**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>SAFEHOUSE, a Pennsylvania nonprofit Corporation,<br><br>and<br><br>JOSE A. BENITEZ, as President and Treasurer of Safehouse,<br><br>Defendants.<br><br>SAFEHOUSE, a Pennsylvania nonprofit Corporation,<br><br>Counterclaim Plaintiff,<br>v.<br><br>UNITED STATES OF AMERICA,<br><br>Counterclaim Defendant,<br>and<br><br>U.S. DEPARTMENT OF JUSTICE; WILLIAM P. BARR, in his official capacity as Attorney General of the United States; and WILLIAM M. McSWAIN, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania,<br><br>Third-Party Defendants. | : | Civil Action No. 19-0519 |

**BRIEF OF THE DISTRICT OF COLUMBIA AND THE STATES OF COLORADO, DELAWARE, MICHIGAN, MINNESOTA, NEW MEXICO, OREGON, AND VIRGINIA AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT/COUNTERCLAIM PLAINTIFF**

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## GLOSSARY

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| CDC | Center for Disease Control and Prevention |
| CSA | Controlled Substances Act |
| HHS | U.S. Department of Health and Human Services |
| MAT | Medication-Assisted Treatment |
| SIS | Safe Injection Site |

## INTEREST OF *AMICI CURIAE*

The District of Columbia and the States of Colorado, Delaware, Michigan, Minnesota, New Mexico, Oregon, and Virginia (collectively "the *Amici* States") file this brief as *amici curiae* in support of Defendant/Counterclaim-Plaintiff Safehouse. The *Amici* States are battling an unprecedented nationwide opioid crisis that claims over 130 lives every day. States are working to address this urgent epidemic, developing robust interventions to prevent opioid use disorder, and to treat those suffering from opioid dependence. But, as the data demonstrate, neither States nor the federal government have solved this crisis yet. The *Amici* States share a goal of preventing overdose deaths, but the means of achieving that important goal must vary based on the nature of the epidemic on a local level, the risk factors in individual communities, and the resources available.

Safehouse's proposed intervention—the operation of a safe injection site ("SIS")—is a critical measure designed to save lives and to fill a time-sensitive gap in medical care that many localities struggle to overcome. Other States, relying on empirical evidence of their effectiveness, are also considering implementing SISs. As laboratories of experimentation and the primary regulators of public health, States should be free to adopt cutting-edge medical interventions. The federal government's opposition and threat of criminal prosecution under the Controlled Substances Act ("CSA"), however, promises to interfere with States' power to implement SISs and other innovative strategies. The *Amici* States have a strong interest in preserving their traditional authority over public health and safety, and in ensuring that the federal government does not undermine their crucial work in addressing the opioid crisis.

## SUMMARY OF ARGUMENT

1. Every day, Americans die from overdoses caused by opioids. The deaths are widespread, and each State feels the sting of losing its citizens to these highly addictive drugs. The crisis is not new. Opioid deaths have been on the rise since 1999, based largely on the proliferation of opioid prescriptions. But as the use of opioids has evolved, there has been a significant increase in overdose deaths due to street drugs like heroin and synthetic opioids such as fentanyl. Death can occur within minutes of heroin or fentanyl use—too rapidly for emergency personnel to be called to the scene before lives are lost.

The *Amici* States are on the front lines of this crisis, battling each day to save their citizens from the deadly effects of opioids. But even States' significant efforts have not ended this epidemic. As fentanyl and heroin use increases, States need the freedom to implement innovative treatment programs to save lives.

2. States have a traditional and well-established role in protecting the health and welfare of their citizens. The opioid crisis, like so many other public health issues, is a matter of local concern. The cause and characteristics of the crisis in each state differ. Rural areas may lack substance abuse and medical programs, whereas metropolitan areas are also dealing with long-term illegal drug use, homelessness, and racial disparities in medical treatment. As laboratories of democracy, States must be able to use their broad powers to develop the tailored interventions needed to save lives.

States on the forefront of public health crises often develop successful, novel interventions that become the nationwide standard. Good Samaritan laws that offer limited legal immunity to encourage bystanders to seek help for overdose victims began in New Mexico in 2007; as of May 2018, similar laws have been enacted in 45 states and the federal government highlights these laws

as a successful intervention. Similarly, States have eliminated barriers for Medicaid recipients who need medication-assisted treatment to treat opioid use disorder. Syringe exchange programs were also once limited to a single locale but are now viewed as a standard harm-reduction approach to prevent the spread of disease. And many more interventions that are now commonplace were initially pioneered by the States.

Operating or endorsing safe injection sites falls within the States' power to implement public health measures. Although the sites are new to the United States, over 100 sites operate in 60 different cities in Canada, Australia, and many European nations. After studying these sites, many States and cities are considering them as a means of saving lives. The studies predict that the sites will reduce deaths and costs. And they are a unique solution to the common problem in many urban areas of rapid, unintended overdoses of heroin or fentanyl.

3. The CSA should not be interpreted to prevent States from exercising their police power to develop innovative public health solutions. Section 856 of the CSA was developed to shut down "crack houses," not community health clinics. SISs, unlike crack houses, do not distribute, manufacture, or encourage drug possession. The sole purpose of an SIS is to prevent death and provide medical care along with substance abuse services.

Moreover, the federal government's interpretation of Section 856 raises significant constitutional questions about Congress's ability to intrude on traditional state police powers. The States—not the federal government—regulate the practice of medicine, and SISs are medical interventions. Indeed, given the local nature of an SIS and its purpose of preventing deaths, it is implausible to believe that an SIS like Safehouse would affect interstate commerce, which is a prerequisite to the exercise of federal authority under the Commerce Clause. Courts are obligated to avoid serious constitutional questions, including federalism and Commerce Clause issues, where

an alternative interpretation is fairly possible. Here, Safehouse has provided a fair interpretation that allows States to retain their traditional role in protecting the public health. The Court should therefore embrace that reasonable interpretation.

## ARGUMENT

### I. The Opioid Crisis Profoundly Affects The States, And They Must Be At The Forefront Of Any Solution.

#### A. Opioid abuse is a problem on a national scale that affects every state.

The nationwide opioid crisis affects all of the *Amici* States, taking a daily, devastating toll on their citizens.[1] Moreover, the crisis has proven extremely difficult to solve, in part because the opioid epidemic is unique: opioids are often-prescribed, highly addictive, frequently contaminated when purchased illegally, and affect victims across geographies and socioeconomic classes. *See* Ctrs. for Disease Control & Prevention, *Understanding the Epidemic*, CDC.gov, https://www.cdc.gov /drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

States have reported staggering numbers of overdose deaths and other dire consequences stemming from the crisis. In Maryland, overdose deaths increased from 570 in 2009 to 2,114 in 2018. Opioid Operational Command Ctr., *Annual Report*: *Before It's Too Late* 3, 7 (2019).[2] In 2017 alone, Michigan reported 2,033 overdose deaths involving opioids. Nat'l Inst. on Drug

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[1] This nationwide crisis has been studied by the Center for Disease Control and Prevention ("CDC") and covered in a variety of news outlets. *See, e.g.*, Ctrs. for Disease Control and Prevention ("CDC"), *Drug Overdose Deaths*, www.cdc.gov/drugoverdose/data/statedeaths.html (last visited June 24, 2019); James Nachtwey et al., *The Opioid Diaries*, Special Report, Time, https://time.com/james-nachtwey-opioid-addiction-america (last visited June 24, 2019); Joel Achenbach and Dan Keating, *Unnatural Causes: Sick and Dying in Small-town America*, Series, Wash. Post, https://www.washingtonpost.com/unnatural-causes/?utm_term=.1c03ebe3ee8c (last visited June 24, 2019); Scott Glover et al., *Dying for Relief: A Times Investigation* (Nov.-Dec. 2012) L.A. Times, http://graphics.latimes.com/prescription-drugs-part-one/ (last visited June 24, 2019).

[2] *Available at* https://beforeitstoolate.maryland.gov/wp-content/uploads/sites/34/2019/05/OOCC-Final-Annual-Report-2018.pdf.

Abuse, *Michigan Opioid Summary*, https://www.drugabuse.gov/opioid-summaries-by-state/michigan-opioid-summary (last updated Mar. 2019).[3] On a nationwide scale, the opioid crisis claims over 130 lives each day. U.S. Dep't of Health & Human Servs., *What is the U.S. Opioid Epidemic?*, www.hhs.gov/opioids/about-the-epidemic/index.html (last updated Jan. 22, 2019). Over 400,000 people have died from opioid-related overdoses in the last 20 years. *Understanding the Epidemic*, *supra*.

Over time, the nature of opioid abuse has evolved, which has made it increasingly difficult to engineer an enduring solution. The CDC explains the opioid crisis as comprising three waves: the first involving primarily prescription opioids, the second indicating increased heroin abuse, and the third heralding an uptick in synthetic opioid use, such as fentanyl. *Id.*

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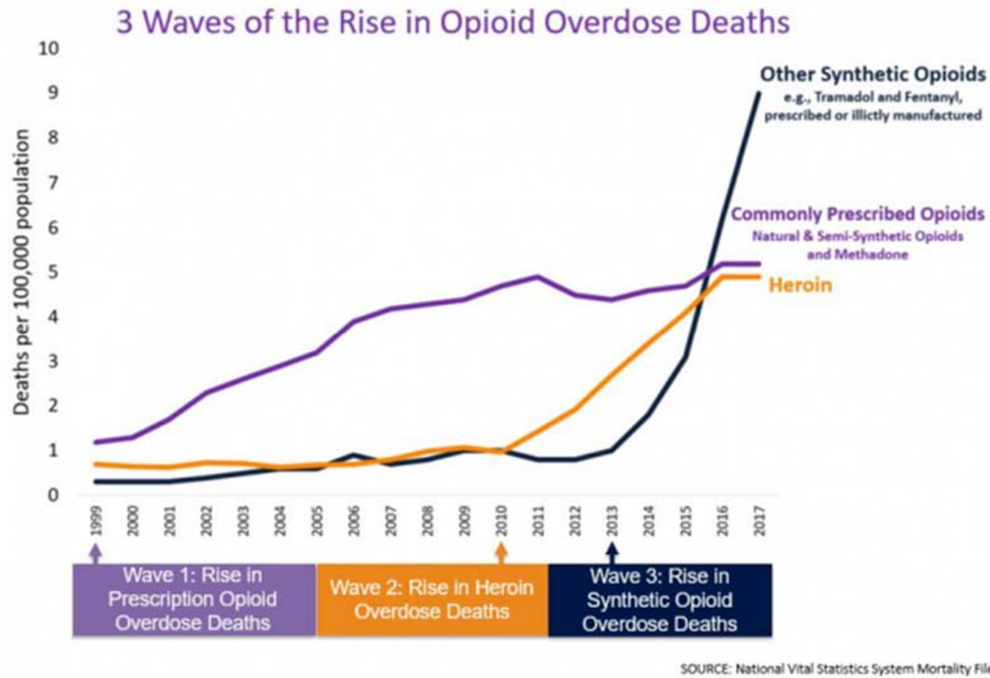
[3] *See generally* Nat'l Inst. on Drug Abuse, *Opioid Summaries by State*, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state (last updated May 2019) (Minnesota overdose deaths increased from approximately 50 to 422 from 1999 to 2017; Oregon's overdose deaths increased from under 150 to 344 between 1999 and 2017; Alaska overdose deaths increased from fewer than 40 to 102 between 2002 and 2017; New Mexico overdose deaths increased from fewer than 200 to 332 between 1999 and 2017).




During the first wave, which began around 1999, almost 218,000 people died from an overdose related to prescription opioids. Ctrs. for Disease Control & Prevention, *Prescription Opioid Data*, CDC.gov, www.cdc.gov/drugoverdose/data/prescribing.html (last updated Dec. 19, 2018). These fatalities correlated with "dramatic increases in [the] prescribing of opioids for chronic pain." Ctrs. for Disease Control & Prevention, *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes* 6 (2018).[4] The prescription-based crisis affected regions across the country. *Id.* at 67-68, tbl. 4.

During the second wave, starting in 2010, overdose deaths due to heroin began to increase. *Understanding the Epidemic*, *supra*. By 2017, there were over 15,000 deaths per year related to heroin use. Ctrs. for Disease Control & Prevention, *Today's Heroin Epidemic*, CDC.gov, www.cdc.gov/drugoverdose/opioids/heroin.html (last updated Dec. 19, 2018). Heroin, which is

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4 *Available at* www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.

illegal, carries unique risks: it is commonly injected, and the use and disposal of syringes increases the risk of blood-borne illnesses such as HIV and Hepatitis B and C. Ctrs. for Disease Control & Prevention, *Heroin Overdose Data*, CDC.gov, www.cdc.gov/drugoverdose/data/heroin.html (last updated Dec. 19, 2018). Heroin users include both people who were prescribed opioids and developed an addiction, as well as longtime drug users. Although heroin is abused everywhere, it has a concentrated impact on cities. *Id*.

During the third wave, which began around 2013, the use of synthetic opioids added additional fuel to the opioid fire. *Understanding the Epidemic*, *supra*.; Ctrs. for Disease Control & Prevention, *Opioid Basics: Fentanyl,* CDC.gov, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html (last updated Dec. 19, 2018). Even in relation to heroin, synthetic opioids pose a serious problem. Fentanyl, for example, is 50 to 100 times more potent than morphine. Ctrs. for Disease Control & Prevention, *Commonly Used Terms*, CDC.gov, www.cdc.gov/drugoverdose/opioids/terms.html (last updated Dec. 19, 2018) (defining fentanyl). Illegally sold fentanyl is often mixed with heroin and other drugs, thereby increasing the risk of overdose for an already potent drug. *Id*. Fentanyl, like heroin, is injected and thus is related to increased risk of blood-borne infections. Large metropolitan areas have shouldered the brunt of this third wave of the crisis. Ctrs. for Disease Control & Prevention, *Synthetic Opioid Overdose Data*, CDC.gov, www.cdc.gov/drugoverdose/data/fentanyl.html (last updated Dec. 19, 2018).

Particularly with fentanyl, overdose deaths can occur within minutes, as Safehouse details in its brief. Safehouse's Memo. in Opp. at 9 (ECF 48). Quick action is essential to prevent death. *See* Ctrs. for Disease Control & Prevention, *Preventing Opioid Overdose: Know the Signs. Save a*

*Life*. 2 ("It's important to recognize the signs [of overdoses] and *act fast*.") (emphasis added).[5] Currently, naloxone is among the best life-saving interventions. It acts to block and reverse the effects of an opioid and "very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing." Nat'l Inst. on Drug Abuse, *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)* (last updated Apr. 2018), https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio. Because of fentanyl's potency, multiple doses of naloxone may be required to restore breathing during an overdose. *Id*. And all patients "given naloxone should be observed constantly . . . and for at least 2 hours by medical personnel after the last dose of naloxone to make sure breathing does not slow or stop." *Id*.

**B. States and localities are instrumental to solving the problem.**

States are on the front lines of addressing this crisis. Acknowledging this reality, the federal government declared the "deadly opioid crisis" a nationwide public emergency with a "'call to action . . . which empowers the real heroes of this fight: the communities on the frontlines of the epidemic.'" Press Release, U.S. Dep't of Health & Human Servs., *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis* (Oct. 26, 2017) (quoting Eric D. Hargan, Acting Sec'y, Health & Human Servs.).[6] As President Trump correctly observed, "Ending the epidemic will require mobilization of government, local communities, and private

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[5] *Available at* https://www.cdc.gov/drugoverdose/pdf/patients/Preventing-an-Opioid-Overdose-Tip-Card-a.pdf.

[6] *Available at* https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

organizations. It will require the resolve of our entire country." *Combatting the Opioid Epidemic: 2019 Budget Fact Sheet*, Exec. Office of the President (quoting President Trump).[7]

The federal government has expended significant resources to fight the opioid crisis. Bipartisan Policy Ctr., *Tracking Federal Funding to Combat the Opioid Crisis* (March 2019).[8] The federal government more than doubled opioid spending from fiscal years 2017 to 2018. *Id.* at 5 (comparing FY 2017 $3.3 billion appropriations to FY 2018 $7.4 billion). Similarly, they have provided the States with significant funds to address the opioid crisis. *Id*. at 35, 43, 52 (detailing increased funds from FY 2017 to 2018, *e.g.*, New Hampshire from $16 million to $59.5 million, Ohio from $119 million to $224.9 million, and Tennessee from $63.3 million to $114.6 million).

Because there is no one-size-fits-all solution, state and local governments and local non-profits must develop strategies "driven by evidence and data" rooted in their communities and "must remain vigilant in maintaining a holistic and grounded understanding of who is at risk of fatal overdose, how that risk is constructed, and what can be done to reduce that risk as much as possible." Jennifer J. Carroll et al., Ctrs. for Disease Control & Prevention, *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States* 3 (2018).[9] For example, States still struggling with the first wave of the crisis may continue to spend the bulk of their time and money combating prescription opioid abuse. By contrast, states with large urban

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[7] *Available at* https://www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Combatting-the-Opioid-Epidemic.pdf. *See also* U.S. Dep't of Health & Human Servs., *Fact Sheet: Combating the Opioid Crisis* 1 (Apr. 2019), https://www.hhs.gov/sites/default/files/opioids-fact-sheet-april-2019.pdf) (noting that "the most effective responses to this crisis are when entire communities come together—doctors, nurses, cops, courts, teachers, mayors, employers, parents, coaches, young people, social workers, faith leaders—everybody").

[8] *Available at* bipartisanpolicy.org/wp-content/uploads/2019/03/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf.

[9] *Available at* www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf.

populations must also contend with the explosion of fentanyl and heroin use and its consequences, including blood-borne diseases and frighteningly rapid overdoses. *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)*, *supra*.

One thing, however, is certain, regardless of geography: As states and localities work to create tailored solutions, lives hang in the balance. And the nature of the crisis continues to morph in ways that call for increased innovation.

## II. The Controlled Substances Act Should Not Be Interpreted To Criminalize Public Health And Safety Interventions, Which Are Traditionally The Subject Of State Regulation.

### A. Medical care and issues of public health and safety are areas of traditional state police power.

It is well established that States have wide latitude to address problems concerning "the protection of the lives, limbs, health, comfort, and quiet of all persons." *Medtronic Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)). This latitude permits States to experiment to solve problems of social policy. *See New State Ice Co. v. Lienmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("[A] state may . . . serve as a laboratory."). In particular, "a vital part of a state's police power" is to regulate medicine and public health. *Barsky v. Bd. of Regents of the State Univ. of N.Y.*, 347 U.S. 442, 449 (1954); *see Great Atl. & Pac. Tea Co., Inc. v. Cottrell*, 424 U.S. 366, 371 (1976) ("[U]nder our constitutional scheme the States retain broad power to legislate protection for their citizens in matters of local concern such as public health." (internal quotation marks omitted)). States must be able to respond creatively to public health crises because the effectiveness of an intervention will unquestionably depend on the specific needs of the state. Indeed, "the essence of federalism is that states must be free to develop a variety of solutions to problems and not be forced into a common, uniform mold." *Addington v. Texas*, 441 U.S. 418, 431 (1979). Especially in the case

of an ever-changing epidemic that persists despite extensive and costly interventions, States must be able to use their broad power to implement new programs in their role as "laboratories for experimentation." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring).

To implement effective interventions, States must have "a clear understanding of the causes and characteristics of local public health problems." Carroll et al., *supra*, at 3. Substance abuse interventions are most effective when programs are centered on "the needs and concerns specific to the local drug using community." *Id.* at 27. In rural areas of the country, the opioid crisis is exacerbated by a lack of substance abuse treatment infrastructure, few physicians providing medication-assisted treatment ("MAT"),[10] and insufficient regional coordination of treatment resources. *National Rural Health Association Policy Brief: Treating the Rural Opioid Epidemic,* Nat'l Rural Health Assoc. 1 (Feb. 2017).[11] Rural terrain makes for longer ambulance transit time, which increases the likelihood of overdose; lack of public transportation hinders access to treatment; and there is often significant social stigma around addiction in small communities. Chiara Corso & Charles Townley, Nat'l Acad. for State Health Pol'y, *Intervention, Treatment, and Prevention Strategies to Address Opioid Use Disorders in Rural Areas: A Primer on Opportunities for Medicaid-Safety Net Collaboration* 14 (Sept. 2016).[12]

In contrast, urban areas face challenges related to high-density populations and racial disparities in healthcare. In the District of Columbia—an exclusively urban jurisdiction—the

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[10] Medication-assisted treatment is the use of behavioral and pharmacological therapy to treat opioid use disorder. Carroll et al., *supra*, at 10. The medications used are approved by the Federal Drug Administration and treat withdrawal symptoms, block the effect of opioids, and reduce cravings. *Id.* The treatment usually requires frequent visits to the administering physician or clinic. *Id.*

[11] *Available at* www.ruralhealthweb.org/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/Treating-the-Rural-Opioid-Epidemic_Feb-2017_NRHA-Policy-Paper.pdf.

[12] *Available at* nashp.org/wp-content/uploads/2016/09/Rural-Opioid-Primer.pdf.

opioid epidemic does not "fit squarely into the public narrative of the modern opioid crisis" because the majority of overdose victims are not "member[s] of the white, rural working class." Swathi Srinivasan, *Hidden Faces of the Opioid Epidemic*, Harv. Pol. Rev. (Feb. 25, 2019).[13] Overdose victims in the District are overwhelmingly African-American and include long-term heroin users. Peter Jamison, *An Opioid Epidemic That Nobody Talks About*, Wash. Post. (Dec. 18, 2018), wapo.st/national-opioids. Effective interventions in the District must both reduce the harm from the rise in fentanyl use and provide treatment for decades-long heroin addictions. *Id.* Additionally, to be effective, local interventions must combat discrimination that African-Americans face in both addiction research and treatment. Marisa Peña, *The Opioid Crisis is Surging in Black, Urban Communities*, NPR (Mar. 8, 2018) ("[The African-American] population has been totally ignored. They are invisible.").[14]

Like the District, California has a host of urban communities struggling with the opioid epidemic, and those communities face their own unique challenges. In San Francisco, for example, approximately 69 percent of people who inject drugs have "reported living on the street, using homeless shelters, or living in [hotels]." San Francisco Safe Injection Servs. Task Force, *2017 Final Report* 5, 7 (2017).[15] This results in widespread public injection, which leads to both unsafe disposal of drug paraphernalia and creates "dangerous and alarming conditions in public spaces for residents, visitors, and [drug users] themselves."[16] *Id.* at app. A. Because "prevention

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13 *Available at* www.harvardpolitics.com/united-states/hidden-faces-of-the-opioid-epidemic.

14 *Available at* www.npr.org/2018/03/08/579193399/the-opioid-crisis-frightening-jump-to-black-urban-areas.

15 *Available at* www.sfdph.org/dph/files/SIStaskforce/SIS-Task-Force-Final-Report-2017.pdf.

16 New York City faces similar issues. *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, NYC Health 10-11,

strategies need to take into account the realities, experiences, and perspectives of those at risk of overdose," Carroll et al., *supra*, at 3, public health officials must consider the high-poverty, densely-populated nature of urban neighborhoods in order to be "responsive to local realities." *Id.*

As with many public health issues, then, the opioid crisis is in many ways highly localized. Accordingly, States need leeway to "develop a variety of solutions to problems and not be forced into a common, uniform mold." *Addington*, 441 U.S. at 431.

### B. Acting as laboratories, many states have implemented and spread successful interventions.

Some of the most successful and widely used opioid interventions originated because a state was empowered to "try novel and social experiments without risk to the rest of the country." *New State Ice Co.*, 285 U.S. at 311. For example, Good Samaritan legislation, which encourages bystanders and fellow users to seek help for those suffering from a drug overdose by offering limited immunity from drug-related charges, was an effort originally pioneered by the States. New Mexico was the first state to pass Good Samaritan laws for overdose prevention in 2007; by May 2018, 45 States had enacted similar laws. Carroll et al., *supra*, at 19. These laws have effectively addressed the fear that many overdose bystanders have of arrest or criminal charges. *See id.* ("An evaluation of 911 Good Samaritan Law education efforts in New York City found that awareness of this law statistically increased the likelihood that a bystander would call 911 in the event of an overdose.").

States have also engaged in meaningful research and creative regulation. A 2016 New York examination of obstacles to opioid-addiction treatment "prompted [major insurance companies] to remove all prior authorization requirements for [patients] seeking [MAT]," an

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www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report.pdf?mc_cid =2a562844de&mc_eid=fec6ed8b11.

insurance formality that leads to unnecessary delay in treatment. *Id.* at 15. Multiple states have since eliminated that requirement for Medicaid recipients and collaborated with insurance companies to do the same, preventing patients from self-medicating with opioids or illegal drugs when faced with delays in treatment.[17]

Syringe exchange programs ("SEPs") too were once limited to a single city in Washington state—Tacoma. Melissa Vallejo, Note, *Safer Bathrooms in Syringe Exchange Programs: Injecting Progress into the Harm Reduction Movement*, 118 Colum. L. Rev. 1185, 1195 (2018). A harm-reduction approach that provides drug users with clean needles at no cost, SEPs help prevent the spread of HIV, Hepatitis B and C, and other blood-borne diseases by providing IV drug users with sterile needles. Carroll et al., *supra*, at 26. SEPs have been controversial because they have been mistakenly viewed as "feeding an addiction," *Needle Exchange Programs: Consideration for Criminal Justice* 1,[18] yet their effectiveness in preventing the spread of disease is well-documented and they now operate as an important harm-reduction approach in most states. *Id.* at 1; *id*. at 3 (SEPs "have com[e] into being [as the result of] civil disobedience; gradual

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[17] Carroll et al., *supra*, at 15 (Rhode Island); Press Release, N.J. Dep't of Human Servs., New Jersey Medicaid Removes Prior Authorization Requirements for Opioid Addiction Treatment Medication (Apr. 1, 2019), www.nj.gov/humanservices/news/press/2019/approved/20190401.html (New Jersey); Press Release, Am. Med. Ass'n., Arkansas Sets Standard for States by Removing Prior Authorization for Treatment of Opioid Use Disorder (Apr. 22, 2019), www.ama-assn.org/press-center/press-releases/arkansas-sets-standard-states-removing-prior-authorization-treatment (Arkansas); Press Release, Am. Med. Ass'n., Pennsylvania Removes Prior Authorization for Opioid Treatment (Oct. 12, 2018), www.ama-assn.org/press-center/press-releases/pennsylvania-removes-prior-authorization-opioid-treatment (Pennsylvania); Press Release, Am. Med. Ass'n, District of Columbia Takes Important Step to Reverse Opioid Epidemic (Apr. 5, 2019), www.ama-assn.org/press-center/press-releases/district-columbia-takes-important-step-reverse-opioid-epidemic (District), Press Release, Am. Med. Ass'n, Iowa Removes Barriers to Treatment of Opioid Use Disorder (May 6, 2019), www.ama-assn.org/press-center/press-releases/iowa-removes-barriers-treatment-opioid-use-disorder (Iowa).

[18] *Available at* harmreduction.org/wp-content/uploads/2012/01/NEPcriminaljusticeCIPP.pdf.

community acceptance and legitimization; and local community or foundation funding and support."). Many states have legalized SEPs by permitting state and local health departments or nonprofits to provide SEP services. *See, e.g.*, Tenn. Code. Ann. § 68-1-136 (2017); Md. Code. Ann., Health-Gen § 24-903 (2016); N.C. Gen. Stat. § 90-113.27 (2017); N.M. Stat. Ann. § 24-2C-1 to 24-2C-6. And in 2016, Congress passed legislation that gives states and localities the ability to use federal funds provided through the Department of Health and Human Services for certain costs of operating SEPs. Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 52, 129 Stat. 2242, 2652 (2015). Once a harm-reduction strategy limited to a single city in a single state, SEPs now help to prevent the spread of disease nationwide.

To be sure, many of the interventions implemented to date focus on the first phase of the opioid crisis—opioid use disorder tied to prescription opioids.[19] Those interventions include regulating and monitoring prescription opioids to reduce the number of prescriptions and to prevent overlapping prescriptions. For example, Oregon developed a prescription drug monitoring program to better regulate the distribution of narcotic pain relievers. Oregon Health Auth., *Prescription Drug Monitoring Program*, Oregon.gov, https://www.oregon.gov/oha/Ph/preventionwellness/safeliving/pdmp/Pages/index.aspx; *see also* New Mexico Bd. of Pharm., *What Is the New Mexico Prescription Monitoring Program?*, http://nmpmp.org/. States are also working with medical professionals for alternatives to chronic pain management. *See, e.g.*, TN Dep't of Health, *Turning the Tide: Collaborating to Prevent Opioid Abuse*, TN Opioid Epidemic Response, https://www.tn.gov/health/health-program-areas/tdh-opioid-coalition/redirect-tn-opioid-epidemic

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[19] Twenty-nine states receive funding from the CDC specifically related to preventing overdose deaths from prescription opioids. Ctrs. for Disease Control & Prevention, *State Information: Prevention for States*, CDC.gov, www.cdc.gov/drugoverdose/states/state_prevention.html (last updated Oct. 23, 2017).

-response/turning-the-tide-collaborating-to-prevent-opioid-abuse.html (last visited July 1, 2019) (detailing efforts by Tennessee); *see also* Oregon Coalition for Responsible Use of Meds, *Regional Summits*, https://orcrm.oregonpainguidance.org/regional-summits/overview (last visited July 1, 2019) (explaining Oregon's programs). For persons already suffering from opioid use disorder, states are increasing access to substance abuse treatment services, including MAT. *See Opioid Addiction Resources: Medication-Assisted Treatment*, Michigan.gov, https://www.michigan.gov/opioids/0,9238,7-377--480836--,00.html (last visited July 1, 2019) (outlining Michigan's MAT program); *see* Oregon Health Auth., *Medication-Assisted Treatment and Recovery*, Oregon.gov, https://www.oregon.gov/oha/HSD/AMH/Pages/UMATR.aspx (last visited July 1, 2019) (detailing Oregon's efforts). And the states, including the District of Columbia, are pursuing opioid drug manufacturers for their deceptive marketing practices. *See, e.g.*, Lenny Bernstein & Katie Zezima, *Purdue Pharma, State of Oklahoma Reach Settlement in Landmark Opioid Lawsuit*, Wash. Post (Mar. 26, 2019) (detailing $270 million settlement obtained by Oklahoma).[20]

To stem the tide of overdose deaths, many states are also expanding first responder access to naloxone.[21] *See, e.g.*, Md. Code. Ann., Health-Gen § 13-3101 to 13-3109 (making naloxone available); Mich. Comp. Laws. Ann. § 333.17701 et seq. (same); Or. Rev. Stat. § 689.681 (2017) (same); N.M. Stat. Ann. § 24-23-1 (2016) (same). Indeed, in Pennsylvania, the Physician General has issued a standing order that constitutes a statewide prescription for eligible persons to obtain

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[20] *Available at* https://www.washingtonpost.com/national/health-science/purdue-pharma-state-of-oklahoma-reach-settlement-in-landmark-opioid-lawsuit/2019/03/26/69aa5cda-4f11-11e9-a3f7-78b7525a8d5f_story.html?utm_term=.762395547b65.

[21] Network for Pub. Health, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws* 2, https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf.

naloxone. Pa. Dep't of Health, Standing Order DOH-002-2018: Naloxone Prescription for Overdose Prevention 2 (2018).[22]

States, then, have been serving successfully as laboratories of experimentation, pioneering solutions that spread to other jurisdictions and that have even been endorsed by the federal government. It is crucial that States and localities maintain this flexibility.

### C. Despite substantial efforts from multiple states, new and innovative interventions are needed.

While there has been some progress—for example, there has been a consistent overall reduction in the number of opioid prescriptions nationwide since 2010—the number of deaths continues to increase. See Ctrs. for Disease Control & Prevention, *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes* 6.[23] And synthetic opioids are the greatest cause of those deaths. *Understanding the Epidemic*, *supra*.

States and localities that are experiencing overdose deaths due to synthetic opioids are considering SIS—similar to the sites proposed by Safehouse—to reduce those deaths. New York City recently published a report on SISs and acknowledged that "[t]he opioid overdose epidemic . . . persists despite current efforts, which include availability of treatment services, collaborative interventions between public health and law enforcement, and increased access to the emergency overdose rescue medication naloxone." *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, NYC Health

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[22] *Available at* www.health.pa.gov/topics/Documents/Opioids/General%20Public%20Standing%20Order.pdf.

[23] *Available at* www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.

3.[24] Similarly, Maryland has been considering developing SISs on a pilot basis, and a recent Johns Hopkins study revealed that a "large majority of people who use heroin and fentanyl would be willing to use safe consumption spaces where they could obtain sterile syringes and have medical support in case of overdose." News Release, Johns Hopkins Bloomberg Sch. of Pub. Health, *Safe Consumption Spaces Would Be Welcomed By High-Risk Opioid Users* (June 5, 2019).[25]

States and localities considering employing SISs should be empowered to do so. In doing so, they would join an international community that has successfully been operating these facilities to save lives. Nearly 100 SISs operate across 60 different cities in Australia, Canada, Denmark, France, Germany, Luxembourg, the Netherlands, Norway, Spain, and Switzerland. Alex Kreit, *Safe Injection Sites and the Federal "Crack House" Statute*, 60 B.C. L. Rev. 413, 415 n.2 (2019). In Vancouver, Canada, SIS professionals intervened in over 300 overdoses during the site's first five years of operation. Amber A. Leary, Note, *A Safe Harbor in the Opioid Crisis: How the Federal Government Should Allow States to Legislate for Safe Injection Facilities in Light of the Opioid Public Health Emergency*, 84 Brook. L. Rev. 635, 660 (2019). The site also saw "no evidence of increases in drug-related loitering, drug dealing, or petty crimes" near the facility. *Id.*

Like Philadelphia, most states and localities in the United States that have considered SISs contain densely populated urban areas where public injections frequently occur due to elevated rates of homelessness. The New York City Department of Health and Mental Hygiene investigated both the feasibility and potential benefits of creating SISs, paying special attention to "neighborhood-specific estimates" for overdose deaths given the "variation in mortality among

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[24] *Available at* www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report .pdf?mc_cid=2a562844de&mc_eid=fec6ed8b11.

[25] *Available at* https://www.jhsph.edu/news/news-releases/2019/safe-consumption-spaces-would-be-welcomed-by-high-risk-opioid-users.html.

different neighborhoods." *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection* 33 (May 3, 2018).[26] The homeless population in New York City dies from overdoses at more than six times the rate of the general population. *Id.* at 34. The city found that SISs would address the problem that "homeless or unstably housed [individuals] may be most likely to inject in public or semi-public settings," and that the facilities would have both life-saving benefits and cost savings. *Id.*

In California, San Francisco has also advocated for SISs, identifying four specific regions where they would be most effective. San Francisco Safe Injection Servs. Task Force, *2017 Final Report* 7 (2017).[27] In Maryland, Baltimore has considered their use, but unlike San Francisco, the drug use in Baltimore is "dispersed throughout the city." Susan Sherman, et al., *Safe Drug Consumption Spaces: A Strategy for Baltimore City*, 29 Abell Rep. 11 (2017).[28] A Johns Hopkins-led study therefore urged opening two SISs based on these unique conditions, one on the east side of the city and one on the west side, to maximize accessibility. *Id.* Additionally, many states—including California, Colorado, Maryland, Maine, Massachusetts, New Jersey, Vermont, and Washington—have introduced bills in their state legislatures to create safe consumption sites based on their track record of success elsewhere in the world.[29]

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[26] *Available at* www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report.pdf.

[27] *Available at* www.sfdph.org/dph/files/SIStaskforce/SIS-Task-Force-Final-Report-2017.pdf.

[28] *Available at* https://www.abell.org/sites/default/files/files/Safe%20Drug%20Consumption%20Spaces%20final.pdf

[29] *See, e.g.*, Assemb. B. 362, 2019 Reg. Sess. (Cal. 2019); S.B. 18-040, 71st Gen. Assemb. (Co. 2018); H.B. 139, 2019 Reg. Sess. (Md. 2019); Leg. Doc. 949, 129th Leg., First Reg. Sess. (Me. 2019); S.B. 1081, 191st Gen. Court (Mass. 2018); S.B. 3293, 218th Leg. (N.J. 2019); S.B. 107, 2017 Gen. Assemb. (Vt. 2017); S.B. 5380, 2019 Legis., Reg. Sess. (Wash. 2019).

As these examples demonstrate, solutions to the opioid crisis—including ones targeted at reducing deaths from fentanyl—are highly localized. SISs are among the more promising interventions in urban areas to address widespread public injection and overdose. States that are home to metropolitan areas should be free to experiment with this potentially lifesaving intervention, as well as others, without fear that public health nonprofits or doctors in their jurisdictions will be subject to prosecution.

## II. The Controlled Substances Act Should Not Be Interpreted To Prevent States From Embracing Innovative Public Health Solutions.

Of course, the *Amici* States can continue to experiment with promising and life-saving solutions like SISs only if federal law is read sensibly, to accord States their traditional power over public health policy. The CSA should not be read to prohibit medical interventions like SISs, particularly when those interventions are affirmatively authorized or endorsed by States.

Congress enacted Section 856 of the CSA to target crack houses—not community health clinics. The statute originated from an "explosion of public concern about crack cocaine use in the mid-1980s" and was subsequently amended to prevent "the use of 'ecstasy' by young people at 'rave' parties." 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, 1117-18 (2009). The purpose of the statute was to aid law enforcement in arresting drug dealers and users—not to prohibit life-saving public health interventions. *See* 132 Cong. Rec. 26447 (daily ed. Sept 26, 1986) ("When police raid these crack houses, the dealers and users can easily dispose of the drugs, thus avoiding arrest. [Section 856] makes it a felony to operate such a house." (statement of Sen. Chiles)).

Although Section 856 has been applied beyond crack houses, the federal government has not pointed to any case where it has been applied to medical facilities with the sole purpose of

preventing overdose deaths. U.S. Mot. at 5-6 (ECF 47). Indeed, unlike crack houses or raves, SISs do not distribute, manufacture, or encourage drug possession, but rather "serve a medical purpose by providing counseling to people with a substance use disorder, preventing overdoses, and stopping the use of dirty needles." Kreit, *supra*, at 432. SISs thus do not present the identified dangers that Congress feared when Section 856 was enacted. *See* Office of Nat'l Drug Control Pol'y, *National Drug Control Strategy: A Nation Responds to Drug Use* 6 (1992) (identifying "open-air drug markets, crack houses, drug-exposed infants, abused and neglected children, gang violence, decaying neighborhoods, and drive-by shootings" as significant concerns surrounding the drug epidemic).[30] And contrary to the concern behind the 2003 amendments to the CSA targeting rave parties, SISs do not initiate young people "into the drug culture." *See* Reducing Americans' Vulnerability to Ecstasy Act of 2002: Hearing on H.R. 5519 Before the H. Subcomm. on Crime, Terrorism, and Homeland Sec. of the H. Comm. on the Judiciary, 107th Cong. 2 (2002). Instead, SISs provide potentially life-saving treatments for Americans experiencing the effects of a nationwide epidemic. *See* Safehouse's Memo. in Opp. at 12-14 (ECF 48) (describing the harm reduction model and treatment to be made available at Safehouse). To employ the federal government's proposed application of Section 856 would be to misconstrue its intended reach.

SISs should thus be considered in the same vein as Good Samaritan laws, which also stem from the notion that public health objectives should sometimes defeat an interest in criminal prosecution. *See, e.g.*, *Noble v. State*, 189 A.3d 807, 810 (Md. Ct. Spec. App. 2018). Possession of illicit substances is unquestionably a federal offense, *see* 21 U.S. Code § 844, yet the federal government does not claim that the scores of states with Good Samaritan immunity should cease

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[30] *Available at* https://www.ncjrs.gov/pdffiles1/ondcp/134372.pdf.

prioritizing the public health of their citizens above criminal prosecutions. Quite to the contrary, the federal government encourages the enactment of these laws. Carroll et al., *supra*, at 18.

What is more, the federal government's understanding of Section 856 would raise significant constitutional questions about Congress's ability to intrude on state police powers. The federal government "can exercise only the powers granted to it" and "[f]or nearly two centuries it has been 'clear'" that the federal government lacks "a police power." *Bond v. United States*, 572 U.S. 844, 854 (2014) ("The States have broad authority to enact legislation for the public good—what we have often called a "police power." (quoting *United States v. Lopez*, 514 U.S. 549, 567 (1995)).

As the Court explained in *Gonzales v. Oregon*, 546 U.S. 243 (2006), "[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." *Id.* at 270 ("[T]he structure and limitations of federalism . . . 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." (internal quotation marks omitted)). SISs are medical facilities that provide critical interventions and fall comfortably within the State's powers to regulate; they are not "illicit drug dealing and trafficking" that may implicate Congress's commerce power. *Id*. Indeed, it strains credulity that a local facility which provides medical care to persons overdosing from opioids has any impact on interstate commerce.[31]

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[31] Additionally, while this is a civil matter, the CSA is also a criminal statute and thus the rule of lenity applies. *Leocal v. Ashcroft*, 543 U.S. 1, 12 n.8 (2004) (noting that a statute with both civil and criminal applications must be interpreted consistently and the rule of lenity applies). Under the rule of lenity, the court must resolve ambiguity in favor of the defendant. *Id.*; *United States v. Thompson/Ctr. Arms Co.*, 504 U.S. 505, 525 (1992) (Stevens, J., dissenting) ("The main function of the rule of lenity is to protect citizens from the unfair application of ambiguous punitive statutes.").

However, "[t]he court need not reach those questions" and should instead construe the CSA to avoid constitutional doubt. *INS v. St. Cyr.*, 533 U.S. 289, 300 (2001) ("[W]here an alternative interpretation of the statute is fairly possible, [courts] are obligated to construe the statute to avoid [constitutional] problems." (internal quotation marks and citation omitted)); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."). That is especially true where, as here, there is an alternative application that is far more consistent with congressional purpose and respectful to state sovereignty.

## CONCLUSION

The federal government's motion for judgment on the pleadings should be denied.

Respectfully submitted,

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