authorizing entity, but it comes at a significant potential cost: an SIF that had the

potential to operate indefinitely under legal uncertainty would be required to close down if the court found the facility to violate federal law.

There is a good case for going forward with SIFs as part of a broader effort to minimize the harms of illegal drug use. Related interventions include outreach in shooting galleries and other public injection sites, SEPs, drug treatment, overdose prevention programs, and robust cooperation between public health and law enforcement systems. The experience with SEPs shows the value of persistence, and the possibility that evidence and advocacy can produce legal change. Researchers currently evaluating the feasibility of SIFs in the United States posit that such facilities may be a promising intervention shown by empirical evidence to improve public health without increasing drug use or crime. The path will be rocky, but it is a path that can, with the necessary public health and political leadership, be successfully navigated.

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