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

UNITED STATES OF AMERICA, Plaintiff, v. SAFEHOUSE, a Pennsylvania nonprofit corporation; JEANETTE BOWLES, as Executive Director of Safehouse, Defendants.	Civil Action No.: 2:19-cv-00519
SAFEHOUSE, a Pennsylvania nonprofit corporation, *Counterclaim Plaintiff,* v. UNITED STATES OF AMERICA, *Counterclaim Defendant,* and 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*.	

DEFENDANT SAFEHOUSE'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT, AND THIRD-PARTY COMPLAINT

PRELIMINARY STATEMENT

"The opioid problem is perhaps the greatest public health crisis this city has faced in the last century."[1] Philadelphians and Americans are dying from opioid overdoses at unprecedented

[1] Tr. of Council of City of Phila., Comm. on Pub. Health & Human Servs., at 21:3-5 (Mar. 12, 2018) (Dr. Thomas Farley, Phila. Health Comm'r).

and alarming rates. In the last two years, more than 2,300 of our brothers, sisters, mothers, fathers, sons, daughters, and neighbors died of opioid overdoses in Philadelphia alone.[2] Philadelphia's overdose fatality rate is nearly four times its homicide rate.[3] The overdose crisis has intensified in the past several years due to the influx of fentanyl—a powerful and fast-acting opioid that was involved in 87% of the overdose deaths that occurred in Philadelphia in 2017.[4]

This is the stark reality: in an opioid overdose, a person loses consciousness, stops breathing, and then—absent intervention—will die. Fentanyl increases the risk of overdose, because it is 50-to-100 times more potent and faster-acting than heroin. A person overdosing on fentanyl can stop breathing in as little as 2-to-3 minutes. Opioid receptor antagonists (such as Naloxone) are a lifesaving treatment that will reverse the effects of an overdose—but only if timely medical assistance is available. Tragically, for thousands help arrived too late or not at all.

In Philadelphia, Safehouse intends to prevent as many of these deaths as possible through a medical and public health approach to overdose prevention. The Safehouse model will include medically supervised consumption and observation. Those who are at high risk of overdose death would stay within immediate reach of urgent, lifesaving medical care at the critical moment of consumption. Medical supervision at the time of consumption ensures that opioid receptor antagonists such as Naloxone, and other respiratory and supportive treatments like oxygen, will be immediately available in the event of an overdose. This intervention will not solve the opioid

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[2] *See* City of Phila., Dep't of Pub. Health, *Opioid Misuse and Overdose Report* (Nov. 29, 2018), https://www.phila.gov/media/20181129123743/Substance-Abuse-Data-Report-11.29.18.pdf; City of Phila., *Combating the Opioid Epidemic*, https://www.phila.gov/programs/combating-the-opioid-epidemic/reports-and-data/opioid-misuse-and-overdose-data/ (last visited Apr. 2, 2019); *see also* WHYY, *Fatal opioid overdoses expected to dip in Philly for first time in 5 years* (Dec. 24, 2018), https://whyy.org/articles/fatal-opioid-overdoses-expected-to-dip-in-philly-for-first-time-in-5-years/.

[3] City of Phila., Dep't of Pub. Health, *Philadelphia's Community Health Assessment: Health of the City 2018*, at 5, https://www.phila.gov/media/20181220135006/Health-of-the-City-2018.pdf (last visited Apr. 2, 2019).

[4] *See* City of Phila., Dep't of Pub. Health, *Opioid Misuse and Overdose Report* (Nov. 29, 2018), https://www.phila.gov/media/20181129123743/Substance-Abuse-Data-Report-11.29.18.pdf.

crisis, but it will provide a critical life raft. Safehouse's comprehensive model will also (i) encourage entry into drug treatment by engaging with participants when they are most receptive to counseling, (ii) reduce the transmission of communicable diseases such as HIV and Hepatitis C, (iii) treat and prevent life-threatening infections, (iv) provide primary medical care, and (v) offer a host of essential wraparound services. These measures are informed by medical science and public health data. And, consistent with their Judeo-Christian traditions, Safehouse's overdose prevention service is an exercise of the religious beliefs of its Board of Directors, who hold as core tenets preserving life, providing shelter to neighbors, and ministering to those most in need of physical and spiritual care.

The success of Safehouse's model has been confirmed by clinical and public health research that shows that medically supervised consumption sites save lives and prevent overdose deaths. Medically supervised consumption sites are not a new phenomenon; they have been in operation for more than 30 years. More than 120 sites operate openly worldwide, and *not a single fatal overdose* has been reported inside any similar facility. Extensive public health research of medically supervised consumption sites report a *decrease* in overdose deaths in their immediate vicinity, a *decrease* in the public use of drugs, a *decrease* in discarded drug paraphernalia waste, and a *decrease* in the transmission of infectious diseases. That research also shows that medically supervised consumption sites encourage long-term treatment for opioid addiction and do not contribute to increased crime.[5]

[5] *See* Beau Kilmer et al., Rand Corp., *Considering Heroin-Assisted Treatment and Supervised Drug Consumption Sites in the United States* 31-38 (2018), https://www.rand.org/content/dam/rand/pubs/research_reports/RR2600/RR2693/RAND_RR2693.pdf ("The existing reviews of scientific evaluation of [supervised consumption sites] report positive findings across a broad range of outcomes."); Chloe Potier et al., *Supervised injection services: What has been demonstrated? A systematic literature review*, 145 Drug & Alcohol Dependence, Results (2014) (concluding, after review of seventy-five relevant articles, that supervised consumption sites "were efficacious in promoting safer injection conditions, enhancing access to primary health care, and reducing overdose frequency," that they are "associated with reduced levels of public drugs injections or dropped syringes," and that such sites "were not found to increase drug injecting, drug trafficking or crime in the surrounding environments").

Overdose prevention services, including medically supervised consumption, are nationally and internationally recognized as an appropriate medical and public health measure by the American Medical Association, the American Public Health Association, AIDS United, the European Monitoring Centre for Drugs and Drug Addiction, the Infectious Diseases Society of America, the HIV Medicine Association, the International Drug Policy Consortium, and innumerable public health experts, physicians, and addiction researchers. This measure has locally been endorsed and encouraged by Philadelphia's Mayor, Health Commissioner, Commissioner of the Department of Behavioral Health and Intellectual disAbility Services, and the District Attorney, who all see the critical need for this intervention.

Despite this evidence, the U.S. Department of Justice ("DOJ") has threatened to prosecute Safehouse and seeks a declaratory judgment that Safehouse's proposed overdose prevention services would violate 21 U.S.C. § 856. Providing lifesaving medical services to individuals who are suffering from substance use disorder does not and constitutionally cannot violate Section 856. The DOJ's interpretation of Section 856 ignores Safehouse's planned comprehensive medical model. It is contrary to (i) the statutory regime adopted by Congress in the Controlled Substances Act ("CSA"), Pub. L. No. 91-513, 84 Stat. 1242 (21 U.S.C. § 801 *et seq.*), the Consolidated Appropriations Act, 2016 ("Appropriations Act of 2016"), Pub. L. No. 114-113, § 520, 129 Stat. 2327, and the Comprehensive Addiction and Recovery Act of 2016 ("CARA"), Pub. L. No. 114-198, 130 Stat. 695; (ii) the text, structure, purpose, and history of Section 856; (iii) well-settled canons of construction; (iv) foundational principles of federalism and limited federal government authority underlying the U.S. Constitution; and (v) the Religious Freedom Restoration Act of 1993 ("RFRA"), Pub. L. No. 103-141, 107 Stat. 1488 (42 U.S.C. § 2000bb *et seq.*). The DOJ now asks this Court to declare that the stark realities of the opioid crisis are irrelevant because "the law is

the law"—even though "the law" is not what DOJ claims it to be, and the DOJ has never enforced Section 856 in any analogous circumstance.

Section 856 does not address, much less prohibit, the legitimate, multifaceted, medical, and public health intervention that Safehouse intends to provide. Congress enacted Section 856 as an amendment to the CSA to target "crack houses" and "rave parties" where drug dealers established and maintained houses or temporary warehouses "for the purpose of" the manufacture, sale, and use of drugs in furtherance of their drug distribution and for-profit enterprises. Safehouse is nothing like a "crack house" or drug-fueled "rave." Nor is Safehouse established "for the purpose" of unlawful drug use. Rather, it is established for the exclusive purpose of providing urgent, lifesaving medical care to those at risk of drug overdose. The CSA does not regulate such a legitimate—indeed, critical—medical and public health intervention.

The DOJ claims that Safehouse's overdose prevention services violate federal law. It is wrong. To the contrary, Safehouse's comprehensive model is entirely consistent with the federal government's response to the opioid crisis. The services Safehouse will offer—clean injection equipment, Naloxone access, comprehensive medical services (primary care, wound care, HIV and Hepatitis C treatment), and immediate enrollment into drug treatment—are not only permitted by federal law, they are expressly endorsed by Congress and federal agencies. The U.S. Department of Health and Human Services ("HHS") and the Centers for Disease Control and Prevention ("CDC") expressly approve of comprehensive syringe exchange programs, which include the provision of clean needles, tourniquets, wipes, clean water for injections, and instruction on safer injection techniques. Recently, Congress clarified that federal law not only

permits syringe exchange programs, but now allows those programs to receive federal funding.[6] Congress and federal agencies likewise affirmatively have promoted the availability of Naloxone and other opioid receptor antagonists.[7]

Safehouse will bridge the short, but critical, gap—a matter of seconds to minutes—between the time a person receives a sterile syringe and other clean injection equipment and the need for immediate access to Naloxone and other medical treatment to reverse an overdose. The DOJ does not dispute that Safehouse may provide a person with syringes and consumption equipment and may have Naloxone at the ready. Yet, the DOJ suggests that Safehouse itself, as well as its leadership and personnel, would commit a 20-year felony unless it insists that a person leave the safety of its shelter—and potentially go to an alley, a public street or bathroom, or home alone—at the very moment when access to lifesaving medical supervision and care is most critical, that is, at the time of consumption. Contrary to the DOJ's Complaint, overdose prevention services, including Safehouse's proposed medically supervised consumption site in Philadelphia, will advance—not violate—federal law and policy.

The moral and religious imperative to save lives, medical ethics and practice, the public health data, and federal law all point to the same conclusion: Safehouse offers a lifesaving service that is not prohibited by Section 856. Federal criminal law does not require Safehouse to ignore this overdose crisis while people continue to die at a staggering rate. This Court should deny the DOJ's request for a declaration, and instead should hold that Section 856, under these circumstances, does not criminalize Safehouse's contemplated overdose prevention services.

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[6] CDC, *Program Guidance for Implementing Certain Components of Syringe Services Programs* (2016), https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf.

[7] *See* CARA, § 107, 130 Stat. 703 (42 U.S.C. § 290dd-3).

Defendant Safehouse, by and through its counsel, answer the Complaint of Plaintiff United States of America ("Plaintiff") and aver as follows:

1. Safehouse admits that Plaintiff purports to seek a declaratory judgment under the Declaratory Judgment Act, as amended, 28 U.S.C. § 2201, and under the CSA, 21 U.S.C. § 843(f) (as made applicable by *id*. § 856(e)) and its implementing regulations, 21 C.F.R. § 1301 *et seq*., but denies that Plaintiff is entitled to such relief.

2. Admitted.

3. Admitted.

PARTIES

4. Admitted.

5. Admitted.

6. Denied as stated.

7. Denied.

FACTUAL ALLEGATIONS

8. Admitted. Despite the existence of such nonprofits providing services intended to reduce the harms of the opioid crisis, Philadelphians continue to die of overdoses at rates higher than nearly every other major city.[8]

[8] In 2016, Philadelphia had the second-highest rate of drug overdose deaths among counties with a population of more than one million residents. *See* Pew Tr., *Philadelphia's Drug Overdose Death Rate Among Highest in Nation* (Feb. 15, 2018), https://www.pewtrusts.org/en/research-and-analysis/articles/2018/02/15/philadelphias-drug-overdose-death-rate-among-highest-in-nation.

In 2017, Philadelphia had the highest overdose death rate (65/100,000 residents) of the counties in the top ten largest U.S. cities. Its overdose death rate was three times the rate of the second highest county (Cook County, 23/100,000 residents). *See* CDC, *CDC WONDER Online Database*: *About Underlying Cause of Death, 1999-2017*, https://wonder.cdc.gov/ucd-icd10.html (last visited Apr. 2, 2019).

9. Admitted in part and denied in part. Safehouse's mission, as stated on its website, "is to save lives by providing a range of overdose prevention services."[9] Also as stated, "[t]he leaders and organizers of Safehouse are motivated by the Judeo-Christian beliefs ingrained in [them] from [their] religious schooling, [their] devout families and [their] practices of worship. At the core of [their] faith is the principle that preservation of human life overrides any other considerations."[10] Safehouse will save lives by providing a range of overdose prevention services, including medically supervised consumption and observation. Exhibit A to the Complaint is a writing that speaks for itself. Any attempt by Plaintiff to characterize or interpret Exhibit A is therefore denied.

10. Denied as stated. Upon arrival at Safehouse, all participants must register and provide demographic information. A physical and behavioral health assessment will be conducted and a range of overdose prevention services offered. "[P]articipants will be directed to the medically supervised observation room," where they will be "offered on-site initiation of Medication Assisted Treatment (MAT), wound care, and referrals to primary care, social services, and housing opportunities."[11] Or participants may seek supervised consumption, in which case they "will be directed to the medically supervised consumption room and provided sterile consumption equipment and fentanyl test strips.[12] Participants will safely dispose of used

[9] Safehouse, *Frequently Asked Questions*, https://www.safehousephilly.org/about/faqs (last visited Apr. 2, 2019).

[10] *Id.*

[11] *Id.*

[12] The provision of sterile consumption equipment will reduce of the risk of transmission of infectious diseases. Fentanyl test strips are used to detect the presence of fentanyl prior to consumption. By alerting the participant to the presence of fentanyl and the increased risk of overdose, Safehouse would be practicing a harm reduction strategy that encourages a dosage adjustment to a safer level.

consumption equipment before leaving the supervised consumption area.[13] Under no circumstance will Safehouse make available any illicit narcotic or opioid. From the consumption area, participants will be directed to the medically supervised observation room and again offered opportunities for drug treatment, medical care, and social services .[14] Exhibit A is a printout of the Safehouse website as of February 2019. Exhibit A to the Complaint is a writing that speaks for itself. Any attempt by Plaintiff to characterize or interpret Exhibit A is therefore denied.

11. Admitted in part and denied in part. Paragraph 11 selectively quotes from the Safehouse website as of February 2019, as reflected in Exhibit A. Exhibit A to the Complaint is a writing that speaks for itself. Any attempt by Plaintiff to characterize or interpret Exhibit A is therefore denied.

12. Denied. The averments contained in Paragraph 12 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

13. Denied. The averments contained in Paragraph 13 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

14. Denied. The averments contained in Paragraph 14 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

15. Denied. The averments contained in Paragraph 15 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. Safehouse's provision of overdose prevention services would not violate Section 856(a)(2).

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[13] The safe disposal of consumption equipment will reduce the risk of transmission of intravenous diseases, and will further the goals of city-sponsored programs like the Philadelphia Resilience Project, which aim to alleviate the public littering of consumption equipment that is prevalent in areas of Philadelphia with high drug use. *See* City of Phila., *Philadelphia Resilience Project*, https://www.phila.gov/programs/philadelphia-resilience-project/.

[14] *Id.* (footnotes added).

16. Denied. The averments contained in Paragraph 16 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. Safehouse's overdose prevention services would not fall within the scope of Section 856(a)(2).

17. Admitted in part and denied in part. Safehouse has publicly stated that its planned operations would not violate federal law. The remainder of Paragraph 17 is denied.

18. Admitted in part and denied in part. It is admitted that Safehouse received a letter from U.S. Attorney for the Eastern District of Pennsylvania, William M. McSwain, dated November 9, 2018. Exhibit B to the Complaint is a copy of that letter, which is a writing that speaks for itself. Any attempt by Plaintiff to characterize or interpret Exhibit B is therefore denied.

19. Admitted in part and denied in part. It is admitted that Safehouse sent a letter to U.S. Attorney for the Eastern District of Pennsylvania, William M. McSwain, dated November 26, 2018, explaining (among other things) that a proper and constitutional application of Section 856 does not prohibit Safehouse's overdose prevention services model that would combat the opioid crisis and prevent fatal overdoses. Exhibit C to the Complaint is a copy of that letter, which is a writing that speaks for itself. Any attempt by Plaintiff to characterize or interpret Exhibit C is therefore denied.

20. Admitted.

21. Admitted as stated.

22. Denied.

COUNT I

Violations of the Controlled Substances Act, 21 U.S.C. § 856(a)(2) – Declaratory Judgment

23. Safehouse incorporates by reference its responses to paragraphs 1 through 22 of Plaintiff's Complaint as if set forth fully herein.

24. Denied. The averments contained in Paragraph 24 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

25. Denied. The averments contained in Paragraph 25 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

26. Denied. The averments contained in Paragraph 26 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

27. Denied. The averments contained in Paragraph 27 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

28. Denied. The averments contained in Paragraph 28 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

29. Denied. The averments contained in Paragraph 29 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

30. Denied. The averments contained in Paragraph 30 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

31. Denied. The averments contained in Paragraph 31 constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and is therefore denied.

PRAYER FOR RELIEF

Safehouse denies that Plaintiff is entitled to any relief in connection with the allegations set forth in its Complaint, including, but not limited to, the allegations set forth in Plaintiff's Prayer for Relief.

AFFIRMATIVE DEFENSES

As affirmative defenses to Plaintiff's Complaint, Safehouse asserts as follows without assuming the burden of proof or persuasion on matters for which it has no such burden. In doing

so, Safehouse specifically reserves the right to restate, re-evaluate, or recall any defenses and to assert additional defenses:

1. The cited provision of the CSA, 21 U.S.C. § 856(a)(2), does not apply to Safehouse's proposed conduct.

2. Safehouse's proposed conduct is justified by medical necessity to avoid imminent serious bodily injury and death.

3. The application of Section 856 to Safehouse is barred by RFRA, 42 U.S.C. § 2000bb *et seq.*

4. As applied to Safehouse, Section 856(a)(2) is unconstitutional under the Commerce Clause.

SAFEHOUSE'S COUNTERCLAIMS AND THIRD-PARTY COMPLAINT

Pursuant to Federal Rule of Civil Procedure 13, Counterclaim Plaintiff Safehouse asserts the following counterclaims against Counterclaim Defendant United States of America, and claims against Third-Party Defendants U.S. Department of Justice; William P. Barr, in his official capacity as U.S. Attorney General; and William M. McSwain, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania (collectively, "the DOJ"), and, by and through its counsel, alleges as follows:

INTRODUCTION

1. In this action, Safehouse seeks to have this Court declare 21 U.S.C. § 856 inapplicable to the establishment and carrying out of its overdose prevention services model, which includes medically supervised consumption and observation.

2. Safehouse further seeks a declaration by the Court that any prohibition on its operation of a medically supervised consumption room as part of its overdose prevention services model would violate the Religious Freedom and Restoration Act, 42 U.S.C. § 2000bb *et seq.*, by

substantially burdening the exercise of its religious beliefs that call its Board Members and Directors to provide lifesaving medical treatment to a vulnerable population. The federal government lacks any compelling interest in preventing Safehouse's proposed operation; nor would enforcement of Section 856 against Safehouse be the least restrictive means of advancing any such interest.

JURISDICTION AND VENUE

3. This action arises under 21 U.S.C. § 801 *et seq.* and 42 U.S.C. § 2000bb *et seq.* This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1346. Safehouse seeks remedies under 28 U.S.C. §§ 2201 and 2202.

4. Venue lies in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(b), as the relevant events took place in this District.

DECLARATORY JUDGMENT

5. There is an actual controversy of sufficient immediacy and concreteness relating to the legal rights and duties of Safehouse to warrant relief under 28 U.S.C. § 2201.

6. The harm to Safehouse as a direct result of the actions and threatened actions of the DOJ is sufficiently real and imminent to warrant the issuance of a conclusive declaratory judgment.

7. The DOJ and its officials have asserted that Safehouse's overdose prevention services model, which includes medically supervised consumption and observation, would violate federal criminal law. The DOJ has threatened to commence criminal and civil enforcement proceedings at any time to prevent Safehouse from opening and becoming operational, and brought the instant action resulting in this counterclaim.

8. Safehouse, as well as its leaders and personnel, are thus threatened with federal civil and criminal enforcement unless Safehouse refrains from engaging in entirely lawful conduct in pursuit of its lifesaving mission.

9. Under these circumstances, judicial intervention is warranted to resolve a genuine case or controversy within the meaning of Article III of the U.S. Constitution regarding the proper interpretation and application of Section 856.

10. A declaration that Safehouse would not violate Section 856 once it becomes operational would definitively resolve that controversy for the parties.

THE PARTIES

11. Counterclaim Plaintiff Safehouse is a nonprofit corporation operating under the laws of the Commonwealth of Pennsylvania with a registered address at 1211 Chestnut Street, Suite 600, Philadelphia, Pennsylvania 19107.

12. Counterclaim Defendant is the United States of America.

13. Third-Party Defendant is the U.S. Department of Justice.

14. Third-Party Defendant William P. Barr is sued in his official capacity as U.S. Attorney General.

15. Third-Party Defendant William M. McSwain is sued in his official capacity as the United States Attorney for the Eastern District of Pennsylvania.

I. FACTUAL ALLEGATIONS

16. Safehouse hereby incorporates and re-alleges the Preliminary Statement and each of the factual allegations in its Answer to Plaintiff's Complaint. It further avers as follows:

The Opioid Epidemic in the City of Philadelphia

17. The City of Philadelphia is in the midst of an unprecedented public health emergency due to the opioid epidemic and the opioid overdose crisis.

18. In the last two years, more than 2,300 individuals died as a result of an opioid overdose in Philadelphia.[15] On average, Philadelphia is losing three of its citizens each day to opioid overdoses.

19. On October 3, 2018, the Mayor of Philadelphia issued an Opioid Emergency Response Executive Order declaring that "Kensington and its surrounding neighborhoods are in the midst of a disaster" due to the opioid crisis, and empowering city agencies and officials to lead efforts to reduce opioid deaths and transmission of disease and to increase entry into drug treatment.[16]

20. Since 2011, most opioid-related deaths in Philadelphia have been caused by heroin.[17] In the last several years, Philadelphia has experienced a dramatic increase in the number of deaths related to fentanyl.[18]

21. Fentanyl is a synthetic opioid that is now found in many of the opioids sold on the street in Philadelphia. Fentanyl is often sold to drug users who mistakenly believe that they are purchasing less lethal drugs.

22. Fentanyl is 50-to-100 times more potent than heroin, and its effects are felt within the human body much faster. In the event of an overdose, a person may stop breathing within ***2-***

[15] *See* City of Phila., Dep't of Pub. Health, *Opioid Misuse and Overdose Report* (Nov. 29, 2018), https://www.phila.gov/media/20181129123743/Substance-Abuse-Data-Report-11.29.18.pdf; City of Phila., *Combating the Opioid Epidemic*, https://www.phila.gov/programs/combating-the-opioid-epidemic/reports-and-data/opioid-misuse-and-overdose-data/ (last visited Apr. 2, 2019); *see also* WHYY, *Fatal opioid overdoses expected to dip in Philly for first time in 5 years* (Dec. 24, 2018), https://whyy.org/articles/fatal-opioid-overdoses-expected-to-dip-in-philly-for-first-time-in-5-years/.

[16] City of Phila., Office of the Mayor, *Executive Order No. 3-18 – Opioid Emergency Response Executive Order* (Oct. 3, 2018), https://www.phila.gov/ExecutiveOrders/Executive%20Orders/eo99318.pdf.

[17] *See id*.

[18] *See id*.

to-3 minutes after the consumption of fentanyl. Absent intervention, serious injury or death can occur as quickly as ***3-to-5 minutes*** from the time of consumption.

23. Every second counts in reversing an opioid overdose. When immediately available, the administration of Naloxone and similar opioid receptor antagonists provides lifesaving treatment. These interventions ***will resuscitate and keep a person alive with medical certainty***.

24. The time-sensitive nature of overdose prevention services is complicated by the fact that Philadelphia's Emergency Medical Services ("EMS") is inundated with calls to respond to overdoses, response times are variable, and for 46 percent of calls in 2017, more than 9 minutes elapsed before EMS arrived at the scene.[19]

25. In 2017, Philadelphia's EMS personnel administered Naloxone to more than 5,400 overdose victims.[20] This number has continued to increase in 2018.

26. Emergency rooms, moreover, frequently are not equipped to provide the wraparound services needed to overcome opioid addiction.[21]

27. As part of this growing crisis, the Mayor of Philadelphia created the Task Force to Combat the Opioid Epidemic in Philadelphia (the "Task Force"). The final report issued by the

[19] Adam Thiel, Fire Comm'r, *Philadelphia Fire Department Fiscal Year 2018 Budget Testimony*, at 6, http://phlcouncil.com/wp-content/uploads/2017/04/FY18-Fire-Budget-Testimony-final-version-4.12.17.pdf (last visited Apr. 2, 2019).

[20] *See* City of Phila., Dep't of Pub. Health, *Opioid Misuse and Overdose Report* (Nov. 29, 2018), https://www.phila.gov/media/20181129123743/Substance-Abuse-Data-Report-11.29.18.pdf; City of Phila., *Combating the Opioid Epidemic*, https://www.phila.gov/programs/combating-the-opioid-epidemic/reports-and-data/opioid-misuse-and-overdose-data/ (last visited Apr. 2, 2019)

[21] Hoag Levins, *Optimizing Heroin Users' Treatable Moments in the ER* (June 2017), https://ldi.upenn.edu/news/optimizing-heroin-users-treatable-moments-er (last visited Apr. 2, 2019).

Task Force recommended the implementation of overdose prevention services and expansion of treatment access and capacity.[22]

28. Safehouse would fulfill Philadelphia's dire need for overdose prevention services.

Formation of Safehouse

29. Safehouse, a privately funded nonprofit corporation, was established in 2018 with the mission to save lives by providing a range of overdose prevention services. Its proposed model is part of a broader harm reduction strategy to mitigate the catastrophic losses resulting from the opioid epidemic and overdose crisis in Philadelphia.

30. "Substance use disorder" or "Opioid use disorder" are defined by the CDC to be a medical condition diagnosed "based on specific criteria such as unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home, among other criteria."[23] The Office of the U.S. Surgeon General has reported that more than eleven million Americans use illicit drugs or misuse prescription drugs, but that only one out of four of those people seek specialized treatment for opioid use disorder.[24] In 2016, the Mayor's Task Force reported that more than 14,000 Medicaid recipients in Philadelphia sought treatment for opioid use disorder—a small fraction of those actually suffering from that condition—and estimated that more than 70,000 Philadelphians are active heroin users.[25]

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[22] *See* City of Phila., *The Mayor's Task Force To Combat The Opioid Epidemic in Philadelphia: Final Report and Recommendations* (May 19, 2017), https://dbhids.org/wp-content/uploads/2017/04/OTF_Report.pdf ("*Task Force Report*").

[23] CDC, *Commonly Used Terms: Opioid Overdose*, https://www.cdc.gov/drugoverdose/opioids/terms.html (last visited Apr. 3, 2019).

[24] HHS, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids* 6 (Sept. 19, 2018), https://addiction.surgeongeneral.gov/sites/default/filesfiles/Spotlight-on-Opioids_09192018.pdf.

[25] *Task Force Report* 7-8.

31. "Harm reduction" is an umbrella term for interventions that aim to reduce problematic or otherwise harmful effects of certain behaviors. In the context of substance and opioid use disorders, such interventions are necessary to reduce harm for individuals "who, for whatever reason, may not be ready, willing, or able to pursue full abstinence as a goal." Harm reduction strategies are an essential aspect of public health initiatives. Harm reduction can include reducing the frequency of substance use, preventing diseases caused by substance use (such as HIV and Hepatitis C), providing syringe exchange, and offering medication-assisted treatments, overdose prevention, and wound care. Harm reduction strategies are necessary in light of the psychology of addiction and substance use disorder, and seek to help individuals engage in treatments to reduce, manage, and stop their substance use when appropriate.[26]

32. Safehouse will combat the opioid crisis through the use of a comprehensive harm reduction strategy.

33. Safehouse's overdose prevention services include the assessment of an individual's physical and behavioral health status, provision of sterile consumption equipment, provision of drug testing (*i.e.*, fentanyl test strips), medically supervised consumption and observation, overdose reversal, wound care and other primary care services, on-site education and counseling, on-site MAT and recovery counseling, distribution of Naloxone, and access to wraparound services such as housing, public benefits, and legal services.

34. Safehouse's overdose prevention services model provides those at highest risk of an opioid overdose with immediate access to medical care, including overdose reversal agents. Under this model, Safehouse can offer assurance, to a medical certainty, that people within its care will not die of a drug overdose.

[26] *See* Diane E. Logan & G. Alan Marlatt, *Harm Reduction Therapy: A Practice-Friendly Review of Research,* 66 J. Clinical Psychol. 201 (2010).

35. Safehouse will not provide any illicit drugs for consumption, nor will it tolerate any sale of illicit drugs or drug sharing at its facility.

36. Safehouse's comprehensive services will encourage entry into drug treatment, reduce the burden on emergency services and first responders, prevent the transmission of infectious diseases, and create a safer community by reducing public consumption of illicit drugs and discarded needles and other consumption equipment.

37. Safehouse will save lives by preventing and averting overdose deaths. It will also save lives by preventing death and serious health complications caused by infections and disease transmitted by intravenous drug use.

38. Studies estimate that an overdose prevention site like Safehouse could reduce overdose deaths annually by 30% in the site's immediate vicinity.[27]

Threat of Prosecution

39. On November 9, 2018, the U.S. Attorney for the Eastern District of Pennsylvania, William M. McSwain, sent a letter to Safehouse declaring the DOJ's intent to pursue "appropriate legal remedies" for a purported "violation of the CSA." A true and correct copy of the November 9, 2018 letter is attached as Exhibit B to the Complaint.

40. Similarly, in a widely published op-ed, U.S. Deputy Attorney General Rod Rosenstein argued that safe injection facilities violate federal law and could result in "up to 20 years in prison."[28]

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[27] Sharon Larson et al., *Supervised Consumption Facilities – Review of the Evidence* 20 (2017), https://dbhids.org/wp-content/uploads/2018/01/OTF_LarsonS_PHLReportOnSCF_Dec2017.pdf ("*Supervised Consumption Facilities*").

[28] *See* Rod J. Rosenstein, *Fight Drug Abuse, Don't Subsidize It,* N.Y. Times (Aug. 27, 2018), https://www.nytimes.com/2018/08/27/opinion/opioids-heroin-injection-sites.html.

41. On February 5, 2019, the DOJ filed a complaint for a declaratory judgment that Safehouse's medically supervised consumption room would violate 21 U.S.C. § 856(a)(2).

42. Violation of 21 U.S.C. § 856(a)(1) or (a)(2) carries with it severe criminal and civil penalties, including fines of up to $2,000,000 and imprisonment for up to twenty years. *See* 21 U.S.C. § 856(b) and (d).

II. SAFEHOUSE'S OVERDOSE PREVENTION SERVICES ARE ENTIRELY CONSISTENT WITH FEDERAL LAW AND POLICY

43. Efforts to expand drug treatment have been at the heart of the CSA, 21 U.S.C. § 801 *et seq*. since its passage in 1970. In the bill enacting the CSA, Congress identified "increased efforts in drug abuse prevention and rehabilitation of users" as one of three important objectives of the CSA. *See* H.R. Rep. No. 91-1444, *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4567; *see also* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236.

44. Under the CSA, health care practitioners licensed by the U.S. Drug Enforcement Administration ("DEA") may lawfully dispense or prescribe controlled substance "in the course of professional practice." 21 U.S.C. § 802(21); 21 C.F.R. § 1306.04. The CSA does not generally "regulate the practice of medicine," except "insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). Outside of those delineated spheres, the CSA does not limit the appropriate medical response to the risk of drug overdose.

45. Federal law permits, and indeed encourages, a facility like Safehouse to provide safe and clean equipment for intravenous drug users, notwithstanding 21 U.S.C. § 863, and to provide them with medical treatment, including immediate access to Naloxone and other opioid reversal agents.

46. Safehouse's overdose prevention services model allows those at high risk of overdose death to stay within immediate reach of urgent, lifesaving medical care at the critical moment of consumption. Medical supervision and direct access to treatment can reverse an overdose with medical certainty and ensures that participants in Safehouse's care will stay alive.

47. It would be entirely inconsistent with the CSA, recent Congressional changes to federal law, and federal agency policy to find that Section 856 requires doctors, nurses, and medically trained volunteers to turn their backs on patients at their most vulnerable moment. Section 856 does not prohibit overdose prevention services, including the medical supervision of drug consumption designed to provide immediate access to lifesaving care and to encourage entry into long-term drug treatment.

A. *The CSA Does Not Regulate Medical Treatment or Overdose Prevention Measures.*

48. Although the CSA creates a comprehensive statutory and regulatory regime regarding the manufacture, distribution, and possession of controlled substances, it does not regulate medical treatment or the practice of medicine. *See Oregon*, 546 U.S. at 270 ("[T]he statute manifests no intent to regulate the practice of medicine generally.").

49. Under Subchapter I of the CSA, a medical professional licensed by the DEA is empowered to administer controlled substances in accordance with its schedules and regulations. *See id.* § 829 (setting forth registration requirements for manufacture and distribution of controlled substances). Moreover, DEA regulations implementing Subchapter I of the CSA permit the dispensing, prescribing, and administering of non-Schedule I controlled substances "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *See* 21 C.F.R. § 1306.04.

50. Neither the CSA nor the DEA regulate medical practitioners (or others providing wraparound services, counseling, or volunteer support) who are not dispensing, prescribing, or distributing controlled substances.

51. Section 856 does not dictate the appropriate means of preventing and treating opioid overdoses.

52. Safehouse's health care professionals and other volunteers will not distribute, dispense, prescribe, or administer controlled substances as part of its medically supervised consumption service. Safehouse will not administer any illicit drugs. Safehouse's health care professionals will supervise consumption with the singular goal of assessing and reversing overdoses using Naloxone and other opioid reversal agents (which are not prohibited or regulated by the CSA), with respiratory support, and by providing other lifesaving care.

53. In addition, Safehouse will provide comprehensive overdose prevention services including medical care, provision of sterile consumption equipment, education, counseling, and wraparound services such as housing, access to public benefits, and legal services. None of those activities are addressed by the CSA.

54. The CSA does not prohibit medical practitioners from supervising and remaining proximate to individuals at risk of overdose and death with the goal of providing immediate lifesaving care.

55. Section 856 accordingly does not prohibit Safehouse from providing urgent medical treatment through its proposed overdose prevention services, including medically supervised consumption.

B. ***Federal Law Endorses and Funds Syringe Exchange Programs.***

56. Recent changes in federal law demonstrate official federal approval of certain harm reduction strategies to address the opioid crisis.

57. In 2011, amid growing evidence of the positive effect of syringe exchange programs in treating drug abuse, the U.S. Surgeon General issued a determination "that a demonstration needle exchange program . . . would be effective in reducing drug abuse and the risk of infection."[29]

58. In pertinent part, the U.S. Surgeon General recognized that syringe exchange programs promote entry into treatment and can reduce a drug user's injections. The determination relied upon a 2000 study, which concluded that:

> [N]ot only were new [syringe services program] participants five times more likely to enter drug treatment than non-[syringe exchange program] participants, former [syringe exchange program] participants were more likely to report significant reduction in injection, to stop injecting altogether, and to remain in drug treatment.[30]

59. In 2012, the CDC implemented summary guidance to prevent HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for drug users. This guidance recommended the implementation of integrated prevention services that would enable drug users to receive comprehensive care at the time they participate in clean syringe exchange.[31] The CDC

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[29] *Determination That a Demonstration Needle Exchange Program Would be Effective in Reducing Drug Abuse and the Risk of Acquired Immune Deficiency Syndrome Infection Among Intravenous Drug Users,* 76 Fed. Reg. 10038 (Feb. 23, 2011).

[30] *Id.* (citing Holly Hagan et al., *Reduced injection frequency and increased entry and retention in drug treatment associated with needle-exchange participation in Seattle drug injectors*, 19 J. of Substance Abuse Treatment 247–252 (2000)).

[31] *See* CDC, *Morbidity And Mortality Weekly Report: Integrated Prevention Services For Hiv Infection, Viral Hepatitis, Sexually Transmitted Diseases, And Tuberculosis For Persons Who Use Drugs Illicitly: Summary*

guidance provided that "a comprehensive service program" may include "[p]rovision of sterile needles, syringes and other drug preparation equipment (purchased with non-federal funds) and disposal services" and "[p]rovision of Naloxone to reverse opioid overdoses."[32]

60. Federal law now permits federal funding of most elements of local- and state-sponsored syringe exchange programs, notwithstanding the criminalization of interstate distribution of drug paraphernalia in 21 U.S.C. § 863. In 2016, Congress drastically relaxed a nearly thirty-year ban on the use of federal funds for state and local programs that furnish "sterile needles or syringes for the hypodermic injection of any illegal drug." *See* Appropriations Act of 2016, § 520, 129 Stat. 2652. That same year, HHS adopted the CDC's 2012 Guidance to support the implementation of new federal funding for syringe exchange programs.[33]

61. Safehouse will provide comprehensive overdose protection services that are entirely consistent with the CDC and HHS guidelines, and will provide sterile syringes, other sterile consumption equipment, syringe disposal services, Naloxone, primary care, and wraparound services. Although Safehouse is not a local or state entity seeking federal funding, it is indisputable that its comprehensive syringe exchange and Naloxone services are entirely legal under, and indeed, encouraged by federal law.

62. Yet, under the DOJ's rationale, a syringe exchange program is transformed from a legal, federally endorsed public health measure into a 20-year felony simply by allowing participants to remain within the same facility and under the supervision of its medical practitioners at the critical moment of consumption when death is most likely to occur. That is the

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Guidance From Cdc And The U.S. Department Of Health And Human Services (2012), Https://Www.Cdc.Gov/Mmwr/Preview/Mmwrhtml/Rr6105a1.Htm (last visited Apr. 3, 2019).

[32] CDC, *Program Guidance for Implementing Certain Components of Syringe Services Programs* (2016), https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf.

[33] *See* HHS, *Implementation Guidance to Support Certain Components of Syringe Services Programs* (Mar. 29, 2016), https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs.

very moment when proximity to urgent medical care may mean the difference between life and death.

63. It cannot be that compassionate and conscientious medical providers may establish a clinic, well-stocked with emergency overdose reversal medication, staff the clinic with trained medical practitioners, and provide individuals with sterile consumption equipment (all plainly permitted by federal law) only to confront a stark choice: cast those individuals away from lifesaving medical care or else suffer serious criminal liability. That is not a reasonable interpretation of federal law.

64. The DOJ's interpretation of Section 856 cannot be reconciled with the medical facts recognized by Congress, the CDC, and federal health policy—syringe exchange programs and overdose prevention services save lives, decrease disease transmission, and reduce the harms of this opioid crisis.

65. Safehouse's modest extension of already-endorsed harm reduction measures will close a short, but critical gap in care at the time of drug consumption.

66. Medical supervision for those at risk of overdose advances federal policy and does not violate federal law.

C. *The Federal Government and Pennsylvania State Law Encourage Access to Naloxone to Combat the Opioid Crisis.*

67. Safehouse's overdose prevention model is entirely consistent with federal and state laws and policies that have expanded access to Naloxone and other opioid reversal agents.

68. Opioid receptor antagonists, like Naloxone, are highly effective—if given in time and in sufficient quantity, they will reverse an otherwise fatal overdose with medical certainty.

69. Naloxone can only work if someone is close by to administer it. A person experiencing an overdose loses consciousness and therefore cannot self-administer Naloxone.

Once a person loses respiratory function, which can occur within minutes of consumption, time is of the essence in providing respiratory support and Naloxone. The more time that elapses, the greater the risk of serious injury and death.

70. Naloxone is designed to be easily administered as an intra-nasal spray. It has been widely dispensed, with the help of federal, state, and local funding. At times, however, a single dose of Naloxone is not sufficient to reverse an overdose. Multiple doses or intramuscular injections of Naloxone are sometimes required. Oxygen and respiratory support may also be beneficial, and can serve as an alternative first-line treatment. Outside of a medically supervised environment, even when help does arrive for an overdose victim, first responders, family members, and Good Samaritans sometimes lack sufficient doses of Naloxone or lack training in other respiratory support required to resuscitate that person.

71. Congress recognized the importance of Naloxone access when it enacted the Comprehensive Addiction and Recovery Act. *See* CARA § 101, 130 Stat. 697. CARA established a coordinated, public health-focused strategy to address the opioid crisis, including increased funding for education and awareness campaigns and improved access to overdose treatment.

72. CARA also amended the CSA to expand prescribing privileges for MAT, like buprenorphine and suboxone, to nurses and physicians assistants. *See id.* § 303(a)(l)(C)(v)-(iv), 130 Stat. 720-723.

73. CARA includes several measures that expand and encourage access to opioid reversal agents such as Naloxone. Title I, Section 107 of CARA empowers HHS to award grants to eligible entities providing overdose reversal treatment, including Naloxone. *See id.* § 107, 130 Stat. 703 (42 U.S.C. § 290dd-3). Section 703 of CARA requires evaluation of state Good Samaritan laws that provide civil and criminal immunity to individuals who administer Naloxone

to an individual experiencing an overdose. *See id.* § 703, 130 Stat. 741. CARA also directs that "[t]he Secretary shall maximize the availability of opioid receptor antagonists, including [N]aloxone, to veterans." *See id.* § 911, 130 Stat. 759 (38 U.S.C. § 1701).

74. Pennsylvania state law similarly recognizes the importance of Naloxone access. In light of the growing opioid crisis, in 2010, the Pennsylvania General Assembly amended its state drug law (the Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780–101 *et seq.*) by enacting the Drug Overdose Response Immunity statute ("the Good Samaritan Statute"). That statute provides immunity from prosecution for persons who call authorities to seek medical care for a suspected overdose victim. *See id.* § 780–113.7. The Good Samaritan Statute also provides criminal, civil, and professional immunity to anyone who, in good faith, administers Naloxone to an individual experiencing an overdose.[34] Former Governor of Pennsylvania, Tom Corbett, stated the Good Samaritan statute "will save lives and ensure those who help someone in need aren't punished for doing so."[35]

75. On April 18, 2018, the Pennsylvania Physician General issued Standing Order DOH-002-2018, providing a statewide prescription for eligible persons to obtain Naloxone. The purpose of the Order is to "ensure that residents of the Commonwealth of Pennsylvania who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose

[34] To date, forty States and the District of Columbia have enacted some form of a Good Samaritan statute or law that provides criminal immunity when an individual experiencing an opioid-related overdose or witnesses an opioid-related overdose calls 911, administers Naloxone, or seeks medical assistance. *See* Nat'l Conf. of State Legis., *Drug Overdose Immunity and Good Samaritan Laws* (June 5, 2017), http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx.

[35] *See* David Wenner, *Pa. Painkiller-Heroin Crisis: Corbett Signs Bill Intended To Save Lives*, PennLive (Sept. 30, 2014), https://www.pennlive.com/midstate/2014/09/corbett_heroin_good_samaritan.html.

. . . , are able to obtain Naloxone."[36] The Pennsylvania Physician General has continued to renew this Standing Order, consistent with Pennsylvania Governor Tom Wolf's Proclamation and as the opioid crisis continues in Pennsylvania.

76. Safehouse's medically supervised consumption spaces will be staffed at all times by medically trained practitioners supplied with sufficient doses of Naloxone and able to provide other forms of respiratory support. This model permits proximity and access to Naloxone during and immediately after the time of use—which is the moment when Naloxone is most needed.

77. The Safehouse model is entirely consistent with CARA, federal policy, and Pennsylvania state law, all of which include strong measures to increase Naloxone access.

III. SECTION 856 DOES NOT PROHIBIT SAFEHOUSE'S PROPOSED OVERDOSE PREVENTION MODEL

78. Despite the federal endorsement of a public health-focused strategy to combat the opioid crisis, the DOJ seeks to prohibit Safehouse's overdose prevention services model under 21 U.S.C. § 856. The history, purpose, and text of Section 856 confirm that it has no application to Safehouse's proposed medical and public health response to the opioid crisis.

A. *Section 856 Was Enacted to Target Crack Houses and Rave Parties, Not Legitimate Medical Interventions to Prevent Drug Overdoses.*

79. The DOJ's proposed application of Section 856 to Safehouse's overdose prevention services model would be an unprecedented expansion of that discrete statutory provision.

80. Congress enacted Section 856 to target drug dealers and party promoters who established locations for manufacture, distribution, and use of illicit drugs to facilitate their for-profit enterprises.

[36] Pa. Dep't of Health, Standing Order DOH-002-2016: Naloxone Prescription for Overdose Protection, https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Documents/SN%20-%20Naloxone%20Prescription%20for%20Overdose%20Prevention%20(Standing%20Order%20DOH-002-2016).pdf.

81. The federal government has never sought to use Section 856 to prosecute or enjoin any public health measure or legitimate medical activity remotely analogous to Safehouse's proposed overdose prevention model.

82. In 1986, Congress enacted Section 856 as part of the Anti-Drug Abuse Act of 1986 ("1986 Act"), Pub. L. No. 99-570, 100 Stat. 3207. The 1986 Act established a comprehensive scheme that not only expanded federal drug enforcement and interdiction measures, but also sought "to provide strong Federal leadership in establishing effective drug abuse prevention and education programs," and "to expand Federal support for drug abuse treatment and rehabilitation effort[t]s." 132 Cong. Rec. S26473 (daily ed. Sept. 26, 1986).

83. The passage of Section 856 was intended to authorize federal prosecution of "crack houses" and similar premises. The Senate Report stated that Congress's purpose in enacting Section 856 was to "[o]utlaw[] operation of houses or buildings, so-called 'crack houses', where 'crack' cocaine and other drugs are manufactured and used." *See* 132 Cong. Rec. at S26474. In legislative debate on the 1986 Act, sponsoring Senator Lawton Chiles noted that this provision would address law enforcement's difficulties in arresting "crack house" operators: "When police raid these crack houses, the dealers and users can easily dispose of the drugs, thus avoiding arrest. This bill makes it a felony to operate such a house, to be present at the house." *See* 132 Cong. Rec. at S26447 (statement of Sen. Chiles).

84. Likewise, in 2003, Congress amended Section 856 to add subsection (a)(2), "after holding a series of hearings regarding the dangers of Ecstasy [*i.e.*, MDMA, a synthetic drug with combined stimulant and hallucinogenic effects] and the rampant drug promotion associated with some raves." 149 Cong. Rec. S10606 (daily ed. July 31, 2003) (statement of Sen. Biden); Illicit Drug Anti-Proliferation Act of 2003 ("2003 Amendment"), Pub. L. No. 108-21, 117 Stat. 691.

("Rave," in this context, refers to commercial dance parties, popular in the 1990s, featuring electronic "club" music and often involving widespread drug use, in particular MDMA.) Senator Biden, who sponsored the 2003 Amendment, noted that the new provision clarified that Section 856 prohibited not only the operation of premises with ongoing drug distribution activities, but also "'single-event' activities, including an event where the promoter has as his primary purpose the sale of Ecstasy or other illegal drugs." *Id.* Thus, Senator Biden stated that it was appropriate under the amendment "to prosecute rogue rave promoters who profit off of putting kids at risk," by "knowingly and intentionally hold[ing] an event for the purpose of drug use, distribution or manufacturing." *See id.*

85. Plainly, Safehouse's lifesaving medical and public health mission is far from the concerns that led Congress to originally enact Section 856 or the 2003 amendment. Nothing in Section 856's legislative history suggests Congress ever contemplated that Section 856 would be used to prosecute medical professionals, public health workers, and volunteers who seek to prevent opioid overdoses, reduce disease transmission, encourage drug treatment, and provide urgent lifesaving care, as Safehouse now proposes to do.

B. *Section 856 Does Not Apply Where Conduct Is "Authorized by this Subchapter," Which Permits Legitimate Medical Practice.*

86. Section 856 expressly exempts conduct "authorized by [Subchapter I]" from its criminal and civil penalties. Section 856 does not regulate the practice of medicine nor does it dictate the appropriate means of preventing and treating opioid overdoses. Neither the CSA nor the DEA regulate medical practitioners (or others providing wraparound services, counseling, or volunteer support) who are not dispensing, prescribing, or distributing controlled substances.

87. In any event, DEA regulations implementing Subchapter I of the CSA expressly permit the dispensing, prescribing, and administering of non-Schedule I controlled substances "for

a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *See* 21 C.F.R. § 1306.04.

88. Safehouse's overdose prevention services are a legitimate medical and public health measure that have been recognized and endorsed by prominent national and international medical and public health associations including American Medical Association, the American Public Health Association, AIDS United, the European Monitoring Center for Drugs and Drug Addiction, the Infectious Diseases Society of America, the HIV Medical Association, the International Drug Policy Consortium, and innumerable public health experts, physicians, and addiction researchers.

89. Safehouse's overdose prevention model is also a measure that has been endorsed and encouraged by Philadelphia's Public Health Commissioner and its Commissioner of the Department of Behavioral Health and Intellectual disAbility Services, who have announced that overdose prevention, including supervised consumption, is a critical medical and public health intervention.

90. Safehouse's overdose prevention services are legitimate medical services that fall under Section 856's express exemption.

C. *Section 856 Does Not Apply to Safehouse Because It Will Not Operate "For The Purpose Of" Illegal Drug Use.*

91. The CSA, 21 U.S.C. § 856(a) states:

> Except as authorized by this subchapter, it shall be unlawful to—
>
> (1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, ***for the purpose of*** manufacturing, distributing, or using any controlled substance;
>
> (2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent,

> lease, profit from, or make available for use, with or without compensation, the place ***for the purpose of*** unlawfully manufacturing, storing, distributing, or using a controlled substance.

Id. (emphasis added).

92. Safehouse's singular purpose is to provide lifesaving medical treatment, primary care, and wraparound services to a vulnerable population at high risk of overdose death and complications from opioid use disorder.

93. Safehouse will not provide these services "for the purpose" of unlawful drug use within the meaning of Section 856—they are for the purpose of providing immediate, proximate access to lifesaving medical care to those at high risk of overdose death.

94. Safehouse's legitimate and urgent medical and public health mission and purpose removes its proposed activities from Section 856's scope.

D. *The CSA Does Not Define "Unlawful . . . Use" of Controlled Substances.*

95. Section 856(a)(2) prohibits management or control of a place for the purpose of "***unlawfully*** manufacturing, storing, distributing, or ***using a controlled substance***." 21 U.S.C. § 856(a)(2) (emphases added). Although the CSA elsewhere expressly defines and prohibits the unauthorized manufacture, storage, or distribution of controlled substances (*see generally id.* §§ 802 (definitions), 841(a) (prohibition of manufacture, possession and distribution)), nowhere does it define or proscribe "unlawful[] . . . us[e]." It is unclear from either Section 856 or the CSA as a whole what "unlawful[] . . . us[e]" means.

96. Safehouse will not manufacture, store, or distribute any controlled substances. The only possible portion of Section 856(a)(2) that could apply is the prohibition against providing a place for "unlawful[] . . . us[e]"—an undefined term that does not plainly encompass Safehouse's

medically supervised consumption services model, which allows drug use in its facility only for the purpose of enabling access to a critical medical intervention.

E. *The Rule of Lenity Forecloses the DOJ's Expansive Interpretation of Section 856.*

97. The DOJ's unprecedented interpretation of Section 856 cannot be reconciled with several canons of construction, including the rule of lenity and the clear statement canon.

98. If the Court is left with "any doubt about the meaning of" Section 856 it should invoke the rule that "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity"—*i.e.*, in favor of a criminal defendant. *Yates v. United States*, 135 S. Ct. 1074, 1088 (2015) (citation omitted); *see United States v. Flemming*, 617 F.3d 252 (3d Cir. 2010).

99. The rule of lenity favors adopting Safehouse's interpretation of a criminal statute where both interpretations of the government and the defendant are "plausible." *Flemming*, 617 F.3d at 270. Similarly, when a "choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite." *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221–22 (1952); *Yates*, 135 S. Ct. at 1089.

100. The phrases "except as authorized by," "for the purpose of," and "unlawful[]. . . us[e]" in Section 856 are ill-defined and cast substantial doubt on the statute's application to Safehouse's proposed overdose prevention services.

101. That doubt is only magnified when Section 856 is examined in the context of the CSA as a whole. Because a court's "duty . . . is 'to construe statutes, not isolated provisions,'" the Supreme Court instructs that "when deciding whether the language is plain, we must read the words 'in their context and with a view to their place in the overall statutory scheme.'" *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (citations omitted). The Supreme Court thus observed that

"oftentimes the 'meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.'" *Id.* (citation omitted).

102. Here, the words of Section 856 must be read in the context of the CSA as a whole, its purpose, and its history, which evince no intent to criminalize Safehouse's medical and public health intervention to prevent overdose deaths, much less do so unambiguously.

103. Section 856 must also be interpreted in harmony with other federal statutes, including CARA and the Appropriations Act of 2016, which endorse and provide federal funding to a continuum of overdose prevention and harm reduction services. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("A court must . . . interpret [a] statute 'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole.' Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." (citations omitted)).

104. The DOJ's incongruous interpretation of Section 856 would criminalize the provision of medical care in the short gap between otherwise legal and federally endorsed syringe exchange services and overdose reversal administration. That result would be entirely inconsistent with the federal scheme established by the CSA, CARA, and HHS and CDC federal guidance and policy.

105. The rule of lenity therefore strongly counsels in favor of Safehouse's proposed interpretation of Section 856.

IV. APPLICATION OF SECTION 856 TO REGULATE LOCAL, NON-COMMERCIAL CONDUCT WOULD EXCEED THE AUTHORITY GRANTED BY THE COMMERCE CLAUSE AND UNCONSTITUTIONALLY UPSET THE BALANCE BETWEEN FEDERAL AND STATE AUTHORITY.

106. The DOJ's proposed interpretation of Section 856, as applied to Safehouse, exceeds the bounds of Congress's constitutional authority to regulate interstate commerce.

107. Congress lacks a general police power. *See United States v. Morrison*, 529 U.S. 598, 618–19 (2000); *Jones v. United States*, 529 U.S. 848, 850 (2000). Such power is granted only to the States. While "[t]he States have broad authority to enact legislation for the public good" through their "police power," the "Federal Government, by contrast, has no such authority." *Bond v. United States*, 572 U.S. 844, 854 (2014).

108. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *Bond*, 572 U.S. at 853–54.

109. In light of those limits on federal authority, the Supreme Court found that the CSA "manifests no intent to regulate the practice of medicine generally," and observed, "[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.'" *Oregon*, 546 U.S. at 269–70 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996)).

110. Through this action, however, the DOJ interprets Section 856 in a way that would create a general police power for Congress.

111. Safehouse's proposed conduct has no substantial effect on interstate commerce. It is not activity that is economic in nature.

112. Safehouse is a non-profit corporation. Its operation will charge no fees, and will produce no revenue. Safehouse's facility will be entirely local and will not be engaged in facilitating commerce of any kind. Safehouse will not charge participants for its harm reduction and overdose prevention services; will not manufacture, sell, or administer unlawful drugs; will not permit the distribution or sale of drugs on site; will not provide any of its services across state lines; will not permit the exchange of any currency; will not allow participants to share consumption equipment or help another person consume drugs; and will not allow staff to handle illegal drugs or help participants consume drugs. No link therefore exists between Safehouse's proposed conduct and interstate commerce.

113. The operation of Safehouse's overdose prevention services will have no adverse impact on the legitimate CSA goal of suppressing the interstate market for illegal drugs. In fact, studies show that medically supervised consumption sites actually reduce drug use.

114. Section 856 lacks a jurisdictional element to ensure that the reach of the law has an explicit connection with or effect on interstate commerce.

115. Congress has never found that any conduct remotely similar to Safehouse's proposed model affects interstate commerce. In particular, while Congress found in 21 U.S.C. § 801(2) that "illegal importation, manufacture, distribution, and possession *and improper use* of controlled substances have a substantial and detrimental effect on *the health and general welfare* of the American people," its finding in Section 801(3) with respect to the effect on interstate commerce of local drug activities extends only to "manufacture, local distribution, and possession," *not* "use." *See id*. § 801(3) (emphases added). Similarly, the findings in Sections 801(4), (5) and (6) concerning the interstate impact of local drug activities conspicuously omit

"use" from the listed activities. The application of Section 856 to entirely local and noncommercial "use" is therefore of doubtful constitutionality.

116. States and localities, under our constitutional regime, are laboratories of experimentation that may develop new and innovative solutions to pressing issues of public health and policy. Safehouse attempts to employ such a solution to a pressing local health crisis.

117. Local officials, including the Philadelphia's Mayor, Public Health Commissioner, Director of the Department of Behavioral Health, and District Attorney, support Safehouse's efforts to mitigate the opioid crisis.

118. Similar overdose prevention efforts have proven to be effective in other countries and by clinically sound data.

119. Serious federalism concerns are raised by the DOJ's extension of federal law to interfere with traditionally local activities and to exercise powers traditionally reserved to the State, such as the regulation of volunteer medical treatment.

120. This Court should avoid an interpretation of Section 856 that implicates these serious constitutional concerns. "[S]o long as the statute is found to be susceptible of more than one construction"—one of which "raises a serious doubt as to its constitutionality"—the constitutional avoidance canon applies. *Guerrero-Sanchez v. Warden York Cty. Prison*, 905 F.3d 208, 223 (3d Cir. 2018) (citation and internal quotation marks omitted). But the DOJ seeks to disrupt the traditional balance of federal and state authority over public health initiatives, without any clear indication that Congress intended to thwart the traditional rights of States and localities.

121. To preserve these principles of federalism, "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 (citation and internal quotation marks

omitted). No such certainty exists with respect to Section 856, however, because the CSA "manifests no intent to regulate the practice of medicine generally." *Oregon*, 546 U.S. at 270.

122. Because the government's proposed interpretation of Section 856 would significantly disrupt the traditional balance of state and federal authority in the realm of public health, this Court should reject the government's unprecedented interpretation of Section 856. *See Jones*, 529 U.S. at 858 (explaining that, where Congress enacts criminal law that touches on areas traditionally falling within the authority of the States, courts will assume—"unless Congress conveys its purpose clearly"—that Congress "will not be deemed to have significantly changed the federal-state balance in the prosecution of crimes." (citation and internal quotation marks omitted)).

123. This Court could avoid these constitutional concerns about federalism and the scope of Congress's power to regulate commerce by rejecting the DOJ's interpretation of Section 856 and declaring that Section 856 does not prohibit Safehouse's provision of urgent, lifesaving medical treatment.

V. SAFEHOUSE'S LIFESAVING MISSION IS AN EXERCISE OF ITS FOUNDERS' AND DIRECTORS' RELIGIOUS BELIEFS

124. Safehouse's board members are adherents of religions in the Judeo-Christian tradition. For example:

i. Frank A. James III is a Christian and President of Missio Seminary (formerly known as Biblical Theological Seminary).

ii. Chip Mitchell is an adherent of and Lead Evangelist at the Greater Philadelphia Church of Christ.

iii. Board President José Benitez was raised and educated as a Roman Catholic; his entire professional life, including as Director of Prevention Point, has been an exercise in living out that faith and those teachings.

iv. Board Vice President Ronda Goldfein was raised with strong Jewish values and still worships in the small South Jersey synagogue cofounded by her grandfather; her entire professional life, including as Executive Director of the AIDS Law Project of Pennsylvania, has been an exercise in living out that faith and those teachings.

125. The board members' religious beliefs have been ingrained in them by their religious schooling, their devout families, and their practices of worship.

126. At the core of all board members' faith is the principle that the preservation of human life is paramount and overrides any other considerations.

127. This principle is rooted in scripture, and appears throughout the Old and New Testaments. For example:

i. According to the Shulchan Aruch, the Code of Jewish Law, "the Torah has granted the physician permission to heal, and it is a religious duty which comes under the rule of saving an endangered life. If he withholds treatment, he is regarded as one who sheds blood." Shulchan Aruch, Yoreh De'ah 336:1.

ii. The Book of Leviticus contains the clear commandment: "You shall not go up and down as a talebearer among your people; neither shall you stand idly by the blood of your neighbor: I am the Lord." Leviticus 19:16.

iii. In Deuteronomy, Moses conveys God's commandment: "You shall open wide your hand to your brother, to the needy and to the poor, in your land." Deuteronomy 15:11.

iv. The Talmud teaches: "It was for this reason that man was first created as one person [Adam], to teach you that anyone who destroys a life is considered by Scripture to have destroyed an entire world; and anyone who saves a life is as if he saved an entire world." Mishnah Sanhedrin 4:5

v. In the Gospel of John, Jesus refused to condemn to death a woman who had sinned, and cautioned fellow believers, "[l]et any one of you who is without sin be the first to cast a stone." John 8:7-11.

vi. The Gospel of John also counsels Christians: "The way we came to know love was that [Jesus] laid down his life for us; so we ought to lay down our lives for our brothers. If someone who has worldly means sees a brother in need and refuses him compassion, how can the love of God remain in him? Children, let us love not in word or speech but in deed and truth." 1 John 3:16-18.

vii. Matthew 25:34-40 directs believers to take in and care for the sick: "Then the king will say to those on his right, 'Come, you who are blessed by my Father. Inherit the kingdom prepared for you from the foundation of the world. For I was . . . ill and you cared for me. . . . Amen, I say to you, whatever you did for one of the least brothers of mine, you did for me.'"

viii. And in his Epistle to the Galatians, Paul the Apostle instructs Christians to "[b]ear one another's burdens, and so fulfill the law of Christ." Galatians 6:2.

128. The board members' religious beliefs obligate them to take action to save lives in the current overdose crisis, and thus to establish and run Safehouse in accordance with these tenets. Specifically, the board members believe that the provision of overdose prevention services

effectuates their religious obligation to preserve life, provide shelter to our neighbors, and to do everything possible to care for the sick.

129. The DOJ's threats and the initiation of a lawsuit against Safehouse burdens Safehouse by forcing it to choose between the exercise of its founders' and directors' religious beliefs and conformity with the DOJ's interpretation of Section 856.

130. The DOJ's interest in enforcement of Section 856 against Safehouse furthers no legitimate, much less a compelling interest, and the DOJ will be unable to meet its burden under RFRA to prove that it does.

131. To the contrary, enforcement of Section 856 against Safehouse will result in preventable deaths.

132. The government will also not be able to meet its burden of proving that preventing Safehouse from opening is the least restrictive means of fostering any compelling interest it may invoke.

133. Declaring Safehouse to be illegal will not reduce the manufacture, distribution, or possession of illegal drugs. Rather, when Safehouse does open, the demand for illegal drugs will decrease because some of its beneficiaries will seek and be provided with drug treatment.

CAUSES OF ACTION

COUNT I
Declaratory Judgment Regarding the Application of Section 856 to Safehouse

134. Safehouse repeats and re-alleges Paragraphs 1 through 133 as if fully set forth herein.

135. The CSA provides, in pertinent part:

> Except as authorized by this subchapter, it shall be unlawful to—

> (1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, ***for the purpose of*** manufacturing, distributing, or ***using*** any controlled substance;
>
> (2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place ***for the purpose of unlawfully*** manufacturing, storing, distributing, or ***using*** a controlled substance.

21 U.S.C. § 856(a) (emphases added).

136. Safehouse will not make its premises available "for the purpose of unlawfully . . . using a controlled substance."

137. Safehouse will operate only for the purpose of providing lifesaving medical treatment and critical wraparound services to a vulnerable population at risk of overdose death and complications from substance use disorder.

138. Safehouse will furnish legitimate and urgent medical services, which are not prohibited under 21 U.S.C. § 856.

139. Accordingly, pursuant to 28 U.S.C. § 2201, Safehouse is entitled to a declaration that it will not violate 21 U.S.C. § 856(a) by operating in accordance with its overdose prevention services model.

140. Safehouse is also entitled to a permanent injunction preventing the U.S. Attorney General from enforcing 21 U.S.C. § 856 against Safehouse.

COUNT II
Violation of the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*

141. Safehouse repeats and re-alleges Paragraphs 1 through 140 as if fully set forth herein.

142. Allowing individuals at risk of an overdose to remain under medical supervision and in close proximity to urgent medical care is an exercise of the religious belief of Safehouse

and its board members that the preservation of human life is paramount and overrides other considerations. In the exercise of their religion, Safehouse and its principals intend to open and operate Safehouse as described above in this Counterclaim, as they are called to do.

143. The DOJ's interpretation of 21 U.S.C. § 856, and in particular its present effort to enforce that interpretation, substantially burdens Safehouse's exercise of its religious commitments.

144. The DOJ's threat to prosecute Safehouse substantially burdens Safehouse's exercise of its religion.

145. The DOJ's ongoing litigation against Safehouse substantially burdens Safehouse's exercise of its religion.

146. Counterclaim Defendant and Third-Party Defendants will not be able to carry its burden of proof to show that their attempts to prevent Safehouse's religious exercise are in furtherance of a compelling governmental interest.

147. Counterclaim Defendant and Third-Party Defendants will not be able to carry their burden of proof to show that these attempts are the least restrictive means of furthering any compelling governmental interest.

148. The DOJ's actions violate Safehouse's right to free religious exercise guaranteed by RFRA, 42 U.S.C. § 2000bb *et seq*.

149. Without injunctive and declaratory relief against the government, Safehouse has been and will continue to be harmed.

PRAYER FOR RELIEF

Safehouse respectfully requests that this Court enter judgment in its favor and grant the following relief:

i. A declaration that Safehouse's establishment and proposed operation of its overdose prevention services model will not violate 21 U.S.C. § 856;

ii. A declaration that a prohibition or penalizing of Safehouse's establishment and proposed operation of its overdose prevention services model will violate 42 U.S.C. § 2000bb;

iii. A declaration that 21 U.S.C. § 856, as applied to Safehouse, violates the Commerce Clause of Article I of the U.S. Constitution;

iv. An injunction permanently enjoining the Third-Party Defendants from enforcing or threatening to enforce 21 U.S.C. § 856 against Safehouse;

v. An order awarding such additional relief as the Court may deem appropriate and just under the circumstances.

Dated: April 3, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2019, the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system.

Notice will be sent to all CM/ECF registrants in this action via the CM/ECF system. Pursuant to Federal Rule of Civil Procedure 4(i), a copy of the foregoing was also sent via USPS certified mail to:

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