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MEMORANDUM

DATE: November 3, 2017

TO: Voices of Community Activists & Leaders
("VOCAL-NY")

FROM: Brett R. Friedman
Drew M. Clary
Kathryn A. Greis

SUBJECT: Legal Framework for Proposed Pilot Program to Research Supervised Injection
Facilities in New York State

VOCAL-NY, which is a member of a consortium of individuals and health care providers working in the harm reduction field in New York State ("NYS" or the "State"), which also includes Housing Works, Southern Tier AIDS Program, St. Ann's Corner of Harm Reduction and the Washington Heights Corner Project, requested that we prepare this memorandum to examine the legal framework and potential pathways for the creation of a pilot program to research the effectiveness of supervised injection facilities, which are also commonly known as supervised consumption sites (collectively, "SIFs"). In furtherance of this analysis, this memorandum proceeds in four parts: (1) provides background on SIFs and the nature of the treatment delivered in these programs; (2) describes NYS's police power authority to study public health issues, which may include the approval of SIFs; (3) discusses the relationship between NYS police power authority and federal laws that are potentially implicated by the operation of SIFs; and (4) delineates the types of NYS support that may serve as a necessary predicate to the operation of SIFs.

Executive Summary

NYS, as with much of the United States, faces a serious opioid crisis. The current presidential administration has formally acknowledged the crisis and announced on October 26, 2017 its objective "to reduce the number of deaths and minimize the devastation" that the opioid epidemic inflicts upon the public.¹ To that end, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the "President's Commission") issued on November 1, 2017 a set of 56 recommendations to combat the crisis. Not surprisingly, some of these

¹ See Presidential Memorandum for the Heads of Executive Departments and Agencies re Combatting the National Drug Demand and Opioid Crisis.

recommendations focus on overdose prevention, treatment and research,² all of which are potentially furthered by the purpose of SIFs. SIFs already operate in various cities throughout the world (although not yet in the United States), providing opportunities for health care providers to educate and treat people who use injectable controlled substances. The impact and benefit of SIFs—both in reducing fatalities from preventable drug overdoses and in enabling individuals to access the health care system and receive treatment—is well-known. As a result, many harm reduction providers currently operating in the areas of the State hardest hit by the opioid epidemic, including New York City, Central New York and the Southern Tier, have been working with NYS, including the AIDS Institute within the New York State Department of Health (“DOH”), to obtain support for the authorization of SIFs on a limited trial or pilot basis. This objective of this pilot study is to help providers and public health authorities determine whether SIFs are an effective public health intervention in our communities and help combat the opioid epidemic. amfAR, The Foundation for AIDS Research (“amfAR”), has agreed to support the harm reduction community in this research initiative and would provide research funding in support of SIFs.

Notwithstanding these important objectives, a potential hurdle to these efforts is the federal “Crack House Statute” (“CHS”), which makes it unlawful to “knowingly . . . use or maintain any place . . . for the purpose of . . . using any controlled substance” (emphasis added).³ Significantly, the plain language of this statute clearly can be read to encompass SIF activities, which provide a safe location for the injection of controlled substances, and federal enforcement of the CHS against SIFs is a risk. However, a close analysis of the legislative history regarding enactment and amendment of this statute, and case law interpreting the CHS, can support a narrower reading consistent with the operation of SIFs. Additionally, an analysis of federal preemption principles allows for a reading that Congress intended CHS to be applied to operations such as crack houses and warehouse raves, not to State-authorized programs or research studies conducted in furtherance of public health goals of drug prevention, treatment and research.

Notwithstanding the availability of this nuanced interpretation of federal law, the study of SIF efficacy is predicated on State authorization under its broad “police power” authorities. Specifically, NYS’s police power to act on public health matters is longstanding and rooted firmly in the Tenth Amendment to the United States Constitution, Supreme Court case law, the NYS Constitution and NYS statutes and case law. Given the limited parameters of federal drug enforcement law to supersede or “preempt” State action, including an exercise of its traditional police powers to address pressing public health matters, a clear and affirmative statement of support from the State is necessary to mitigate the risk of potential federal enforcement of CHS and other provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the “CSA”). Accordingly, this State support—which could come in the form of legislation, regulation or affirmative action through DOH authorization of a formal pilot program to research the effectiveness of SIFs—is critical in order for SIFs to co-exist with federal drug laws. Without this State support, the remaining federal enforcement risks would undermine, and potentially constrain entirely, the ability of VOCAL-NY and others members of the harm reduction

² See President’s Commission on Combating Drug Addiction and the Opioid Crisis Report, Recommendation Nos. 16, 33, 44, 52-56 at pp. 6-11, available at <http://www.modernhealthcare.com/assets/pdf/CH112917111.PDF>.

³ 21 U.S.C. § 856.

community to study SIF efficacy as an intervention designed to combat the opioid epidemic and associated drug overdose deaths.

Part 1: Background on SIFs

Similar to other regions of the United States, NYS faces an opioid epidemic that has introduced widespread injection drug use to parts of the State where it previously was uncommon.⁴ This spread has resulted in an increasing number of fatal drug overdoses. SIFs are one form of harm reduction—a drug treatment philosophy that differs from an abstinence-based approach and promotes practical strategies aimed at reducing negative consequences associated with drug use.⁵ Both domestic and international research support findings that harm reduction programs are associated with reduced rates of (i) transmission of HIV and hepatitis C; (ii) fatal overdoses; and (iii) long-term intravenous drug abuse, all of which correspond to health care cost-saving for cities and states.⁶ The Injection Drug Users Health Alliance, of which VOCAL-NY and other harm reduction providers are part, has studied the issue and recommended that individual- and community-level health risks would be reduced by implementing SIFs, particularly in New York City and other regions of the State hardest hit by this epidemic.⁷

Syringe exchange is another, long-accepted form of harm reduction with proven public health benefits. The Commissioner of DOH has the statutory authority, under N.Y. Public Health Law § 3381(4), to authorize syringe exchanges, and a number of these programs already operate in the State. SIFs take the syringe exchange concept one step further, providing not only clean needles, but also a safe, sanitary place to inject drugs in the presence of staff who monitor the individuals for signs of drug overdose and can provide access points for larger health care services.⁸ This monitoring is especially important given the increased incidence of the many-times-more-potent fentanyl being mixed with heroin, which has led to a spike in inadvertent drug overdoses. In addition to the health benefits SIFs provide to individuals who use drugs, SIFs may also serve as a place in which to test the chemical composition of the drugs being consumed onsite and then inform public health and enforcement authorities of the chemical composition of the drugs sold on the streets in neighboring communities.

Although no SIFs are currently operational in the United States,⁹ the concept has been successfully implemented in a number of other locations, most notably in Vancouver and

⁴ The current presidential administration on October 26, 2017 acknowledged this “unprecedented epidemic of drug abuse and overdose” in a Presidential Memorandum for the Heads of Executive Departments and Agencies re Combatting the National Drug Demand and Opioid Crisis, available at <https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies>.

⁵ *Principles of Harm Reduction*, HARM REDUCTION COALITION, <http://harmreduction.org/about-us/principles-of-harm-reduction/> (last visited Oct. 25, 2017).

⁶ See, e.g., David P. Wilson et al., *The Cost-Effectiveness of Harm Reduction*, 26 INT’L J. OF DRUG POL’Y Supp. 1 (2015) and *The Global State of Harm Reduction 2014*, HARM REDUCTION INTERNATIONAL, <https://www.hri.global/files/2015/02/16/GSHR2014.pdf> (2014).

⁷ See Injection Drug Users Health Alliance, *Harm Reduction in New York City: Citywide Evaluation Study 2015 Report*, p. 12, available at <https://hepfree.nyc/wp-content/uploads/2016/09/IDUHA-Citywide-Study-Report-2015-3.pdf?x41468>.

⁸ See Sanjay Gupta, *Opioid Addiction and the Most Controversial Bathroom in New York*, CNN.COM (Oct. 26, 2017), available at <http://www.cnn.com/2017/10/25/health/opioid-addiction-bathroom-safe-injection-site/index.html>.

⁹ King County, Washington is in the process of establishing a SIF program; see Section I.B of this memorandum.

Montreal. A number of cost-benefit analyses show that Vancouver’s program results in societal savings of millions of dollars as a result of prevention of HIV infections and overdose deaths.¹⁰ In NYS, a bill introduced in June 2017 would add a new Article 33-B, the Safer Consumption Services Act, to the N.Y. Public Health Law¹¹; this would provide a framework in which SIFs could operate. However, legislation is not the only way for NYS to support the study of SIFs and their ability to combat the opioid epidemic as one of the State’s biggest public health challenges. A State-authorized pilot research study, under the auspices of DOH or the AIDS Institute pursuant to its police power authority, would provide NYS with the opportunity to study a public health approach that can be replicated across the country.

Part 2: New York State Has Police Power Authority to Test the Efficacy of SIFs

Since the inception of the United States, the doctrine of state police power has allowed states to regulate certain behavior within its borders in order to promote the health, safety and general welfare of the inhabitants of the state.¹² This authority comes from the Tenth Amendment to the U.S. Constitution, which grants that “powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”¹³ Matters of public health, a category in which SIFs clearly belong, have long been concerns of the state—not the federal government. For example, landmark case *Jacobson v. Massachusetts* confirmed that states have the authority to act regarding the public health matters of compulsory vaccination and quarantine.¹⁴ The Court in *Jacobson* recognized “the authority of a State to enact . . . ‘health laws of every description’ . . . indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other States.”¹⁵ SIFs not only directly address matters of public health (HIV and hepatitis C transmission, overdoses and dangers caused to the public by individuals injecting drugs in public areas), but they do not infringe on individual rights, which is a common reason for state police power to be called into question.

NYS’s authority to act on matters of public health lies generally in the doctrine of police power, and more specifically in the following state constitutional provision, state statutes and case law. The NYS Constitution provides that “[t]he protection and promotion of the health of the inhabitants of the state are matters of public concern and provision therefor shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine.”¹⁶ Specifically, in the New York Public Health Law, the DOH Commissioner’s responsibilities include “tak[ing] cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto . . . investigat[ing] the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health [and] obtain[ing], collect[ing] and preserv[ing] such

¹⁰ See, e.g., Lianping Ti & Thomas Kerr, *The Impact of Harm Reduction on HIV and Illicit Drug Use*, 11 Harm Reduction J. 7 (2014) and Martin A. Andersen & Neil Boyd, *A Cost-Benefit and Cost-Effectiveness Analysis of Vancouver’s Supervised Injection Facility*, 21 INT’L J. OF DRUG POL’Y 1 (2009).

¹¹ N.Y. Legis. Assemb. A-8534. Reg. Sess. 2017-2018 (June 20, 2017).

¹² See generally Jorge E. Galva et al., *Public Health Strategy and the Police Powers of the State*, 120 Public Health Rep. Supp 1 (2005).

¹³ U.S. Const. amend. X.

¹⁴ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

¹⁵ *Id.* at 25.

¹⁶ N.Y. Const. art. XVII, § 3.

information relating to marriage, birth, mortality, disease and health as may be useful in the discharge of his duties or may contribute to the promotion of health or the security of life in the state . . .”¹⁷ Additionally, “whenever required by the governor, the [C]ommissioner shall make an examination concerning nuisances or questions affecting the security of life and health in any locality . . .”¹⁸ The research functions and benefits of the proposed SIFs would relate to such an examination concerning life and health of the residents of NYS.

New York case law echoes the state police power authority regarding public health that has been established in cases in other jurisdictions and in the Supreme Court: the New York Court of Appeals has held that “[a]mong all the objects to be secured by governmental laws none is more important than the preservation of the public health”¹⁹ and that “[t]he police power, which belongs to every sovereign state, may be exerted by the legislature . . . whenever the exercise thereof will promote the public health, safety or welfare.”²⁰ Since the pilot program proposed by the harm reduction community involves the operation of SIFs within New York City, it is worth noting that the New York City Department of Health and Mental Hygiene has its own power to “take such action as may become necessary to assure the maintenance of public health, the prevention of disease, or the safety of the City and its residents.”²¹ The operations of a SIF would certainly help to achieve all three of these objectives, and New York City has exercised this authority to act on matters of public health before (*e.g.* city smoking bans). However, the DOH Commissioner still exercises general supervision over local health officers,²² and state authorization is the optimal pathway for establishing a SIF research pilot, as opposed to relying solely on city authorization, to further avoid any potential conflict between State-wide general purpose drug enforcement authorities and local public health initiatives.²³ Specifically, consistent with other NYS initiatives that further health care reform and public health goals, DOH can waive—at least on a temporary basis during the pendency of any pilot programs or research studies—application of any state laws, regulations or authorities that may otherwise present legal hurdles to the study of SIFs.²⁴

¹⁷ N.Y. Pub. Health Law § 206(1).

¹⁸ N.Y. Pub. Health Law § 1301(1)

¹⁹ *Crayton v. Larabee*, 220 N.Y. 493, 501 (1917).

²⁰ *Viemeister v. White*, 179 N.Y. 235, 238 (1904).

²¹ N.Y.C. Health Code § 3.01(c). Note also that certain N.Y. Pub. Health Law provisions governing control of contagious diseases do not apply to New York City, and therefore the New York City Health Code, New York City Charter, and New York City Administrative Code would apply to those subject areas. See *New York State Public Health Legal Manual*, NEW YORK STATE UNIFIED COURT SYSTEM AND NEW YORK STATE BAR ASSOCIATION, <https://www.nycourts.gov/whatsnew/pdf/PublicHealthLegalManual.pdf> (2011).

²² N.Y. Pub. Health Law § 206(1)(b).

²³ An example of city authorization without state support comes from New Jersey, where Atlantic City had an ordinance establishing a syringe exchange program, but the court found that the ordinance was preempted by state criminal law and thus invalid. See *State ex rel. Atl. Cty. Prosecutor v. City of Atl. City*, 879 A.2d 1206, 1209 (N.J. Super. Ct. App. Div. 2005).

²⁴ For example, the Delivery System Reform Incentive Payment (“DSRIP”) Program allows for the waiver of certain NYS regulations in order for NYS to reinvest \$8 billion in federal savings generated by Medicaid Redesign Team reform. See *DSRIP Overview*, NEW YORK STATE DEPARTMENT OF HEALTH, https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/overview.htm (last visited Oct. 30, 2017).

Part 3: Federal Law Challenges for SIFs Are Mitigated through an Exercise of State Police Power Authority

Although it is well within NYS's police power to authorize SIFs, it also is necessary to consider the interplay with federal drug law; specifically, whether federal law would in any way "preempt" and thus nullify any state authorization. Preemption generally applies when a federal law addresses the same subject matter or conduct to which a state law or regulation applies.²⁵ We must consider whether any State action authorizing SIFs, either on a permanent or on a pilot basis, implicates federal restrictions under the CSA and would both invalidate the State authorization and subject the provider community to a risk of enforcement. Based on an analysis of the applicable provisions of the CSA that would likely be implicated by the operation of SIFs,²⁶ our research leads to the conclusion that, although not obviated, the risk of a strong federal enforcement response is mitigated by several factors, especially when compared against the precedent of medical marijuana distribution.²⁷ Additionally, there is a strong and positive distinction to be drawn that, while medical marijuana dispensaries or prescriptions are organized for the purpose of direct distribution and sale of marijuana in conflict with federal drug laws and in violation of the CSA, SIFs involve only supervised use of drugs monitored by health care providers for the purposes of shared public health goals and without pecuniary considerations.²⁸ Thus, an exercise by NYS of police power in support of a SIF initiative would be consistent with, and favorably compared with but distinguished from, other state actions regarding the use of controlled substances.

A. Federal "Crack House" Statute

1. The broader purposes of CHS can be read to permit the operation of SIFs

In response to the *War on Drugs* in the 1980s,²⁹ Congress amended the CSA to add 21 U.S.C. § 856, which allows the government to prosecute property owners who intentionally allow their property to be used for the distribution or use of illicit drugs.³⁰ Section 856, commonly referred to as the "Crack House Statute," makes it unlawful to "(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance; (2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance."³¹ Although upon a plain reading, the prohibitions articulated in the CHS appear broad and could be read to preclude the operation of SIFs—

²⁵ See, e.g., *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

²⁶ 21 U.S.C. § 801-976 (2006).

²⁷ See *Gonzales v. Raich*, 545 U.S. 1, 9 (2005) (holding that application of CSA provisions criminalizing manufacture, distribution, or possession of marijuana to intrastate growers and users of marijuana for medical purposes does not violate the Commerce Clause).

²⁸ Scott Burris, et al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 St. Louis U. L.J. 1089 (2009).

²⁹ Ronald Reagan, *Radio Address to the Nation on Federal Drug Policy* (October 2, 1982), text available online at <https://www.reaganlibrary.archives.gov/archives/speeches/1982/100282a.htm>.

³⁰ 21 U.S.C. § 856(a) (2006).

³¹ *Id.*

without a doubt, SIF operators knowingly and intentionally use and maintain SIFs for the purpose of individuals' unlawful use of controlled substances—a more nuanced and refined interpretation provides otherwise. Specifically, applying the CHS to SIFs would run contrary to legislative intent, case law and, in many ways, the plain text of the statute.

With respect to legislative intent, Congress has generally indicated that “[t]he success of Federal drug abuse programs and activities requires a recognition that *education*, treatment, rehabilitation, *research*, *training*, and law enforcement efforts are interrelated” and that “[c]ontrol of drug abuse requires . . . both effective law enforcement . . . and effective health programs” (emphasis added).³² The bill that created the CSA listed “drug abuse prevention and rehabilitation” as one of three important objectives in “dealing with the growing menace of drug abuse.”³³ Similarly, the CHS was part of a comprehensive drug bill passed in October 1986 designed to “provide strong Federal leadership in establishing effective drug abuse prevention and education programs, [and] to expand Federal support for drug abuse treatment and rehabilitation efforts, and for other purposes.”³⁴ Thus, based on these purposes, neither the CHS specifically nor the CSA generally was intended to reach public health activities that promote the type of “research,” “education” and “training” that would be performed by personnel in SIFs to individuals that use injection drugs in these facilities. In fact, such a reading would run counter to other provisions of the CSA that avoid complete preemption and encourage states to implement their own methods to combat drug abuse and addiction.³⁵

With respect to case law, courts have upheld enforcement of the CHS as applied to buildings being used primarily for drug *profiteering*, which adds a further important distinction between the general intent of the CHS and the purposes of SIFs, which are in no way relate to profit.³⁶ In 2002, Congress amended the CHS to include “rogue promoters” who were knowingly using property on a one-time basis for illegal drug use, *i.e.*, raves.³⁷ Although occasional property users were included within the ambit of the CHS, the amendments confirmed that the CHS was focused on places maintained for illegal drug use and people who profit from such places.³⁸ Courts have held that distribution of a controlled substance by a physician is permissible under the CSA where the physician has a legitimate, medical purpose, apart from commercial gain.³⁹ It logically follows that SIFs could be similarly permitted under the CSA

³² 21 USC §1101 (2006).

³³ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. 18583, 91st Cong. (1970), H.R. Rep. No. 1444 (1970), as reprinted in 1970 U.S.C.C.A.N. 4566, 4567.

³⁴ *United States v. Chen*, 913 F.2d 183, 188 (5th Cir. 1990) (quoting H.R. 5484, 99th Cong. (1986), 132 Cong. Rec. S13779 (daily ed. Sept. 26, 1986)).

³⁵ 21 U.S.C. § 903 provides that the CSA is not to supersede any state law on the same subject matter which would otherwise be within the authority of the state.

³⁶ *See, e.g., United States v. Bilis*, 170 F.3d 88, 89-90 (1st Cir. 1999) (upholding conviction of defendant bar owner purchased drugs and warned drug dealers of police surveillance under section 856); *United States v. Tamez*, 941 F.2d 770, 772-73 (9th Cir. 1991) (holding that section 856 applied to defendant who used car dealership for cocaine trafficking, used cocaine, and purchased cars for business with proceeds from illegal drug activity); *United States v. Chen*, 913 F.2d 183, 186 (5th Cir. 1990) (upholding conviction of defendant motel owner alerted drug sellers of police presence, stored drugs on premises, and loaned money for the purchase of drugs for resale under section 856).

³⁷ Illicit Drug Anti-Proliferation Act of 2003, Pub. L. No. 108-21, §608, 117 Stat. 650, 691 (2003) (codified as amended at 21 U.S.C. §856 (2006)).

³⁸ *Id.*

³⁹ *See United States v. Moore*, 423 U.S. 122, 142 (1975) (holding that physicians acting within the bounds of ‘professional practice’ could have protection against prosecution under the CSA and that the defendant physician’s

because these facilities (i) will not be used for drug profiteering and (ii) will “provid[e] a space for use of controlled substances not for its own sake or for profit, but in order to promote drug treatment, prevent disease, and avoid overdose mortality.”⁴⁰

Finally, the text of both subsections of the CHS demonstrate that the “purpose” of the distribution is key. Conviction under the statute requires that the facility be “*for the purpose of manufacturing, distributing, or using*” a controlled substance.⁴¹ A plain reading of the CHS indicates that, as with the CSA, an illicit commercial drug scheme would be illegal under CHS, while health care professionals deploying controlled substances for medical purposes, or allowing the use of such substances at a SIF, would be permissible and not subject to enforcement. A SIF performs a supportive health care function through licensed or otherwise certified health care providers “for a therapeutic and preventive health purpose.”⁴² Moreover, the interventions undertaken by staff at SIFs are even more limited than a traditional licensed facility. Under common SIF models, the staff is composed of trained individuals who supervise the client’s own injection practices and administer aid or other interventions (*e.g.*, training, referrals to other drug treatment providers or health care services) only as the situation demands. The staff members do not, under any circumstances, consistent with the parameters of the CSA and the purposes of SIFs, directly administer or assist in the administration of the drugs to clients. These supervision, education, research and training functions satisfy the “purpose” test of the CHS because a SIF is operates to “promote drug treatment, prevent disease, and avoid overdose mortality,” and not to encourage, promote or profit from illegal drug use.⁴³ In other words, providing a safe space for the use of drugs is not the “purpose” of a SIF, but the means of achieving the multi-faceted purpose of SIFs to promote drug treatment, prevent disease and avoid overdose mortality.⁴⁴

2. The CSA does not prevent NYS’s ability to authorize SIFs

Aside from applicability of the CHS to SIFs (*vel non*), a related question is whether the federal CSA preempts a state’s power to authorize a SIF research pilot to determine whether this type of intervention is effective at addressing a public health crisis. Upon our review of preemption principles and associated guidance and the text of the CSA, we identified a basis for concluding that the CSA preserves the rights of a state to regulate SIFs consistent with its police power authorities. This position ultimately derives from U.S. Supreme Court precedent, which, in addressing preemption issues, assumes “that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”⁴⁵ That assumption “applies with particular force when Congress has legislated in a

conduct “exceeded the bounds of ‘professional practice’” when he failed to give physical examinations, ignored the results of the tests, distributed methadone prescriptions without taking precautions against its misuse, and prescribed as much methadone as patients demanded).

⁴⁰ Scott Burris et. al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 St. Louis U. L.J. 1089, 1133 (2009).

⁴¹ *Id.* at 1130 (emphasis added).

⁴² *Id.* at 1133.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

field traditionally occupied by the States.”⁴⁶ As a result, “when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”⁴⁷

As a basic precept, courts likely would disfavor preemption in the case of SIFs. As the Supreme Court recently pronounced, “[t]he protection of public health falls within the traditional scope of a State’s police powers.”⁴⁸ Because of this police power, the CSA “manifests no intent to regulate the practice of medicine generally.”⁴⁹ The Supreme Court has remarked that CSA’s silence is “understandable given the structure and limitations of federalism, which allow the States ‘great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.’”⁵⁰ In its analysis, a court would consider two main types of preemption: field preemption and conflict preemption. Field preemption “reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards.”⁵¹ An example of field preemption is alien registration.⁵² There is no issue of field preemption in the case of SIFs and the CHS because Section 903 of the CSA specifically states that Congress does not intend to supersede state action:

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.⁵³

Thus, by this section, known as a “savings clause,” Congress limited the preemptive effect of the CSA,⁵⁴ and a state-authorized SIF research pilot—to the extent it implicates the CSA—would not be precluded generally by the CHS.⁵⁵

Conflict preemption is unlikely to present an issue. Conflict preemption occurs where “compliance with both federal and state regulations is a physical impossibility,”⁵⁶ or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁵⁷ With respect to compliance, SIFs do not mandate or even encourage drug use, rather just the opposite, so it is entirely possible to for a state to authorize operation of

⁴⁶ *Id.*

⁴⁷ *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

⁴⁸ *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 596, 131 S. Ct. 2653, 2681, 180 L. Ed. 2d 544 (2011).

⁴⁹ *Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006).

⁵⁰ *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996)) (internal quotation marks omitted).

⁵¹ *Arizona v. United States*, 567 U.S. 387, 401 (2012).

⁵² *Id.*

⁵³ 21 U.S.C. § 903.

⁵⁴ *Id.*

⁵⁵ Scott Burris et. al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 St. Louis U. L.J. 1089, 1135 (2009).

⁵⁶ *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)).

⁵⁷ *Id.* (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

a SIF and for such state action not to run afoul of the CHS.⁵⁸ With respect to standing as an obstacle, SIFs are compatible with the CHS.⁵⁹ The “purpose” of the CHS to prohibit property owners from intentionally maintaining their property for the distribution or use of drugs and profiting therefrom.⁶⁰ As discussed above, Congress intended to exclude *bona fide* health facilities (and related public health and treatment facilities) authorized under state law from the CSA’s reach.⁶¹ Thus, a federal prosecutor seeking to enforce the CSA against SIFs as a violation of the CHS provisions—while within the federal prosecutor’s enforcement ability and discretion—would have to make a difficult case that runs contrary to compelling interpretations of the CHS, applicable legislative history and longstanding principles of federalism based on Supreme Court precedent.

B. Marijuana and Similar Cases Are Instructive for State Approval of SIFs

The principles of federalism that govern the interaction between state public health decisions authorized by the police power and federal drug law is illustrated in case law on state marijuana legalization and medical aid in dying. In *Gonzales v. Raich*, the Court held that the federal government was within its rights under the Commerce Clause to criminalize the production and use of homegrown marijuana, despite California’s legalization of marijuana for medicinal use.⁶² Therefore, the power of the federal government to enforce federal prohibitions, over the objection of states, against marijuana remains.⁶³ However, SIFs are distinguishable from the facts of *Gonzales v. Raich* in that they are not engaged in the act of commerce. Moreover, unlike the dispensaries at issue in *Raich*, and consistent with the application of the CHS to SIFs, SIFs are not-for-profit enterprises that undertake a public health intervention for the common good and engage in research to determine whether these interventions promote public health in the form of reduced mortality and increased access to drug treatment, rather than entities that engage in the profiteering or dispensing of an illegal drug. SIFs’ functions are far more similar to the administration of health care services through supervision and monitoring than a business enterprise. As such, any challenge or enforcement action by the federal government would necessarily implicate whether such action exceeds the federal government’s Constitutional authority under the CSA act in light of the Commerce Clause.

The dissent in *Gonzales v. Raich* is important for its comment that “a single courageous State may, if its citizens choose, serve as a laboratory, and try novel social and economic experiments without risk to the rest of the country” and that state police power has always “included authority to define criminal law” and protect the health of its citizens.⁶⁴ There are a multitude of cases showing that it is appropriate for the federal government to show some deference to states on their marijuana laws; in Connecticut, for example, the court found that the

⁵⁸ Scott Burris et. al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 St. Louis U. L.J. 1089, 1135 (2009).

⁵⁹ *Id.*

⁶⁰ 21 U.S.C. § 856(a) (2006).

⁶¹ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. 18583, 91st Cong. (1970), H.R. Rep. No. 1444 (1970), as reprinted in 1970 U.S.C.C.A.N. 4566, 4567.

⁶² See *Gonzales v. Raich*, 545 U.S. 1 (2005).

⁶³ The risk that the government will actually enforce those laws is a separate question, discussed in Section V of this memorandum.

⁶⁴ *Gonzales v. Raich*, 545 U.S. 1, 42 (O’Connor, J., dissenting) (internal citations omitted).

CSA did not preclude enforcement of a Connecticut's Palliative Use of Marijuana Act, which prohibits employers from firing or refusing to hire someone who uses marijuana for medicinal purposes.⁶⁵ In *County of San Diego v. San Diego NORML*, the court found that California's Medical Marijuana Program Act's medical user of marijuana identification card scheme did "not pose a significant impediment to specific federal objectives embodied in the CSA. The purpose of the CSA is to combat recreational drug use, not to regulate a state's medical practices."⁶⁶ The court also noted that the CSA does not compel states to impose criminal penalties for marijuana possession.⁶⁷ Taken together, these cases provide a firm basis for NYS to consider an appropriate exercise of its authority to allow for this exact type of "social and economic experiment" through a limited research pilot into the effectiveness of SIFs as a public health intervention.

Regarding those resources as applied to the marijuana context, a 2013 DOJ memorandum provided guidance to federal prosecutors that marijuana enforcement under the CSA should be a low priority in states that have legalized some form of its use, as long as states have strong and effective regulatory systems in place.⁶⁸ The subsequent Rohrabacher-Farr amendment prohibits the DOJ from spending funds to interfere with the implementation of state medical marijuana laws.⁶⁹ A parallel can be drawn to SIFs, although only if authorized by the state in which they operate; in fact, with state authorization, the case for SIFs is even stronger, since federal enforcement action against SIFs, with their proven positive public health outcomes, would run counter to the current presidential administration's objective, announced October 26, 2017, "to reduce the number of deaths and minimize the devastation" that the opioid epidemic inflicts upon the public.⁷⁰ In some respects, it would be antithetical for DOJ to undertake a strict enforcement of the CSA and CHS (as would be required to prosecute SIFs under the interpretations advanced above) at the same time the federal government is exploring ways to halt the spread of opioid-related deaths.

This position by NYS is further buttressed through an analogy to state authorization under the Oregon Death with Dignity Act. Under that Act, Oregon physicians could prescribe certain lethal controlled substances to certain patients with incurable and irreversible diseases. The U.S. Attorney General sought to prosecute under the CSA the physicians who did so, but the Supreme Court held that Congress intended the CSA to prevent physicians only from engaging in illicit drug dealing, not to define general standards of state medical practice.⁷¹ Moreover, the CSA did not authorize the Attorney General to declare a medical practice authorized under state law to be illegitimate.⁷² This deference to state police power, even in the face of federal drug

⁶⁵ See *Noffsinger v. SSC Niantic Operating Co. LLC*, 2017 U.S. Dist. LEXIS 124960, at *9 (D. Conn. Aug. 8, 2017).

⁶⁶ *County of San Diego v. San Diego NORML*, 81 Cal. Rptr. 3d 461, 482 (Cal. Ct. App. 2008).

⁶⁷ *Id.* at 481.

⁶⁸ See James M. Cole Memorandum: Guidance Regarding Marijuana Enforcement (August 29, 2013), Office of the Deputy Attorney General, United States Department of Justice, available at <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

⁶⁹ See Rohrabacher-Farr Amendment, first signed into law as part of the Consolidated and Further Continuing Appropriations Act, 2015, P.L. 13-235 (113th Congress).

⁷⁰ See Presidential Memorandum for the Heads of Executive Departments and Agencies re Combatting the National Drug Demand and Opioid Crisis, *supra* note **Error! Bookmark not defined.**

⁷¹ *Gonzales v. Oregon*, 546 U.S. 243, 301 (2006).

⁷² *Id.*

laws, is instructive for the regulation of SIFs, especially as staff at SIFs would be neither prescribing nor administering any controlled substance, but instead would be supervising and educating individuals on their behavior to achieve agreed-upon public health outcomes.

C. SIFs Are Being Supported in Other States

In Washington state, the Heroin and Prescription Opiate Addiction Task Force of King County (where Seattle is located), has recommended establishing SIFs, to be called Community Health Engagement Locations, in King County and is now working to make the concept operational.⁷³ In January 2017, the King County Board of Health passed a resolution adopting the recommendations of the task force, but opponents then proposed a local initiative that would ban the SIFs. On October 16, 2017, the King County Superior Court declared that this anti-SIF initiative was invalid in its entirety because it extended beyond the scope of the local initiative power.⁷⁴ Although the decision was based primarily on local initiative processes and not on the merits of the decision to implement SIFs, it is worth noting that neither the court nor the initiative questioned whether SIFs are legal; arguably, if SIFs were presumptively illegal, such an initiative presumably might not have been needed to stop them.

Part 4: Impact of State Support on Prevailing Enforcement Risks and Uncertainty

No statute or case law directly prohibits the establishment and operation of SIFs as a specific form of drug treatment. Notwithstanding this lack of explicit authority, and the encouragement that can be drawn from the progress made by the King County SIF project, federal enforcement risks remain under the CSA and CHS, even if NYS were to exercise its broad policy authority to permit the operation of SIFs as a drug treatment pilot. With that said, the questions that necessarily would be addressed in any federal enforcement action against SIFs—not just the substantive issues regarding whether the CSA and CHS can be interpreted to prohibit SIFs, but also whether the federal government under principles of federalism and state deference is capable of challenging NYS’s exercise of its police powers—would be influenced heavily by a specific authorization of a research pilot involving SIFs by NYS. Put another way, clear state support for a pilot program to research the effectiveness of SIFs would provide greater certainty in what otherwise would be an uncertain legal environment—in this sense, state support is in reality a prerequisite.⁷⁵

Given this need for State support, different types of State action are capable of serving this purpose, including enactment of legislation (*e.g.*, N.Y. Legis. Assemb. A-8534) and promulgation of emergency regulations by DOH. However, it would also be sufficient for DOH,

⁷³ Heroin and Prescription Opiate Addiction Task Force [of King County, Washington], Final Report and Recommendations (September 15, 2016), available at <http://www.kingcounty.gov/~media/depts/community-human-services/behavioral-health/documents/herointf/Final-Heroin-Opiate-Addiction-Task-Force-Report.ashx?la=en>.

⁷⁴ *Protect Public Health v. Joshua Freed, Impaction, Citizens for a Safe King County, and Julie Wise*, Superior Court of the State of Washington in and for King County, No. 17-2-21919-3 SEA, Order Granting Plaintiff’s Motion for Declaratory Judgment and Injunctive Relief (October 16, 2017), available at <https://drive.google.com/file/d/0B8eWyAlyInRGZk44TU1XaWRRa00/view>.

⁷⁵ See Sanjay Gupta, *Opioid Addiction and the Most Controversial Bathroom in New York*, CNN.COM (Oct. 26, 2017), available at <http://www.cnn.com/2017/10/25/health/opioid-addiction-bathroom-safe-injection-site/index.html>.

through the AIDS Institute or another State agency, to authorize formally a research pilot designed to evaluate the effectiveness of SIFs in achieving harm reduction and State public health goals. Importantly, for this research pilot to succeed, the authorization from NYS should be clearly stated and in furtherance of its police power authority, such that providers of SIF services can use this documentation to demonstrate that their actions are based on that State support.

Conclusion

The opioid crisis confronts large swaths of the country and the State. We understand that SIFs, in their focus on overdose prevention, treatment and research, may be a highly effective tool to combat this crisis, and that the harm reduction community wishes to take a lead role in a pilot program to research the effectiveness of SIFs, if such a pilot program is legally permissible. There is a strong basis for an interpretation of the CSA and CHS as being consistent with and permitting SIFs, and the current presidential administration has expressed, both broadly and with specific recommendations from the President's Commission, its desire to fight the opioid crisis, in part through overdose prevention, treatment and research. However, given the plain language of the CHS, the possibility of federal enforcement against SIFs remains. For SIFs to operate in NYS with a greater amount of legal certainty, NYS authorization (as an exercise of NYS's longstanding and well-established state police power to act regarding matters of the public health) is a condition precedent to any such SIF pilot. State authorization could take one of a few forms, including legislation, State regulation and action through a formal research pilot program under the auspices of DOH or the AIDS Institute.