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

SAFEHOUSE, a Pennsylvania nonprofit corporation, *Counterclaim Plaintiff,* v. UNITED STATES OF AMERICA, *Counterclaim Defendant*, U.S. DEPARTMENT OF JUSTICE; TODD BLACHE, in his official capacity as Acting Attorney General of the United States; DAVID METCALF, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania, *Third-Party Counterclaim Defendants*.	Civil Action No.: 2:19-cv-00519

SAFEHOUSE'S THIRD AMENDED COUNTERCLAIMS FOR DECLARATORY AND INJUNCTIVE RELIEF

Pursuant to Federal Rule of Civil Procedure 13, Counterclaim Plaintiff Safehouse asserts the following counterclaims against Counterclaim Defendant United States of America, and Third-Party Counterclaim Defendants U.S. Department of Justice; Todd Blanche, in his official capacity as Acting Attorney General of the United States; and David Metcalf, in his official capacity as United States 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.*, and the First Amendment to the U.S. Constitution 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 threatened enforcement of Section 856 to Safehouse, notwithstanding the multitude of federal exemptions from the Controlled Substances Act for similar, non-religiously motivated conduct, burdens Safehouse's religious exercise in a manner that is not generally applicable, thereby subjecting its position with respect to Safehouse to strict scrutiny under the Free Exercise Clause of the First Amendment. The DOJ cannot meet that rigorous standard here because it 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 have commenced the instant declaratory action resulting in this counterclaim.

8. Safehouse, as well as its leaders and personnel, are threatened with federal civil and criminal enforcement unless Safehouse refrains from engaging in entirely lawful conduct in pursuit of its lifesaving mission, which is protected by RFRA and the First Amendment to the U.S. Constitution, regardless of whether Safehouse's conduct is prohibited by Section 856.

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—including a declaration that enforcement against Safehouse would violate RFRA and the First Amendment—would definitively resolve that controversy for the parties. Although this long-running litigation has effectively prevented Safehouse from becoming operational, Safehouse remains committed to opening and operating a supervised consumption facility as soon as feasible once the legal barriers are removed, including when Safehouse prevails on either (or both) of its RFRA or First Amendment claims.

THE PARTIES

11. Counterclaimant 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 Counterclaim Defendant is the U.S. Department of Justice.

14. Third-Party Counterclaim Defendant Todd Blanche is sued in his official capacity as Acting Attorney General of the United States.

15. Third-Party Counterclaim Defendant David Metcalf is sued in his official capacity as the U.S. 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 and Overdose 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 2018-2019, more than 2,300 individuals died as a result of an opioid overdose in Philadelphia.[1] In 2020, fatal overdoses claimed the lives of 1,214 Philadelphians. 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.[2]

[1] *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/.

[2] 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.

20. Since 2011, most opioid-related deaths in Philadelphia have been caused by heroin. In the last several years, Philadelphia has experienced a dramatic increase in the number of deaths related to fentanyl.[3]

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 people who use drugs mistakenly believing 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-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 nine minutes elapsed before EMS arrived at the scene.[4]

25. In 2017, Philadelphia's EMS personnel administered Naloxone to more than 5,400 overdose victims.[5] This number has continued to increase in 2018 and 2019. Over 60,000 doses of Naloxone have been distributed by the City of Philadelphia in 2019.

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[3] *See id*.

[4] 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 Sept. 17, 2021).

[5] *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.,

26. Frequently, neither emergency rooms nor emergency responders are equipped to offer treatment or provide the wraparound services needed to overcome opioid addiction.[6]

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 Task Force recommended the implementation of overdose prevention services and expansion of treatment access and capacity.[7]

28. In the years since the Task Force issued these recommendations—and during the pendency of this years-long litigation—thousands of people have died from opioid and other drug overdoses in Philadelphia. And this crisis is not limited to Philadelphia: According to the Centers for Disease Control and Prevention (CDC), more than one million people have died from drug overdoses since 1999, with opioids involved in over 70% of these deaths in recent years. In 2023, more than 105,000 Americans died from overdoses. While opioid overdose death rates have decreased somewhat in recent years, the opioid and overdose crisis persists in Philadelphia.

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

Formation of Safehouse and Safehouse's Overdose Prevention Model

30. 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.

Combating the Opioid Epidemic, https://www.phila.gov/programs/combating-the-opioid-epidemic/reports-and-data/opioid-misuse-and-overdose-data/ (last visited Sept. 17, 2021).

[6] 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 Sept. 17, 2021).

[7] *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*").

31. Article IV of Safehouse's Articles of Incorporation states that Safehouse is "organized and operated exclusively for charitable purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, … specifically for the purposes of reducing the harms associated with drug use by providing a range of public health and social services."

32. As used in this context, the term "charitable" is a broad umbrella term that encompasses other tax-exempt purposes, including the "advancement of religion." Indeed, the corresponding governing and authoritative Treasury regulation provides that "charitable is … not to be construed as limited by the separate enumeration in section 501(c)(3) of other tax-exempt purposes which may fall within the broad outlines of charity as developed by judicial decisions," including the "advancement of religion." 26 C.F.R. § 1.501(c)(3)–1(d)(2). As the IRS explains: (i) "an exempt organization may qualify for exemption under more than one purpose and/or activity," and (ii) "[c]haritable purposes and/or activities will, oftentimes, be combined with religious" purposes. See IRS Publication 5781, TG 3-3: Exempt Purposes - Charitable IRS Section 501(c)(3), Section I.A(5) at page 5 (Feb. 1, 2024), Publication 5781 (Rev. 2-2024).

33. The Treasury Regulations corresponding to Code Section 501(c)(3) explain that the term "charitable" is used in Code Section 501(c)(3) in its generally accepted legal sense and therefore must not be construed as limited to the enumerated purposes set forth under Code Section 501(c)(3); accordingly, the term "charitable" is defined broadly in the Code and the corresponding Treasury Regulations to include not only relief of the poor and distressed or of the underprivileged, but also to describe organizations that, for example, support the advancement of religion and promote social welfare to defend human and civil rights secured by law. A "charitable purpose[]" therefore is entirely consistent with the exercise of religious beliefs.

34. Similarly, under Pennsylvania state tax exemption law, "charitable purposes" include: "The relief of poverty, the advancement and provision of education, including post-secondary education, the advancement of religion, the prevention and treatment of disease or injury, including mental retardation and mental disorders, governmental or municipal purposes, and any other purpose the accomplishment of which is recognized as important and beneficial to the public." 10 Pa. Stat. § 375(b).

35. "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."[8] 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.[9] 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.[10]

36. "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

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[8] CDC, *Commonly Used Terms: Opioid Overdose*, https://www.cdc.gov/drugoverdose/opioids/terms.html (last visited Sept. 17, 2021).

[9] 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.

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

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.[11]

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

38. 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.

39. 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.

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

41. Safehouse's comprehensive services will encourage entry into drug treatment, reduce the burden on emergency services and first responders, prevent the transmission of

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

infectious diseases, and create a safer community by reducing public consumption of illicit drugs and discarded needles and other consumption equipment.

42. 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.

43. Clinical and public health research confirms that medically supervised consumption sites save lives and prevent overdose deaths.

44. Studies estimate that an overdose prevention site like Safehouse could reduce overdose deaths annually by 30% in the site's immediate vicinity.[12]

45. As another example, in November 2023, the Journal of the American Medical Association (JAMA) published a study on the OPCs, titled "Overdose Prevention Centers, Crime, and Disorder in New York." *See* Chalfin A, del Pozo B, Mitre-Becerril D. Overdose Prevention Centers, Crime, and Disorder in New York City. *JAMA Netw Open.* 2023;6(11). The objective of the study was to assess whether the OPCs were "associated with changes in crime and disorder." The comprehensive study concluded that "[n]o significant changes were detected in violent crimes or property crimes recorded by police, 911 calls for crime or medical incidents, or 311 calls regarding drug use or unsanitary conditions observed in the vicinity of the OPCs." Based on that finding, the authors concluded that their "observations suggest the expansion of OPCs can be managed without negative crime or disorder outcomes." They further concluded that the "findings also suggest that a cooperative relationship between police and OPCs can enhance their

[12] 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*").

effectiveness as a lifesaving intervention while minimizing behaviors that would erode public support for such initiatives."

46. A 2022 JAMA study of the first two months of operation found that 75% of clients would have used drugs in public spaces (e.g., parks or bathrooms) without the sites, suggesting a reduction in public drug use. Harocopos A, Gibson BE, Saha N, et al., *First 2 months of operation at first publicly recognized overdose prevention centers in US*, JAMA Netw Open. 2022;5(7). The study found that the early data suggested "that supervised consumption in these settings was associated with decreased overdose risk" and "that OPCs were associated with decreased prevalence of public drug use."

47. This is consistent with a decade of public-health research on the impact of overdose prevention centers. For instance, in 2022, researchers published a comprehensive scoping assessment of the last decade of research on the subject. *See* Sarah J. Dow-Fleisner, Arielle Lomness, Lucía Woolgar, *Impact of safe consumption facilities on individual and community outcomes: A scoping review of the past decade of research*, Emerging Trends in Drugs, Addictions, and Health, Volume 2 (2022). The publication closely examined two dozen research publications on the topic, which employed "a variety of research methods and analytic approaches, including cross-sectional methods, ethnographic fieldwork, and longitudinal observational analysis." "Among articles examining individual outcomes, 9 focused on injection-related infection and disease transmission, 7 on drug use and treatment access behaviors, 6 on non-fatal overdose, 8 on death, and 6 on other outcomes (e.g. general wellbeing, condom use). Among articles with community-outcomes, 7 focused on drug use in public spaces or public intoxication, 7 on public disposal of syringes and other drug paraphernalia, and 3 on criminal activity. Finally, the three cost-benefit analyses focused on cost savings related to a reduction in disease transmission, loss

of life, and cost of other services." Based on this review of the scientific literature, the authors "found at the individual-level that [OPCs] efficacious in reducing drug use related infection and disease transmission, enhancing access to addiction and other health services, and reducing the risk of non-fatal overdoses, and were not associated with a significant increase in drug use." They also found that, "[a]t the community level, the evidence shows that [OPCs] were not associated with an increased rate of drug-related crime and were linked to a decreased use of other costly public services (e.g. ambulance transport to hospital following an overdose)." They further "found that [OPCs] were associated with a reduction in public disorder, including less public disposal of syringes and use in public spaces." And they found that "there appear to be significant cost-benefits associated with [OPCs]."

48. As these studies confirm, OPCs reduce discarded syringes in public spaces, police interactions and costs to the criminal justice system, public disorder and public drug use, the spread of HIV and Hepatitis C, overdose death, and costs to the healthcare system, while increasing access to medical care, detox, and treatment.

49. Other research shows that overdose prevention centers lower overdose rates and healthcare costs. In short, 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. A collection of available research into OPCs is available at https://opcinfo.org/research.

Threat of Prosecution

50. 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.

51. 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."[13]

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

53. 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, e.g.*, 21 U.S.C. § 856(b) and (d).

54. The threats of criminal and civil enforcement against Safehouse by the DOJ have persisted throughout the pendency of this litigation and persist to this date.

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

55. 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 its report supporting and explaining the CSA, the House Committee on Interstate and Foreign Commerce identified "increased efforts in drug abuse prevention and rehabilitation of users" as one of the Act's three important objectives. *See* H.R.

[13] *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.

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.

56. 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.

57. 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. *See*, *infra*, ¶¶ 56-77.

58. 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.

59. 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.*

60. 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.").

61. 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* 21 U.S.C. § 822 (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.

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

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

64. 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.

65. 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 is addressed by the CSA.

66. 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.

67. 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.*

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

69. 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."[14]

70. 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

[14] *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).

> 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.[15]

71. 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.[16] The CDC 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."[17]

72. 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.[18]

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[15] *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)).

[16] *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 From CDC and the U.S. Department of Health and Human Services* (2012), https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.utm (last visited Sept. 17, 2021).

[17] 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.

[18] *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.

73. 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.

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

75. 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 any federal law.

76. 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.

77. 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.

78. 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.*

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.

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

85. 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).

86. 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 Pa. Stat. § 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.[19] 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."[20]

87. 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 . . . , are able to obtain Naloxone."[21] 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. The Standing Order was most recently updated on March 29, 2021. Governor Wolf signed the 14th renewal of the Opioid Disaster Declaration on May 7, 2021.

88. 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.

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[19] 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.

[20] *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.

[21] 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%20 Prescription%20for%20Overdose%20Prevention%20(Standing%20Order%20DOH-002-2016).pdf.

89. 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

90. 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.*

91. 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.

92. 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.

93. 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—including entities in other states that began providing overdose prevention services similar to those provided by Safehouse during the pendency of this litigation. Indeed, in 2023, the DOJ announced to news organizations that it was implementing a policy of selectively enforcing Section 856(a) against providers of supervised consumption services on a "district-by-district" basis. Sharon Otterman, *Federal Officials May Shut Down Overdose Prevention Centers in Manhattan*, N.Y. TIMES (Aug. 8, 2023), https://www.nytimes.com/2023/08/08/nyregion/drug-overdoses-supervised-consumption-nyc.html. That policy remains in place.

94. 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).

95. 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).

96. 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.) Then-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.*

97. 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.*

98. 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.

99. 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.

100. 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.

101. Safehouse's overdose prevention model has been endorsed and encouraged by Philadelphia's previous and current acting Public Health Commissioner and its current and previous Commissioner of the Department of Behavioral Health and Intellectual disAbility Services. Both Commissioners believe overdose prevention, including supervised consumption, is a critical medical and public-health intervention.

102. 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.*

103. 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).

104. 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.

105. 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.

106. 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.*

107. 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.

108. 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.*

109. 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.

110. 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*, 574 U.S. 528, 547–48 (2015) (citation omitted); *see United States v. Flemming*, 617 F.3d 252 (3d Cir. 2010).

111. 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*, 574 U.S. at 548.

112. 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.

113. 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*, 576 U.S. 473, 474 (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).

114. 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.

115. 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)).

116. 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.

117. 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

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

119. 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. *See* U.S. Const., amend. X. 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).

120. "[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.

121. 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)).

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

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

124. 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 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.

125. 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.

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

127. 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" of controlled substances is therefore of doubtful constitutionality.

128. 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.

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

130. Similar overdose prevention efforts have proven to be effective in the United States and in other countries and by clinically sound data.

131. 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 States, such as the regulation of volunteer medical treatment.

132. 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.

133. 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.

134. 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)).

135. 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 OWN AND ITS FOUNDERS' AND DIRECTORS' RELIGIOUS BELIEFS

136. Since its formation in 2018, Safehouse's mission statement, published prominently on its website, has announced: "The leaders and organizers of Safehouse are motivated by the Judeo-Christian beliefs ingrained in us from our religious schooling, our devout families and our practices of worship. At the core of our faith is the principle that preservation of human life overrides any other considerations."

137. The Board believes, based on their deeply held religious convictions, that they have a duty to do everything possible to keep people who use drugs alive, even for one more day, and

their beliefs include a call to give shelter to the vulnerable and to treat them with dignity and humanity.

138. The Board seeks to exercise these shared religious beliefs by opening an overdose prevention center in the Philadelphia area as soon as feasible.

139. The Board has been acting through Safehouse with this religious purpose and motivation since its formation in 2018, as evidenced by the mission statement that Safehouse published on its website before the DOJ filed this lawsuit.

140. Safehouse's board members are adherents of religions in the Judeo-Christian tradition.

141. Jose Benitez is the President of Safehouse's Board. Board President Jose Benitez was raised and educated as a Roman Catholic; his entire professional life has been an exercise in living out that faith and those teachings. He is committed to opening an overdose prevention center, either through Safehouse or in his individual capacity, once the legal barriers to doing so are removed. Opening an overdose prevention center is an exercise of his sincerely held religious beliefs, including the belief that he personally has a duty to do everything possible to keep people who use drugs alive, even for one more day, and his beliefs include a call to give shelter to the vulnerable and to treat them with dignity and humanity. Mr. Benitez spent much of his professional career as the CEO of Prevention Point Philadelphia (PPP), a public health organization serving communities affected by drug use, utilizing a harm reduction model and providing an array of services including medical care, respite care, shelter services, syringe exchange, medically assisted drug treatment, HIV and Hepatitis C testing and case management, and overdose prevention education. Mr. Benitez has an extensive history of working with underserved populations in Philadelphia, including people who actively use drugs and those in recovery.

142. Like Mr. Benitez, the board members' religious beliefs have been ingrained in them by their religious schooling and their practices of worship.

143. At the core of Mr. Benitez's and all board members' faith is the principle that the preservation of human life is paramount and overrides any other considerations. Although Safehouse is not itself a religious entity or organization, its founders' and leaders' beliefs are those of the corporation, and the pursuit of its mission and conduct of its business will implement those beliefs. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014).

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

i. 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

ii. 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.

iii. Matthew 25:34-40 directs believers to take in and care for the sick: "Then the king [*i.e.*, Jesus Christ] 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.'"

iv. 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.

v. 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.

vi. 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.

vii. 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.

viii. 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.

ix. Mark 12:28:31, Jesus Christ responds as follows to the question of which "commandment is the most important of all?": "The most important is, 'Hear, O Israel: The Lord our God, the Lord is one. And you shall love the Lord your God with all your heart and with all your soul and with all your mind and with all your strength.' The second is this: 'You shall love your neighbor as yourself.' There is no other commandment greater than these."

145. The principle that the preservation of human life is paramount and overrides any other considerations is not only consistent with these scriptures, but also arises from the sincerely held religious belief that human life has inherent value because God created all living things.

146. 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.

147. 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.

148. In particular, because of the DOJ's threatened prosecution of Safehouse, Safehouse and its board members have been unable to offer the lifesaving overdose prevention services that it seeks to provide. Its board members, including Safehouse Board President José Benitez, have been threatened with criminal prosecution if they allow those suffering from addiction to remain under their care and supervision and within their shelter at the time of consumption of opioids, when those individuals are at greatest risk of overdose death. Instead, contrary to their sincere religious beliefs, Safehouse and its board members have been compelled to cast these vulnerable individuals outside of their facilities and have been unable to fulfill their deeply held religious obligation to do everything possible to provide them with critical lifesaving care.

149. Since 2017, this burden has been particularly heavy because Safehouse and its Board Members have been compelled not to provide overdose prevention services while over 10,000 members of its Philadelphia community have died of fatal overdoses and tens of thousands

of others continue to suffer in the grips of opioid addiction and substance use disorder. The people lost to fatal overdose include those that Safehouse Board Members personally have cared for in their work treating those suffering from addiction and those that were beloved members of Board Members' congregations. Safehouse Board Members grieve for every life that was lost to overdose. They believe, based on their deeply held religious convictions, that they should have done everything possible to have kept those individuals alive, even for one more day.

150. During this litigation, the DOJ has called into question whether Safehouse's overdose prevention service model constitutes the sincere exercise of religion under both RFRA and the First Amendment.

151. The Board has thus formally adopted a written statement to reiterate and articulate Safehouse's religious purpose and guiding principles and to amend and restate Safehouse's Bylaws accordingly.

152. On January 7, 2026, the Board formally approved and adopted the following as the "official mission statement of Safehouse":

> Safehouse is a privately funded, 501(c)(3) tax-exempt Pennsylvania nonprofit corporation whose mission is to save lives by providing a range of overdose prevention services.
>
> The leaders and organizers of Safehouse are motivated by the Judeo-Christian beliefs ingrained in us from our religious schooling, our devout families, and our practices of worship. At the core of our faith is the principle that preservation of human life overrides any other considerations.

153. On the same day, the Board amended and restated its Bylaws. Section 1.6 of those Bylaws provides:

> **1.6 Purposes.** _The purposes of the Organization are as provided in the Articles of Incorporation. The Organization acts for charitable and religious purposes, as reflected in the mission statement that has been adopted by the Board, which provides, "the leaders and organizers of Safehouse are motivated by the Judeo-Christian beliefs ingrained in us from our religious schooling, our

> devout families, and our practices of worship. At the core of our faith is the principle that preservation of human life overrides any other consideration."

154. The religious motivations of the Board and Safehouse are reflected in Safehouse's Mission Statement and Section 1.6 of Safehouse's Bylaws.

155. Pennsylvania law confers on a nonprofit corporation's board the authority to govern and act on its behalf, providing that "the business and affairs of every nonprofit corporation shall be managed by or under the direction of, a board of directors." 15 Pa. Cons. Stat. § 5721. The Board thus has the authority to operate for the purpose of religious exercise under Pennsylvania law—regardless of whether Board members are treated like "owners" or "shareholders."

156. Safehouse exists and acts through its Board, which has stated unequivocally since Safehouse's founding, before this litigation began, that Safehouse and its Board "are motivated by the Judeo-Christian beliefs ⋯ [a]t the core [of which] is the principle that preservation of human life overrides any other considerations."

157. As the Pennsylvania Supreme Court has explained, "the interplay between a nonprofit corporation's corporate purpose and that corporation's authority to take corporate action must be construed *in the least restrictive way possible*, limiting the amount of court interference and second guessing, which is reflective of both modern for-profit and not-for-profit corporations, and the modern corporate business laws that govern them." *Zampogna v. L. Enf't Health Benefits, Inc.*, 151 A.3d 1003, 1013 (Pa. 2016).

158. And RFRA does not require the founders of a corporation to "forfeit all RFRA (and Free-Exercise) rights" whenever they "choose to incorporate their businesses—without in any way changing the size or nature of their businesses"—because that would require corporate owners to "either give up the right to seek judicial protection of their religious liberty or forgo the benefits,

available to their competitors, of operating as corporations." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 706 (2014).

IV. THE GOVERNMENT LACKS A COMPELLING INTEREST IN DENYING SAFEHOUSE A RELIGIOUS EXEMPTION FROM ENFORCEMENT OF SECTION 856

159. "A law burdening religious practice that is . . . not of general application must undergo the most rigorous of scrutiny." *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 546 (1993). The DOJ's decision to seek to apply Section 856 to Safehouse does not implement a law of general application.

160. As the Supreme Court recently reiterated, "[a] law is not generally applicable if it 'invite[s]' the government to consider the particular reasons for a person's conduct by providing 'a mechanism for individualized exemptions.'" *Fulton v. City of Phila.*, 141 S.Ct. 1868, 1877 (2021) (quoting *Employment Div., Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872, 884 (1990)). "A law also lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way." *Fulton*, 141 S. Ct. at 1877.

161. Thus, where the government creates exemptions from a law for those engaged in *non-religious* activity, as here, it "may not refuse to extend that system to cases of 'religious hardship' without compelling reason." *Id.* at 1878 (quoting *Smith*, 494 U.S. at 884).

162. "The Government's mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day." *Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 546 U. S. 418, 432 (2006) (observing that "Congress' determination that DMT should be listed under Schedule I simply does not provide a categorical answer that relieves the Government of the obligation to shoulder its burden under RFRA"). And, as in *O Centro*, which involved religious use of *hoasca*, "there is no indication that

Congress," in enacting Section 856, "considered the harms posed by the particular use at issue here" (*id.* at 432-33)—*i.e.*, a religiously motivated non-profit's establishment of a medically supervised consumption site in which people can consume opioids in immediate proximity to medical professionals who can provide life-saving assistance in the event of an overdose.

163. The CSA contains discretionary and highly individualized exemptions from enforcement of the CSA, including (a) for "persons engaged in research," 21 U.S.C. § 872(e); (b) in the Attorney General's discretion to "waive the requirement for registration of certain manufacturers, distributors, or dispensers *if he finds it consistent with the public health and safety.*" 21 U.S.C. § 822(d); (c) for religious use of peyote by Native Americans, 21 C.F.R. § 1307.31; and (d) for possession offenses, for the Attorney General to decide in his discretion to "compromise, modify, or remit, with or without conditions, any civil penalty" imposed for simple possession, 21 U.S.C. § 844a.

164. The CSA itself provides that "[t]he Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. *Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General*." 21 U.S.C. § 872(e) (emphasis added). That exemption would be vitiated if Section 856 penalized such persons for maintaining a place to engage in authorized activities. Indeed, use of lawfully dispensed substances could not constitute "unlawful" use under Section 856.

165. The implementing regulations build on this "[e]xemption from prosecution for researchers." 21 C.F.R. § 1316.24 (catchline). In particular, they provide that, "[u]pon registration of an individual to engage in research in controlled substances under the Controlled Substances

Act (84 Stat. 1242; 21 U.S.C. 801), the Administrator of the Drug Enforcement Administration, on his own motion or upon request in writing from the Secretary or from the researcher or researching practitioner, *may exempt the registrant when acting within the scope of his registration, from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption.*" 21 C.F.R. § 1316.24 (emphasis added).

166. Moreover, the CSA permits the Attorney General to "waive the requirement for registration of certain manufacturers, distributors, or dispensers *if he finds it consistent with the public health and safety.*" 21 U. S. C. § 822(d); *see also* 21 C.F.R. § 1307.03 (permitting the DEA to "grant an exception" from "to the application of any provision of this chapter" to a qualified application). As the Supreme Court observed in *O Centro*, "The fact that the Act itself contemplates that exempting certain people from its requirements would be 'consistent with the public health and safety' indicates that congressional findings with respect to Schedule I substances should not carry the determinative weight, for RFRA purposes, that the Government would ascribe to them." *Id.*

167. In fact, the CSA itself contains a provision exempting certain drug use for religious purposes from prosecution. Since 1970, "there has been a regulatory exemption for use of peyote—a Schedule I substance—by the Native American Church." *Id.* The CSA's implementing regulations provide that "[t]he listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American

Church, however, is required to obtain registration annually and to comply with all other requirements of law." 21 C.F.R. § 1307.31.

168. The government also has discretion under the CSA to prosecute (or refrain from prosecution of) both the conduct of Safehouse and the types of drug-related offenses that would occur on Safehouse's property—that is, simple possession of controlled substances for personal, use under the supervision of medical professionals. (Possession is the only potentially relevant offense because drug "use" is not regulated by the CSA or any federal law whatsoever.) The range of punishment available for simple possession offenses under the CSA ranges from a maximum of one year of imprisonment to no penalty at all.

169. The government has, in the past, exercised authority to decline to prosecute activities that technically violate the CSA, but do not "undermine federal enforcement priorities." *E.g.*, W. Ogden, Deputy Att'y Gen., *Memorandum for Selected United States Attorneys: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana* (Oct. 19, 2009).[22]

170. Section 844 provides that simple possession (absent any prior convictions) is punishable by a "term of imprisonment of not more than 1 year." 21 U.S.C. § 844. The CSA provides for *alternative civil* penalties for such offenses, moreover, permitting the government to impose a civil penalty of up to $10,000 instead of prosecuting criminally. 21 U.S.C. § 844a. The CSA then permits the Attorney General to "compromise, modify, or remit, with or without conditions, any civil penalty" imposed for simple possession.

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[22] James M. Cole, Deputy Att'y Gen., *Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use* (June 29, 2011); James M. Cole, Deputy Att'y Gen., *Memorandum for United States Attorneys:* Guidance Regarding Marijuana Enforcement (Aug. 29, 2013); James M. Cole, Deputy Att'y Gen., *Memorandum for United States Attorneys: Guidance Regarding Marijuana Related Financial Crimes* (Feb. 14, 2014); Monty Wilkinson, Director of the Executive Office for United States Att'ys, *Policy Statement Regarding Marijuana Issues in Indian Country* (Oct. 28, 2014).

171. In fact, the government in general does not prosecute under Section 856 for maintaining, controlling, or making available a place where controlled substances are simply possessed or used but not stored, distributed, or manufactured, despite the statute's reference to "using"; instead, it exempts these offenses from prosecution as a matter of course and on an individualized basis. Indeed, in the 33 years since Section 856 was first enacted, the government has cited no examples of a criminal prosecution under Section 856 involving only simple possession or use—much less prosecutions involving public health interventions similar to Safehouse occurring in other states. Indeed, in 2023, the DOJ announced to news organizations that it was implementing a policy of selectively enforcing Section 856(a) against providers of supervised consumption services on a "district-by-district" basis. Sharon Otterman, *Federal Officials May Shut Down Overdose Prevention Centers in Manhattan*, N.Y. TIMES (Aug. 8, 2023), https://www.nytimes.com/2023/08/08/nyregion/drug-overdoses-supervised-consumption-nyc.html. That policy remains in place.

172. "The question, then, is not whether the [government] has a compelling interest in enforcing its . . . policies generally, but whether it has such an interest in denying an exception" to Safehouse. *Fulton v. City of Phila.*, 141 S. Ct. at 1881.

173. The DOJ's interest in enforcement of Section 856 against Safehouse furthers no legitimate interest—much less a compelling interest—and the DOJ will be unable to meet its burden to prove that it does. To the contrary, enforcement of Section 856 against Safehouse will and has resulted in preventable deaths.

174. The DOJ cannot establish a compelling interest in denying an exemption by relying on "broadly formulated interests" that are defined "at a high level of generality" *Id.* (citing *O Centro*, 546 U. S. at 430–432). "[T]he First Amendment demands a more precise analysis"—*i.e.*,

one that "scrutinizes the asserted harm of granting specific exemptions to particular religious claimants." *Id.* (quoting *O Centro*, 546 U.S. at 431). Put differently, "RFRA requires the Government to demonstrate that the compelling interest test is satisfied *through application of the challenged law 'to the person'*—the particular claimant whose sincere exercise of religion is being substantially burdened." *O Centro*, 546 U.S. at 431-32.

175. As the Court in *O Centro* further stated, RFRA "plainly contemplates that courts would recognize exceptions" to the CSA on religious grounds—"that is how the law works." *Id.* (rejecting the government's "bold argument that there can be no RFRA exceptions at all to the Controlled Substances Act").

176. The DOJ 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.

177. 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 participants will seek and be provided with drug treatment.

<u>CAUSES OF ACTION</u>

<u>COUNT I</u>

Declaratory Judgment Regarding the Application of Section 856 to Safehouse[23]

178. Safehouse repeats and re-alleges Paragraphs 1 through 177 as if fully set forth herein.

179. The CSA provides, in pertinent part:

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

[23] Safehouse is not seeking to relitigate this Counterclaim before this Court. Rather, Safehouse has retained it in this amended pleading for the sake of completeness and for purposes of preserving the issue in this ongoing litigation.

> (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).

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

181. 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.

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

183. 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.

184. 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.*

185. Safehouse repeats and re-alleges Paragraphs 1 through 184 as if fully set forth herein.

186. 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.

187. 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.

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

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

190. Counterclaim 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.

191. Counterclaim 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.

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

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

COUNT III
Violation of the First Amendment to the U.S. Constitution

194. Safehouse repeats and re-alleges Paragraphs 1 through 193 as if fully set forth herein.

195. 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, that they should do everything possible to save and preserve life, and that they should provide shelter and care to the most vulnerable among us, including those suffering from addiction. 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.

196. 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. And the DOJ's ongoing litigation against Safehouse substantially burdens Safehouse's and Safehouse Board Member's exercise of religion.

197. "A law burdening religious practice that is . . . not of general application must undergo the most rigorous of scrutiny." *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 546 (1993).[24] The DOJ's decision to seek to apply Section 856 to Safehouse does not implement a law of general application.

198. Section 856 runs afoul of this general applicability requirement because the government grants exemptions from prosecution for certain individuals engaged in non-religious conduct that otherwise violates the CSA.

[24] This standard is derived from the Supreme Court's decision in *Employment Division, Department of Human Resources of Oregon v. Smith*, 494 U.S. 872, 884 (1990)). While this Court is bound by that decision, Safehouse reserves the right to assert in the appropriate forum that *Smith* was wrongly decided and should be overturned.

199. DOJ has never enforced the CSA in the manner DOJ currently threatens against Safehouse. The CSA confirms that the DOJ is given express statutory authority to allow exceptions for similar, secular activity in some instances, and DOJ has exercised that authority including by regulations providing an exemption for particular religious use of a Schedule I substance and by authorizing DEA to grant exemptions from the statute's prohibitions.

200. Where the government creates exemptions from a law for those engaged in *non-religious* activity, as here, it "it may not refuse to extend that system to cases of 'religious hardship' without compelling reason." *Fulton*, 141 S. Ct. at 1877 (quoting *Smith*, 494 U.S. at 884).

201. The DOJ 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.

202. The DOJ 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. They do not have a compelling reason for their actions, and they have not selected the means least restrictive of religious exercise in order to further their interests.

203. The DOJ's actions violate Safehouse's right to free religious exercise guaranteed by the First Amendment to the U.S. Constitution.

AMENDMENT TO AFFIRMATIVE DEFENSES IN SAFEHOUSE'S ANSWER

In amending its counterclaims, Safehouse also stands on its Answer to the DOJ's Amended Complaint. Safehouse asserts an additional Affirmative Defense that prosecution of Safehouse would violate Safehouse's rights under the First Amendment to the U.S. Constitution. Safehouse requests that its Answer be deemed constructively amended to incorporate this affirmative defense.

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 a prohibition or penalizing of Safehouse's establishment and proposed operation of its overdose prevention services model will violate the Free Exercise Clause of First Amendment to the U.S. Constitution;

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

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

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

Dated: April 13, 2026

Respectfully submitted,

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