UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. SAFEHOUSE, a Pennsylvania nonprofit corporation; JOSE BENITEZ, as President and Treasurer of Safehouse, Defendants.	Case No. 2:19-cv-00519-GAM
SAFEHOUSE, a Pennsylvania nonprofit corporation, Counterclaim Plaintiff, v. UNITED STATES OF AMERICA, Counterclaim Defendant, U.S. DEPARTMENT OF JUSTICE; WILLIAM P. BARR, in his official capacity as Attorney General of the United States; WILLIAM M. MCSWAIN, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania, Third-Party Defendants.	

MOTION OF KING COUNTY, WA; NEW YORK, NY; SAN FRANCISCO, CA; SEATTLE, WA; PITTSBURGH, PA; AND SVANTE L. MYRICK, MAYOR OF ITHACA, NY TO FILE BRIEF AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFF'S MOTION FOR JUDGMENT ON THE PLEADINGS

Pursuant to the Court's Order of May 28, 2019, King County, WA; the City of New York, NY; the City and County of San Francisco, CA; the City of Seattle, WA; the City of Pittsburgh, PA; and Svante L. Myrick, Mayor of Ithaca, NY (collectively, "Localities") respectfully move for leave to file a brief as *amici curiae* in opposition to Plaintiff's motion for judgment on the pleadings. A copy of Localities' proposed brief is attached hereto as Exhibit A.

1. Localities' interest in this case is at the core of their powers and responsibilities as local governments. The opioid crisis is perhaps the single biggest threat to the public health of their communities. As such, Localities have a profound interest in the promise of overdose prevention sites, like the one Safehouse plans to operate, as an evidence-based medical intervention that could stem the staggering loss of life to overdoses, since other methods continue to come up short. The impact of the federal government's attempt to prevent Safehouse from opening will reach each one of Localities' communities and beyond. Indeed, the Department of Justice has publicly announced its intention to bring enforcement actions wherever overdose prevention sites are opened.[1] King County and Seattle, WA have paused their efforts to evaluate and encourage overdose prevention sites until the issue before this Court is resolved; U.S. Attorney Brian Moran warned that Seattle would face federal legal action should it establish an overdose prevention site.[2]

2. Localities respectfully submit that the filing of their proposed brief is desirable. The brief provides relevant information about the various paths Localities are considering to encourage opioid prevention sites, as well their analyses of the feasibility and benefits of opioid

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[1] *See* Bobby Allyn, *Justice Department Promises Crackdown on Supervised Injection Facilities*, NPR (Aug. 30, 2018), https://www.npr.org/sections/health-shots/2018/08/30/642735759/justice-department-promises-crackdown-on-supervised-injection-sites.

[2] *See* Mike Carter, *Seattle's new U.S. Attorney says he won't allow city to open safe-injection site*, The Seattle Times (Apr. 3, 2019), https://www.seattletimes.com/seattle-news/seattles-new-u-s-attorney-says-he-wont-allow-city-to-open-safe-injection-site.

prevention sites. Localities, and in particular their public health departments, have determined that overdose prevention sites like the one proposed by Safehouse serve a legitimate medical purpose, and are evaluating opioid prevention sites as part of Localities' exercise of the police powers granted to states and their subdivisions. The purpose of overdose prevention sites is obviously not to encourage drug use, but rather to improve access to addiction treatment while reducing overdose deaths and the other public health ills caused by opioid addiction. Thus, as explained in Localities' brief, the Controlled Substances Act does not preclude the operation of Safehouse's proposed site, and concluding otherwise would raise serious constitutional questions. Localities respectfully submit that the discussion of these issues in Localities' proposed brief will assist the Court in evaluating Safehouse's statutory and constitutional arguments in opposition to Plaintiff's motion for judgment on the pleadings.

3. All parties have consented to Localities' filing.

4. No party's counsel authored the brief in whole or in part.

5. No party and no party's counsel has contributed money that was intended to fund preparing or submitting Localities' brief.

6. No other person contributed money that was intended to fund preparation of Localities' brief.

For these reasons, Localities respectfully request that this motion be granted.

DATED: July 10, 2019

Respectfully submitted,

/s/ Virginia A. Gibson

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EXHIBIT A

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[PROPOSED] BRIEF OF *AMICI CURIAE* KING COUNTY, WA; NEW YORK, NY; SAN FRANCISCO, CA; SEATTLE, WA; PITTSBURGH, PA; AND SVANTE L. MYRICK, MAYOR OF ITHACA, NY IN OPPOSITION TO PLAINTIFF'S MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

Amici represent the residents of six cities and counties across the United States, more than 12 million Americans. As the level of government closest to the people, *Amici* bear responsibility for protecting public health, giving us a frontline perspective on what is perhaps the single biggest threat to the health of our communities today: opioid addiction and overdose.

As we have with other public health threats, *Amici* and our health departments have taken an evidence-based approach to confronting the opioid crisis, employing a wide array of harm-reduction measures, from medication-assisted treatment, to clean needle exchanges, to the distribution of naloxone and buprenorphine to first responders, all to reduce the morbidity and mortality caused by this epidemic. There is strong evidence that overdose prevention sites will save additional lives by preventing overdoses and improving access to addiction treatment. Like countless public health authorities worldwide, *Amici* recognize that these sites are best understood as an evidence-based medical intervention that can be a critical tool in combatting opioid addiction. Given the gravity of the crisis our nation is facing, no tool can be lightly disregarded.

Despite the evidence of their efficacy, the U.S. Department of Justice ("DOJ") seeks to block overdose prevention sites from opening. It cannot. The DOJ has gone out of its way here to press an interpretation of the Controlled Substances Act ("CSA") that goes beyond any past application of the statute and is fundamentally incompatible with the text, design, and purpose of the statute—not to mention the considered judgment of public health authorities everywhere. In enacting the CSA, Congress never intended to—and did not—prohibit legitimate medical interventions like overdose prevention sites. And, settling any debate, the constitutional implications of encroaching on the police powers reserved to state and local governments compel the rejection of the DOJ's expansive interpretation.

While the DOJ acknowledges the "intolerable number of deaths and misery" caused by opioids (DOJ Br. at 2), its actions here show that it is willing to tolerate the status quo. *Amici* are not. The "multitude of potentially lifesaving options" the DOJ references (*id.*), are among those that *Amici* have employed for several years, only to see them fall short. Overdose prevention sites give medical providers a far greater chance to rescue a person if they overdose than if they were alone or on the street, while also increasing access to treatment and reducing other blights like public drug use and discarded needles that opioid addiction has visited upon our communities. Fortunately, nothing in the CSA prevents the legitimate and life-saving medical intervention that Safehouse intends to offer the people of Philadelphia. The Court should therefore deny the DOJ's motion for judgment on the pleadings.

BACKGROUND

The opioid crisis has taken a major toll on American cities and counties, including ours. Opioid addiction has caused a staggering loss of life. In New York City alone, over a thousand people die every year from opioid overdoses.[1] In 2017, the number was an astonishing 1,216—about one death every seven hours.[2] That means that more New Yorkers die of opioid overdoses than from homicides, suicides, and motor vehicle crashes combined.[3] In Allegheny County, too,

[1] New York City Department of Health and Mental Hygiene, *Unintentional Drug Poisoning (Overdose) Deaths in New York City: 2000 to 2017*, at tbl. 2 (2018), *available at* https://www1.nyc.gov/assets/doh/downloads/pdf/epi/databrief104.pdf; New York City Department of Health and Mental Hygiene, *Unintentional Drug Poisoning (Overdose) Deaths: Quarter 1, 2018, New York City*, at 1 (2018), *available at* https://www1.nyc.gov/assets/doh/downloads/pdf/basas/provisional-overdose-report-first-quarter-2018.pdf.

[2] *Unintentional Drug Poisoning (Overdose) Deaths in New York City: 2000 to 2017*, *supra*, at tbl. 2.

[3] *Compare id. with* New York City Department of Health and Mental Hygiene, *Summary of Vital Statistics 2017*, at tbl. M1 (2019), *available at* https://www1.nyc.gov/assets/doh/downloads/pdf/vs/2017sum.pdf; *see also* New York City

opioid overdose deaths have more than doubled since 2014.[4] The county, home to Pittsburgh, lost more than 640 people to opioid overdoses last year.[5] The advent of fentanyl—which is over 50 times more powerful than heroin—has made things worse; while it can take half an hour or longer to die from a heroin overdose, a person can die from a fentanyl overdose in just five minutes, and from an amount as small as a grain of sand.[6] In San Francisco, for instance, fentanyl-related deaths spiked from six in 2010 to 57 in 2018—more than heroin (39) or prescription opioids (53).[7] The alarming statistics go on and on for municipalities across the United States.

These trends have continued despite extensive efforts by local governments and health departments to curb the crisis, including policies to expand medication-assisted treatment, clean needle exchanges, and the distribution of naloxone to first responders and public health workers. As of July 2017, Prevention Point Pittsburgh was handing out 5,000 needles a week in the city as part of a clean needle exchange program.[8] In King County, Washington, the number of people entering the publicly funded treatment system for heroin use disorders grew from 1,439 in 2010

Office of the Mayor, *HealingNYC: Preventing Overdoses, Saving Lives* 9 (2017), *available at* https://www1.nyc.gov/assets/home/downloads/pdf/reports/2017/HealingNYC-Report.pdf.

[4] *Information About Opioids and Overdose Prevention*, Allegheny Cty., https://www.alleghenycounty.us/Health-Department/ Programs/Special-Initiatives/Overdose-Prevention/Information-About-Opioids.aspx (last visited July 9, 2019).

[5] *Id.*

[6] Erin Allday, *Fentanyl rising as killer in San Francisco – 57 dead in a year*, S.F. Chronicle (June 23, 2019), https://www.sfchronicle.com/health/article/Fentanyl-rising-as-killer-in-San-Francisco-57-14030821.php.

[7] *Id.*

[8] Sheldon Ingram, *State of Addiction: Prevention Point Pittsburgh*, Pittsburgh's Action News (July 19, 2017, 6:53 PM), https://www.wtae.com/article/state-of-addiction-prevention-point-pittsburgh/10324261.

to 2,886 in 2014.[9] Around the same time, admissions to opioid treatment programs that dispense methadone and buprenorphine more than doubled, increasing from 696 in 2011 to over 3,600 in 2015, with some programs maintaining waitlists for treatment. *Id.* The number of needles exchanged in the county has more than tripled—from 2,029,243 in 2000 to 6,998,794 in 2015.[10] And 8,736 naloxone kits were distributed throughout the county in 2017, reversing over 2,200 overdoses.[11] Even so, over 250 people died from opioid overdoses the following year.[12] Similarly, in New York City, EMS agencies administered naloxone 7,321 times in 2017.[13] But in part due to the growing specter of fentanyl, now contributing to more than half of overdose deaths, it was still the city's deadliest year for drug overdoses on record.[14]

Amici have marshaled our human and financial resources to stop the loss of our residents to addiction and overdose. Despite our efforts, the existing methods of combatting the opioid

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[9] King County Heroin & Prescription Opiate Addiction Task Force, *Final Report and Recommendations* 5 (2016), *available at* https://www.kingcounty.gov/depts/community-human-services/mental-health-substance-abuse/task-forces/heroin-opiates-task-force.aspx#recommendations.

[10] King County Heroin & Prescription Opiate Addiction Task Force, *Heroin and Opioid Trends Infographic*, https://www.kingcounty.gov/depts/community-human-services/mental-health-substance-abuse/task-forces/heroin-opiates-task-force.aspx#recommendations (last visited July 9, 2019).

[11] King County Heroin & Prescription Opiate Addiction Task Force, *2017 Year End Summary Infographic*, https://www.kingcounty.gov/depts/community-human-services/mental-health-substance-abuse/task-forces/heroin-opiates-task-force.aspx#recommendations (last visited July 9, 2019).

[12] Seattle & King County Public Health, *2018 Overdose Death Report* (June 2019), *available at* https://www.kingcounty.gov/depts/health/examiner/~/media/depts/health/medical-examiner/documents/2018-overdose-death-report.ashx

[13] The New York State Department of Health, *County Opioid Quarterly Report* 125 (Jan. 2019), *available at* https://www.health.ny.gov/statistics/opioid/data/pdf/nys_jan19.pdf.

[14] *Unintentional Drug Poisoning (Overdose) Deaths in New York City: 2000 to 2017*, *supra*, tbls. 2 & 5; *see also* The New York City Department of Health and Mental Hygiene, *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection* 3 (2018), *available at* https://www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report.pdf.

crisis have proven to be too little, or at least too late, for far too many of our residents. Because tolerating the preventable deaths of tens of thousands of Americans is not an option, *Amici* have been forced to explore additional strategies to address the crisis. As we explain below, one of those strategies—a medical intervention with considerable promise—is to support the opening of overdose prevention sites in our communities.

ARGUMENT

Amici and our respective public health departments take an evidence-based approach to fulfilling our missions to ensure the health and safety of our residents. To this end, we look to scientific evidence and scholarship to identify legitimate medical interventions to stem the tide of the opioid epidemic. That evidence strongly suggests that overdose prevention sites will decrease overdose deaths, increase enrollment in treatment services, and address the litany of other public health problems caused by opioid addiction. In order to achieve these benefits, jurisdictions around the country hope that centers of the type described in Safehouse's pleadings can be established in their local communities. Permitting such sites is consistent with federal law and policy, as established by Congress and numerous federal agencies. The Court should reject the DOJ's attempt to halt such efforts to protect public health, especially given the constitutional concerns raised by the DOJ's actions.

I. RESEARCH DEMONSTRATES THAT OVERDOSE PREVENTION SITES SAVE LIVES AND IMPROVE ACCESS TO ADDICTION TREATMENT.

The success of overdose prevention sites as a legitimate medical intervention is well-documented. There are over a hundred overdose prevention sites operating worldwide, in

countries such as Canada, Australia, Germany, the Netherlands, and France.[15] Dozens of studies show that these sites reduce overdose frequency and public drug use without increasing drug trafficking or crime.[16] As explained in a review of 75 articles on the subject in a respected, peer reviewed journal, "[a]ll studies converged to find that [safe injection sites, or SISs,] were efficacious in attracting the most marginalized [people who inject drugs], promoting safer injection conditions, enhancing access to primary health care, and reducing the overdose frequency. SISs were not found to increase drug injecting, drug trafficking or crime in the surrounding environments. SISs were found to be associated with reduced levels of public drug injections and dropped syringes."[17]

Particularly instructive is the experience of InSite, the first overdose prevention site in North America, which has been running in Vancouver for over 15 years.[18] Over thirty peer reviewed studies have been published about InSite's first six years of operation alone.[19] A 2007 study showed that the opening of the site was associated with a 30% increase in detoxification service use, which in turn was associated with increased rates of long-term addiction treatment

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[15] Beau Kilmer et al., *Considering Heroin-Assisted Treatment and Supervised Drug Consumption Sites in the United States* 30-31 (2018), *available at* https://www.ehidc.org/sites/default/files/resources/files/RAND_RR2693.pdf.

[16] *See, e.g., id* at 32-35 (review of nine most rigorous of 65 outcome-related articles suggests that sites cause decrease in drug overdoses and drug use without increasing crime).

[17] Chloe Potier et al., *Supervised injection services: What has been demonstrated? A systematic literature review*, Drug and Alcohol Dependence, Dec. 1, 2014, at 48, *available at* *https://www.sciencedirect.com/science/article/abs/pii/S0376871614018754*.

[18] *See* Brandon DL Marshall et al., *Reduction in overdose mortality after the opening of North America's first medically supervised safer injecting facility: a retrospective population-based study*, 377 The Lancet 1429 (Apr. 23, 2011), *available at* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)62353-7/fulltext.

[19] The Urban Health Research Initiative of the British Columbia Centre for Excellence in HIV/AIDS, *Findings from the Evaluation of Vancouver's Pilot Medically Supervised Safer Injecting Facility – Insite* 5 (2009), *available at* http://www.bccsu.ca/wp-content/uploads/2016/09/insite-report-eng.pdf.

initiation and reduced injecting at the site.[20] A 2008 cost-benefit analysis estimated that the drop in needle sharing, increase in safe injection practices, and increase in referrals to methadone maintenance treatment caused by the site would result in incremental net savings of more than $18 million and a gain of 1,175 life-years.[21] A 2011 study examined overdose death rates in the period roughly two years before and two years after the site opened and compared the area within 500 meters of the site to the rest of the city. The study found that fatal overdoses in the 500 meter area surrounding the site decreased by 35%, while the rate in the rest of the city decreased by only 9.3%.[22] "During InSite's [first] 3 years, a remarkable consensus that the facility reduces harm to users and the public developed among scientists, criminologists and even the Vancouver Police Department. Research, all positive, was published in 15 peer-reviewed journals, including the CMAJ [Canadian Medical Association Journal], Lancet and the New England Journal of Medicine."[23] A 2006 study found that all measures of public disorder evaluated by the researchers *decreased* in the 12 weeks after InSite opened compared to the six weeks before the site opened.[24] The daily mean number of incidents of public injection, publicly

[20] Evan Wood et al., *Rate of detoxification service use and its impact among a cohort of supervised injecting facility users*, 102 Addiction 916 (May 22, 2007), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1360-0443.2007.01818.x.

[21] Ahmed M. Bayoumi & Gregory S. Zaric, *The cost-effectiveness of Vancouver's supervised injection facility*, 179 Can. Med. Ass'n J. 1143, 1143 (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2582765/.

[22] Marshall et al., *supra*.

[23] Deborah Jones, *Injection site gets 16-month extension*, 175 Can. Med. Ass'n J. 859, 859 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1586084/ .

[24] Evan Wood et al., *Vancouver's safer injecting facility has been associated with an array of community and public health benefits without evidence of adverse impacts*, 175 Can. Med. Ass'n J. 1399, 1401 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1635777/#r37-20.

discarded syringes, and injection-related litter were roughly cut in half—down from 4.3 to 2.4, 11.5 to 5.4, and 601 to 310 respectively.[25]

Research indicates that overdose prevention sites would have similar effects in U.S. cities. For example, cost-benefit studies of the feasibility of opening sites in Baltimore, Philadelphia, and San Francisco all found that the costs of operation would be more than offset by the savings realized by preventing HIV, hepatitis, and other infections, increasing enrollment in medication-assisted treatment, and reducing hospitalizations and deaths from opioid overdoses.[26]

II. *AMICI* SUPPORT OVERDOSE PREVENTION SITES TO BOLSTER EFFORTS TO FIGHT THE OPIOID EPIDEMIC.

It is because of this robust body of evidence that many localities, including *Amici*, are considering ways that overdose prevention sites can help fight opioid addiction in our communities. Overdose prevention sites are a promising, evidence-based medical intervention that can be a key part of a comprehensive approach to the crisis.

Amici offer our experiences as examples. New York City employs a multi-pronged approach of preventing overdose deaths, reducing misuse and diversion, enabling effective treatment, and limiting supply. The New York City Council provided funding to its Department of Health and Mental Hygiene ("DOHMH") to assess the efficacy and feasibility of overdose prevention sites. The resulting DOHMH report included an impact assessment prepared by

[25] *Id.*

[26] See, e.g., Amos Irwin et al., *Mitigating the heroin crisis in Baltimore, MD, USA: a cost-benefit analysis of a hypothetical supervised injection facility*, Harm Reduction J (May 12, 2017), *available at* https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186/s12954-017-0153-2; Amos Irwin et al., *A Cost-Benefit Analysis of a Potential Supervised Injection Facility in San Francisco, California, USA*, J. of Drug Issues (2016), *available at* https://idhdp.com/media/531280/sifsanfrancisco.pdf; Sharon Larson et al., *Supervised Consumption Facilities – Review of the Evidence* 6-7 (2017), *available at* https://dbhids.org/wp-content/uploads/2018/01/OTF_LarsonS_PHLReportOnSCF_Dec2017.pdf

researchers at the Weill Cornell Medicine Department of Health Care Policy and Research.[27] That assessment concluded that opening just one overdose prevention site in the neighborhood with the most opioid overdose fatalities could save 19 to 37 lives per year.[28] If four sites were opened in the most affected neighborhoods, that number could go up to between 67 and 130 lives per year.[29] Opioid overdoses currently cost the New York City health care system an estimated $50 million per year in EMS calls, emergency room visits, and hospitalizations.[30] Approximately $6 million of these costs are associated with fatal opioid overdoses.[31] Just one site could save the City's health care system between $1 million and $2 million; opening four sites could save as much as $3.6 million.[32]

After a close review of the DOHMH's findings, New York City proposed a research program with up to four overdose prevention sites financed and operated by non-profit providers, with trained staff to administer overdose-reversal medication and connect people to treatment, care, and support.[33] The program would require each site to obtain state approval and comply with state-approved guidelines, receive the support of the local City Council members and District Attorney's Office, and refrain from using City funds for overdose prevention services. Sites would be selected only after extensive community outreach and engagement. A consortium of providers under the umbrella of Research for a Safer New York has agreed to operate under

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[27] *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, *supra*, at 3.
[28] *Id* at 84.
[29] *Id*.
[30] *Id.*
[31] *Id.*
[32] *Id.* at 85.
[33] William Neuman, *De Blasio Moves to Bring Safe Injection Sites to New York City*, N.Y. Times (May 3, 2018), https://www.nytimes.com/2018/05/03/nyregion/nyc-safe-injection-sites-heroin.html.

this framework. The consortium intends to integrate overdose prevention sites into established care networks, leveraging the deep experience of pre-existing syringe exchange programs with developing security protocols and collaborating with public health officials and law enforcement to provide effective care without disturbing the neighborhoods they call home. As Mayor de Blasio explained, "[a]fter a rigorous review of similar efforts across the world, and after careful consideration of public health and safety expert views, we believe overdose prevention centers will save lives and get more New Yorkers into the treatment they need to beat this deadly addiction."[34]

In 2017, the San Francisco Board of Supervisors voted to urge the Department of Public Health to convene a Safe Injection Services Task Force to make recommendations to the Mayor, the Board of Supervisors, and City departments regarding the opening of overdose prevention sites in San Francisco. After studying the matter, the task force recommended that San Francisco operate multiple overdose prevention sites.[35] In August 2018, a group of non-profit organizations opened a full-scale, operational demonstration model of an overdose prevention site in San Francisco's Tenderloin neighborhood.[36] Mayor London Breed released the following statement regarding the opening: "I refuse to accept what we see on our streets—the needles, the open drug use, the human suffering caused by addiction—as the new status quo. Safe injection sites are a proven, evidence-based approach to solving this public health crisis. This

[34] *Id*.
[35] San Francisco Department of Public Health, *San Francisco Safe Injection Services Task Force: Final Report* 6 (2017), *available at* https://www.sfdph.org/dph/files/SIStaskforce/SIS-Task-Force-Final-Report-2017.pdf.
[36] Dominic Fracassa, *SF demonstrates how safe injection sites for drug users would work*, S.F. Chronicle (Aug. 29, 2018), https://www.sfchronicle.com/bayarea/article/SF-demonstrates-how-safe-injection-sites-for-drug-13189444.php.

demonstration shows that these sites will not only help provide treatment and prevent the spread of disease, but also reduce public drug use and the discarded needles seen on our streets."[37]

In King County, Washington, the County Executive, Mayor of Seattle, and other local mayors convened a Heroin and Prescription Opiate Addiction Task Force in March 2016, comprised of doctors, paramedics, hospitals, drug treatment providers, fire, police, and governmental and non-profit service agencies. To reduce the death rate, the spread of HIV and hepatitis B and C viruses, and other drug-related medical problems, the Task Force recommended, among other interventions, opening a minimum of two overdose prevention sites. After a thorough review of numerous studies published worldwide, the Task Force concluded that overdose prevention sites are effective in reducing these public health ills for those who use intravenous drugs and can also increase the use of detoxification and treatment services. In January 2017, King County's public health supervisory and regulatory authority, the Board of Health, vetted and endorsed all of the Task Force's recommendations. The Board called for local officials to implement the Task Force's recommendations, including opening two overdose prevention sites. The County Executive, Mayor of Seattle, Sheriff, Prosecuting Attorney, and majorities of both the county and city councils were united in their support of the plan. Focusing first on the hardest hit Seattle neighborhoods, both the health department and city staff worked to find a suitable location for the first overdose prevention site.[38]

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[37] Shayna Yasuhara, *Safer Inside: Whether You Call It A Safe Injection Site Or An Overdose Prevention Site, The Goal Is To Save Lives*, Tenderloin Community Benefit District (Aug. 30, 2018), https://tlcbd.org/blog/2018/6/6/safer-inside.

[38] *See* King County Heroin & Prescription Opiate Addiction Task Force, *Final Report and Recommendations*, *supra*. King County and Seattle have paused their efforts until the issue before this Court is resolved. U.S. Attorney Brian Moran warned that Seattle would face federal legal action should it establish an overdose prevention site. *See* Mike Carter, *Seattle's new U.S. Attorney says he won't allow city to open safe-injection site*, The Seattle Times (Apr. 3, 2019),

III. OVERDOSE PREVENTION SITES TAILORED TO THE NEEDS OF LOCAL COMMUNITIES ARE CONSISTENT WITH FEDERAL DRUG LAWS AND POLICY.

A. Criminalizing Medical Interventions Aimed at Connecting People to Treatment and Preventing Overdoses Would Hamstring Local Governments in the Face of Federal Policy Encouraging Local Action.

While *Amici's* desire to promote effective public health solutions is driven by our fundamental responsibilities to our residents, *Amici* also take seriously the federal government's repeated calls for local governments to mobilize in response to the opioid crisis. A prime example is Congress's pronouncement in Title 21 of the United States Code, which also includes the Controlled Substances Act ("CSA"): "Local governments with high concentrations of drug abuse should be actively involved in the planning and coordination of efforts to combat drug abuse." 21 U.S.C. § 1101(14) ("Congressional Findings" at Chapter 16, "Drug Abuse Prevention, Treatment, and Rehabilitation"). *Amici* are a collection of the very local communities referenced in § 1101, struggling with high concentrations of drug abuse in the midst of the national opioid crisis, and we could not agree more with Congress's findings. In light of those findings, Congress unequivocally "declare[d] that it is the policy of the United States…to meet the problems of drug abuse through…the development and support of community-based prevention programs." 21 U.S.C. § 1102(2).

Federal agencies have similarly sought to engage local governments in combatting opioid addiction rather than tying their hands. One prominent example is the U.S. Department of Health and Human Services' five-point strategy to combat the opioid crisis. The strategy is

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https://www.seattletimes.com/seattle-news/seattles-new-u-s-attorney-says-he-wont-allow-city-to-open-safe-injection-site/.

expressly designed to "empower local communities on the frontlines."[39] And one of the pillars of the strategy is "better targeting of overdose-reversing drugs,"[40] which is one of the prime benefits of overdose prevention sites, especially when arming everyone from police officers to librarians with naloxone has not stopped overdose deaths from rising.[41] Thus, overdose prevention sites of the type described in Safehouse's pleadings, along with federally endorsed initiatives like clean needle exchanges and distribution of overdose reversal treatments, are exactly the kinds of "community-based prevention programs" the federal government has pledged to support. 21 U.S.C. § 1102(2). Embracing them honors express legislative and executive judgments.

The DOJ should not be permitted to distort the express and intended meaning of the provisions of Title 21 in order to criminalize a proven method of overdose prevention, particularly one that local governments may wish to support as part of their comprehensive public health responses to the opioid crisis. Surely, Congress did not intend the CSA as a vehicle for overreaching federal prosecutors to hamstring the efforts of local governments across the

[39] U.S. Dept. of Health & Human Services, *Strategy to Combat Opioid Abuse, Misuse, and Overdose* (2017), https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.

[40] *Id.*; *see also, e.g.*, White House Office of National Drug Control Policy, *An Update on the President's Commission on Combating Drug Addiction and the Opioid Crisis: One Year Later* 17 (2019) ("Timing is critical when dealing with an overdose and having overdose reversing drugs readily available can be the difference between life and death. . . . After an overdose is reversed, it is critical the correct treatment is readily available."); White House Office of National Drug Control Policy, *Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis* 47 (2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf ("To achieve the desired ultimate outcome — reduction in drug use — the campaign needs the support of locally implemented evidence-based prevention programming.").

[41] *See* Darran Simon, *The opioid epidemic is so bad that librarians are learning how to treat overdoses*, CNN (June 24, 2017), https://www.cnn.com/2017/06/23/health/opioid-overdose-library-narcan/index.html.

country to advance life-saving, evidence-based medical interventions that would fulfill express federal policy.

B. Overdose Prevention Sites of the Type Proposed by Safehouse Are Not Prohibited by the CSA.

1. *Section 856(a)(2) does not criminalize facilities established "for the purpose of" providing substance abuse treatment and overdose prevention services.*

The straightforward application of the CSA advanced by Safehouse is undoubtedly correct, particularly as applied to the type of overdose prevention site described in the pleadings. Where, as here, the site will not manufacture, store, prescribe, distribute, or administer controlled substances, and the purpose of the facility is to provide lifesaving medical treatment and wraparound rehabilitation services, there is no CSA violation under the plain language of Section 856. *Amici* adopt and endorse Safehouse's arguments in this regard and respectfully urge the Court to apply the statutory language to permit such facilities. (*See generally* Safehouse Br. at 19-38.) The DOJ's proposed reading of Section 856(a)(2), on the other hand, would require ignoring the language and structure of this provision several times over, all in service of a curious desire to prosecute organizations running facilities for the purpose of addressing public health needs and *combatting* illicit drug use.

A federal statutory scheme passed to combat illicit drug use in *coordination* with local governments should not be read to foreclose the viable public health options local governments may consider to achieve that goal. *Amici* are considering various paths to encourage overdose prevention sites due to the limited number of successful treatment options available to combat the intractable opioid epidemic, which have not to date worked to stop the rising number of overdose deaths. Threatening federal criminal liability against organizations that open and operate overdose prevention sites, or the municipalities and local officials exercising their police

power by opening pathways for such sites to operate, would only be counterproductive to the federal government's stated goals and policy. It defies reason for the DOJ to suggest that a public health intervention designed and proven to *reduce* drug abuse is actually being advanced "for the purpose of" promoting illicit drug use. That is plainly not the purpose of operators like Safehouse, or of the localities that would welcome their efforts to fight addiction. The DOJ's contrary suggestion ignores the comprehensive services that sites like Safehouse would offer, not only the administration of naloxone in an emergency, but also connection to medication-assisted addiction treatments, addiction recovery counseling, and other health care services. It also ignores the abundant information indicating that overdose prevention sites are quite effective in fulfilling their public health purpose. As set forth above and in Safehouse's pleadings, all available scientific literature studying the effects of such sites concludes that they do indeed *decrease* drug abuse in the surrounding neighborhood. If the purpose of such sites is, as the DOJ suggests, to promote illegal drug use, then they are failing spectacularly.

2. *The CSA does not criminalize public health interventions with a legitimate medical purpose.*

At bottom, overdose prevention sites are medical facilities staffed by medical professionals engaged in the legitimate practice of medicine. As such, these facilities would fall outside of the CSA's proscriptive sections entirely. As Safehouse aptly points out (*see* Safehouse Br. at 28-32), the CSA is in no way intended to criminalize the legitimate practice of medicine—even to the extent that such practice involves the use of controlled substances—at the local level. In *Gonzalez v. Oregon*, the Supreme Court stated in no uncertain terms that the CSA "manifests no intent to regulate the practice of medicine generally." 546 U.S. 243, 270 (2006). The Court continued, "[t]he 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." *Id.* Instead, the CSA is understood to regulate "illicit drug dealing and trafficking as conventionally understood." *Id.* at 269-270. There is utterly no "conventional[] underst[anding]" of "illicit drug dealing and trafficking" that could encompass overdose prevention sites.

Rather, as discussed at length above, several *Amici* have evaluated overdose prevention sites of the type at issue here and have concluded that they serve a legitimate medical purpose. For example, the New York City DOHMH has recognized overdose prevention sites as "an evidence-based health intervention for people who inject drugs."[42] According to DOHMH, "[s]cientific evidence suggests that [overdose prevention sites] can prevent overdose and reduce the harms associated with injection drug use, including HIV and hepatitis C transmission."[43]

Similarly, the San Francisco Department of Public Health's Safe Injection Services Task Force has recognized that "research consistently demonstrates that safe injection services are an evidence-based harm reduction strategy that can address this public health issue [*i.e.*, the opioid crisis in San Francisco]."[44] According to King County's Heroin and Opiate Addiction Task Force, "[p]ublished evaluations from existing SCSs [supervised consumption sites], show that SCSs can reduce overdose deaths and behaviors that cause HIV and hepatitis C infection … reduce unsafe injection practices, increase use of detox and substance use disorder treatment services, reduce public drug use and the amounts of publically discarded injection equipment; and, do not increase drug use, crime, or other negative impacts in the area of the SCS."[45] And

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[42] *See Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, *supra*.
[43] *Id.*
[44] *See San Francisco Safe Injection Services Task Force: Final Report*, *supra*.
[45] King County Heroin & Prescription Opiate Addiction Task Force, *Final Report and Recommendations*, *supra*.

according to Pittsburgh mayor Bill Peduto, overdose prevention sites have "a proven record of being able to lessen the number of people who die, of being able to provide a safe environment to stop blood-borne diseases, and provide[] the gateway for people to say, 'I need help.'"[46]

Amici respectfully urge this Court to recognize that facilities like the one described in Safehouse's pleadings are engaged in the locally regulated practice of medicine in furtherance of a legitimate public health response to a public health crisis.

IV. CONSTRUING SECTION 856(A)(2) TO PROHIBIT THE MEDICAL SUPERVISION OF PEOPLE WHO USE DRUGS AT OVERDOSE PREVENTION SITES WOULD RAISE SERIOUS CONSTITUTIONAL QUESTIONS.

The constitutional issues with the DOJ's interpretation of Section 856 only further compel its rejection. Under the DOJ's reading of the statute, Section 856 may well exceed Congress's power under the Commerce Clause, and would undoubtedly infringe on the authority of state and local governments to protect public health and safety. Because alternative readings of the statute are at least plausible, the Court should reject the DOJ's view.

The Constitution grants states and their political subdivisions "broad authority to enact legislation for the public good"—what the Supreme Court has "often called a 'police power.' The Federal Government, by contrast, has no such authority and can exercise only the powers granted to it." *Bond v. United States*, 572 U.S. 844, 854 (2014) (citations omitted). The Constitution delegates to Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." Art. I, § 8, cl. 3. The Supreme Court has explained that the Commerce Power extends to conduct that has a "substantial effect on interstate commerce." *Id.* But an act "committed wholly within a State cannot be made an offence against

[46] Rich Lord, *Bill Peduto: City's Opioid Efforts Changing, may Include Safe Injection Sites*, Pittsburgh Post-Gazette (Feb. 1, 2018), *available at* https://www.post-gazette.com/local/city/2018/02/01/Bill-Peduto-Pittsburgh-opioid-crisis-epidemic-safe-injection-sites-Philadelphia/stories/201802010122 (last visited July 6, 2019).

the United States, unless it have some relation to the execution of a power of Congress, or to some matter within the jurisdiction of the United States." *Bond*, 572 U.S. at 854. While the market for illegal drugs is "commerce over which the United States has jurisdiction," *Taylor v. United States*, 136 S. Ct. 2074, 2081 (2016), the Commerce Power does not extend to conduct which is not "economic activity" in the first place. *United States v. Lopez*, 514 U.S. 549, 559 (1995).

Criminalizing overdose prevention sites would test these limits. No drugs would be bought or sold at sites. No fees would be paid for the use of sites. As discussed above, the purpose of sites is not to facilitate drug transactions, or to encourage drug use; it is the opposite. The sites would not participate in any way in the "market for illegal drugs." *Taylor*, 136 S. Ct. at 2081. Rather, they would be places where drug users can obtain medical supervision and treatment. The act of allowing drug users to consume in a supervised environment where they can be rescued if needed, rather than on the street or in a restroom stall, is not the kind of "economic activity" subject to Commerce Clause regulation. *See Lopez*, 514 U.S. at 559 (possession of firearm in designated gun-free school zone not "economic activity" subject to Commerce Clause regulation); *see also Nat'l Fed. of Independent Bus. v. Sebelius*, 567 U.S. 519, 556 (2012) (Commerce Power does not permit healthcare regulation of individuals who "are not currently engaged in any commercial activity involving health care"). Indeed, as Safehouse points out, the Government's reading of Section 856 would extend to a parent who knew their child was addicted to and using drugs in their home, or a homeless shelter that provides housing for people it knows are addicted to and using drugs on the premises. (Safehouse Br. at 22.) The same goes for clinics, libraries, or other locations where people are known to use, and overdose,

on drugs. If Section 856 were intended to extend to these circumstances as urged by the DOJ, it would not have passed constitutional muster.

To be sure, the potential benefits of overdose prevention sites are substantial, and many of those benefits can be measured in economic terms. *See supra* pp. 6-11. But that alone cannot justify Commerce Clause intervention. Indeed, the Supreme Court in *Lopez* specifically rejected the Government's attempt to defend legislation based on the "substantial costs of crime" and the impact of crime on "national productivity," noting this would make it "difficult to perceive any limitation on federal power, even in areas such as criminal law enforcement or education where States historically have been sovereign." *Lopez*, 514 U.S. at 564.

The fact that overdose prevention sites do fall within areas of regulation "where states historically have been sovereign" casts further doubt on the Government's efforts to criminalize them. *Id.* The Supreme Court has repeatedly emphasized the "prominence of the States in matters of public health and safety." Because the "health and safety" of residents are "primarily, and historically, matters of local concern," the Constitution reserves to 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." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). In particular, the "medical profession" is historically "regulated under the States' police powers." *Gonzales v. Oregon*, 546 U.S. at 269-270.

The Constitution's reservation of this power to the states and their subdivisions is crucial in addressing difficult public policy issues, including opioid addiction. Notwithstanding the seemingly universal agreement about the need to address the opioid crisis, including between the parties to this litigation (*see* Safehouse Br. 1), "considerable disagreement exists about how best to accomplish that goal. In this circumstance, the theory and utility of our federalism are revealed,

for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear," especially in "area[s] to which States lay claim by right of history and expertise." *Lopez*, 514 U.S.at 580-581 (Kennedy, J., concurring) (citing *San Antonio Independent Sch. Dist. v. Rodriguez*, 411 U.S. 1, 49-50 (1973); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)). The benefits of the "Nation-State relationship in our federal system" are realized where "[e]ach locality is free to tailor local programs to local needs." *San Antonio Indep. Sch. Dist.*, 411 U.S. at 49-50.

In addition, the Supreme Court has described "the punishment of local criminal activity" as "perhaps the clearest example of traditional state authority." *Bond*, 572 U.S. at 858 (citing *United States v. Morrison*, 529 U.S. 598, 618 (2000)). The Court has also emphasized the prerogative of states *not* to punish local criminal activity. The Supreme Court has "traditionally viewed the exercise of state officials' prosecutorial discretion as a valuable feature of our constitutional system." *Bond*, 572 U.S. at 864-865. By penalizing conduct the state has chosen not to, the federal government "may effectively displace a policy choice made by the State." *Id.* But the DOJ reads Section 856 to intrude on all these areas of state sovereignty.

Each of these concerns warrants rejection of the DOJ's reading of Section 856. "Federal statutes impinging upon important state interests "cannot ... be construed without regard to the implications of our dual system of government ... ." *BFP v. Resolution Tr. Corp.*, 511 U.S. 531, 544 (1994). "It is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides" the "usual constitutional balance of federal and state powers." *Bond*, 572 U.S. at 858 (internal quotations and citation omitted). "[W]hen deciding which of two plausible statutory constructions to adopt, a court must consider the necessary consequences of its choice. If one of them would raise a multitude of constitutional problems, the other should

prevail—whether or not those constitutional problems pertain to the particular litigant before the Court." *Clark v. Martinez*, 543 U.S. 371, 380-381 (2005).

Here, Safehouse has presented an interpretation of the intent requirements of Section 856, as well as the exception for interventions with a legitimate medical purpose, that is at least plausible. The Court should therefore reject the Government's interpretation, which would harm our constitutional structure and impede critical efforts to save lives threatened by opioid addiction.

CONCLUSION

Amici urge the Court to reject DOJ's overreaching and unsupportable interpretation of a statute that expressly addresses the conduct contributing to the very opioid dependence problem that *Amici* are trying to ameliorate. Such a ruling will confirm that *Amici* can safely continue both our conventional and innovative efforts to meet our community responsibilities, to increase access to medically assisted treatment and counseling, to address the opioid scourge that is killing our residents, and to save lives. For the reasons set forth above and in Safehouse's brief, the Court should deny the DOJ's motion for judgment on the pleadings.

DATED: July 10, 2019

Respectfully submitted,

/s/ Virginia A. Gibson

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. SAFEHOUSE, a Pennsylvania nonprofit corporation; JOSE BENITEZ, as President and Treasurer of Safehouse, Defendants.	Case No. 2:19-cv-00519-GAM
SAFEHOUSE, a Pennsylvania nonprofit corporation, Counterclaim Plaintiff, v. UNITED STATES OF AMERICA, Counterclaim Defendant, U.S. DEPARTMENT OF JUSTICE; WILLIAM P. BARR, in his official capacity as Attorney General of the United States; WILLIAM M. MCSWAIN, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania, Third-Party Defendants.	

[PROPOSED] ORDER GRANTING MOTION OF KING COUNTY, WA; NEW YORK, NY; SAN FRANCISCO, CA; SEATTLE, WA; PITTSBURGH, PA; AND SYVANTE L. MYRICK, MAYOR OF ITHACA, NY TO FILE BRIEF AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFF'S MOTION FOR JUDGMENT ON THE PLEADINGS

AND NOW, upon consideration of the Motion of King County, WA; New York, NY; San Francisco, CA; Seattle, WA; Pittsburgh, PA; and Syvante L. Myrick, Mayor of Ithaca, NY to appear as *amici curiae* and to file a brief in opposition to Plaintiff's motion for judgment on the pleadings, **IT IS HEREBY ORDERED** that the motion is **GRANTED**.

BY THE COURT:

Date: _____

_____
GERALD AUSTIN McHUGH
United States District Judge

CERTIFICATE OF SERVICE

I, Virginia A. Gibson, hereby certify that, on July 10, 2019, I caused a true and correct copy of the foregoing Motion of King County, WA; New York, NY; San Francisco, CA; Seattle, WA; and Pittsburgh, PA to File Brief as Amici Curiae in Opposition to Plaintiff's Motion for Judgment on the Pleadings, and all documents filed therewith, to be electronically filed and served via the Court's electronic filing system upon the parties registered to receive electronic filings.

/s/ Virginia A. Gibson.
Virginia A. Gibson