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

UNITED STATES OF AMERICA, :

Plaintiff,

v. : Civil Action No. 19-0519

SAFEHOUSE, a Pennsylvania nonprofit corporation;

JOSE BENITEZ, as President and Treasurer of Safehouse,

Defendants.

SAFEHOUSE, a Pennsylvania nonprofit

corporation,

Counterclaim Plaintiff,

v.

UNITED STATES OF AMERICA,

Counterclaim Defendant,

and

U.S. DEPARTMENT OF JUSTICE; WILLIAM P. BARR, in his official capacity as Attorney General of the United States; and WILLIAM M. McSWAIN, in his official capacity as U.S. Attorney for the Eastern District of Pennsylvania,

Third-Party Defendants.

ANSWER AND AFFIRMATIVE DEFENSES OF PLAINTIFF/COUNTERCLAIM
DEFENDANT UNITED STATES OF AMERICA AND THIRD-PARTY DEFENDANTS
U.S. DEPARTMENT OF JUSTICE, UNITED STATES ATTORNEY GENERAL
WILLIAM P. BARR, AND UNITED STATES ATTORNEY FOR THE EASTERN
DISTRICT OF PENNSYLVANIA WILLIAM M. McSWAIN

Plaintiff/Counterclaim Defendant United States of America and Third-Party Defendants U.S. Department of Justice, United States Attorney General William P. Barr, and United States Attorney for the Eastern District of Pennsylvania William M. McSwain (collectively, the "United States"), by and through undersigned counsel, answer and assert affirmative defenses to the Counterclaims and Third-Party Complaint of Defendant/Counterclaim Plaintiff Safehouse ("Safehouse") as follows:

- 1. Admitted in part and denied in part. The United States admits that Safehouse purports to seek a declaratory judgment that 21 U.S.C. § 856 is inapplicable to its establishment and carrying out of its overdose prevention services model, but insofar as that model includes "medically supervised consumption and observation" ("Consumption Rooms"), it denies that Safehouse is entitled to such relief.
- 2. Admitted in part and denied in part. The United States admits that Safehouse purports to seek a declaratory judgment that any prohibition on its establishment and operation of Consumption Rooms would violate the Religious Freedom and Restoration Act, 42 U.S.C. § 2000bb *et seq.*, but denies that Safehouse is entitled to such relief. The remaining allegations contained in this paragraph constitute conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the allegations are denied.
- 3. This paragraph consists of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the allegations are admitted.

- 4. This paragraph consists of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the allegations are admitted.
- 5. This paragraph consists of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the United States admits that the controversy between the parties is "of sufficient immediacy and concreteness" to warrant adjudication, but denies that Safehouse is entitled to any relief.
- 6. This paragraph consists of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the United States admits that the controversy between the parties is "sufficiently real and imminent to warrant the issuance of a conclusive declaratory judgment," but denies that Safehouse is entitled to any relief.
- 7. Denied as stated. By way of further answer, the United States Attorney for the Eastern District of Pennsylvania sent a letter to Safehouse, dated November 9, 2018, advising that Safehouse's planned operation of one or more Consumption Rooms in Philadelphia would violate the Controlled Substances Act. In the same letter, the United States Attorney expressed support for those aspects of Safehouse's "overdose prevention services model" that comport with federal law. The content of that letter speaks for itself, and any attempt by Safehouse to characterize or interpret that content is denied.
- 8. Admitted in part and denied in part. The United States admits that Safehouse, its leaders, and personnel are subject to federal civil and criminal enforcement related to any violation of the Controlled Substances Act, but denies that Safehouse's planned operation of any Consumption Room would be lawful. To the extent a further response is required, the United

States lacks knowledge or information sufficient to form a response as to the remaining allegations, which are therefore denied.

- 9. This paragraph consists of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the allegations are admitted.
- 10. Admitted in part and denied in part. The United States admits that the issuance of a declaratory judgment in this matter would resolve the controversy between the parties, but denies that Safehouse is entitled to such relief. Safehouse's operation of a Consumption Room would violate 21 U.S.C. § 856(a).
 - 11. Admitted.
 - 12. Admitted.
 - 13. Admitted.
 - 14. Admitted.
 - 15. Admitted.
- 16. This is an incorporation paragraph to which no response is required. To the extent a response is required, the United States incorporates its previous responses as though set forth here in full.
- 17. Admitted in part and denied as stated in part. The United States admits that, like many other large American cities, Philadelphia is experiencing a crisis associated with opioid trafficking, misuse and overdoses, and that, in 2017, the Acting Secretary of the United States Department of Health and Human Services determined that a public health emergency exists nationwide. To the extent a further response is required, the allegations are denied.

- 18. Denied as stated. The allegations contained in this paragraph summarize the content of writings that speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.
- 19. Admitted in part and denied as stated in part. The United States admits that the Mayor of Philadelphia issued an Opioid Emergency Response Executive Order on October 3, 2018, the content of which speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 20. Denied as stated. The allegations contained in this paragraph summarize the content of the Executive Order issued by the Mayor of Philadelphia on October 3, 2018. The content of the order speaks for itself, and any attempt by Safehouse to characterize or interpret that content is denied.
- 21. Admitted in part and denied in part. The United States admits that fentanyl is a synthetic opioid found in many of the illegal opioids sold on Philadelphia streets, but lacks knowledge or information sufficient to form a response as to the remaining allegations, which are therefore denied. By way of further answer, the opioids illegally sold on Philadelphia streets are most commonly a combination of heroin and fentanyl.
- 22. Admitted in part and denied in part. The United States admits that fentanyl is a powerful narcotic, is approximately 50 times more potent than heroin, and greatly enhances the risk of overdose, but lacks knowledge or information sufficient to form a response as to the remaining allegations, which are therefore denied.
- 23. Admitted in part and denied in part. The United States admits that timely administration of Naloxone or similar opioid receptor antagonists can reverse the effects of an

opioid overdose, but denies that it can do so in all circumstances and specifically denies that it will "keep a person alive with medical certainty."

- 24. Admitted in part and denied in part. The United States admits that, in recent years, Philadelphia's Emergency Medical Services ("EMS") has fielded a large volume of calls to respond to opioid overdoses. The remaining allegations of this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied. The United States lacks knowledge or information sufficient to form a response as to any remaining allegations, which are therefore denied.
- 25. Admitted in part and denied in part. The United States admits that, in 2017, EMS personnel administered Naloxone to a large number of overdose victims. The remaining allegations of this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 26. Denied as stated. The allegations of this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 27. Admitted in part and denied in part. The United States admits that the Mayor of Philadelphia formed the Task Force to Combat the Opioid Epidemic in Philadelphia in response to the opioid crisis, and that the Task Force's final report made certain recommendations. The remaining allegations of this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 28. Denied as stated. By way of further answer, Safehouse's proposed Consumptions Rooms would violate the Controlled Substances Act.

- 29. Admitted in part and denied as stated in part. The United States admits that Safehouse is a private nonprofit corporation established in 2018, but lacks knowledge or information sufficient to form a response as to the remaining allegations, which are therefore denied.
- 30. Denied as stated. The allegations contained in this paragraph summarize the content of writings that speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.
- 31. Denied as stated. The allegations contained in this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied. By way of further answer, Safehouse's operation of a Consumption Room, one such proposed "harm reduction" strategy, would violate the Controlled Substances Act.
- 32. Admitted in part and denied in part. The United States admits that Safehouse purportedly would respond to the opioid crisis in Philadelphia by use of what it calls "a comprehensive harm reduction strategy," but lacks knowledge or information sufficient to form a response as to the remaining allegations, which are therefore denied. By way of further answer, Safehouse's "comprehensive harm reduction strategy" consists, in part, of operating Consumption Rooms, which would violate the Controlled Substances Act.
- 33. Admitted in part and denied in part. The United States admits that Safehouse purportedly would provide the "overdose prevention services" set forth in this paragraph, but denies that all of those services would be lawful. By way of further answer, Safehouse's "overdose prevention services" would consist, in part, of operating Consumption Rooms, which would violate the Controlled Substances Act.

- 34. Denied as stated. The United States lacks knowledge or information sufficient to form a response as to the allegations contained in this paragraph, which are therefore denied. By way of further answer, the United States specifically denies that "Safehouse can offer assurance, to a medical certainty, that people within its care will not die of a drug overdose." Safehouse's "overdose prevention services model" would consist, in part, of Consumption Rooms, which would violate the Controlled Substances Act.
- 35. Denied as stated. The United States lacks knowledge or information sufficient to form a response as to the allegations contained in this paragraph, which are therefore denied. By way of further answer, if Safehouse were to "provide illicit drugs for consumption" or "tolerate [the] sale of illicit drugs or drug sharing at its facility," such conduct would be unlawful under the Controlled Substances Act.
- 36. Denied as stated. By way of further answer, the allegations in this paragraph are speculative.
- 37. Denied as stated. By way of further answer, the allegations in this paragraph are speculative.
- 38. Denied as stated. The allegations contained in this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied. By way of further answer, the allegations specific to Safehouse's potential efficacy are speculative and therefore denied.
- 39. Admitted in part and denied in part. The United States admits that, on November 9, 2018, the United States Attorney for the Eastern District of Pennsylvania sent a letter to Safehouse, and that a copy of the letter is attached to Safehouse's Complaint. The content of that

letter speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.

- 40. Admitted in part and denied in part. The United States admits that *The New York Times* published an op-ed written by then United States Deputy Attorney General Rod Rosenstein on or about August 27, 2018. The content of that op-ed speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
 - 41. Admitted.
- 42. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure, and are therefore denied.
- 43. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure, and are therefore denied.
- 44. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure, and are therefore denied. Safehouse's planned Consumption Rooms violate the Controlled Substances Act. Similarly, 21 U.S.C. § 844(a) makes the "participant's" possession of those drugs unlawful.
- 45. Admitted in part and denied in part. The United States admits that the Consolidated Appropriations Act of 2016 includes language authorizing states and localities, in limited circumstances, to use federal funds to support certain aspects of programs providing clean equipment to intravenous drug users, and that the Comprehensive Addiction and Recovery Act (CARA) permitted the Department of Health and Human Services (HHS) to award grants to

certain entities in order to expand access to opioid reversal drugs, such as Naloxone, but denies the remaining allegations contained in this paragraph.

- 46. Denied as stated. Safehouse's plan to operate Consumption Rooms would violate the Controlled Substances Act. Similarly, 21 U.S.C. § 844(a) makes the "participant's" possession of those drugs unlawful. The United States specifically denies that "medical supervision and direct access to treatment can reverse an overdose with medical certainty and ensure[] that participants in Safehouse's care will stay alive."
- 47. Denied as stated. By way of further answer, Safehouse's "overdose prevention services" consist, in part, of operating Consumption Rooms, which would violate the Controlled Substances Act and federal policy.
- 48. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. By way of further answer, the United States states that the Controlled Substances Act creates a comprehensive statutory and regulatory regime regarding, *inter alia*, the manufacture, distribution, and possession of controlled substances. The United States denies that any part of Subchapter I of the Controlled Substances Act authorizes Consumption Rooms.
- 49. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. Any attempt by Safehouse to characterize the legal provisions in this paragraph is denied. By way of further answer, 21 C.F.R. § 1306.04 is accurately quoted as it applies to prescriptions.
 - 50. Denied.
- 51. Denied as stated. By way of further answer, 21 U.S.C. § 856, like other provisions in Part D of Subchapter I of the Controlled Substances Act, proscribes certain conduct

associated with controlled substances, including Safehouse's proposed Consumption Rooms. Similarly, 21 U.S.C. § 844(a) makes Safehouse's "participant's" possession of illegal drugs unlawful.

- 52. Denied as stated. As to the first two sentences of this paragraph, the United States lacks knowledge or information sufficient to form a response as to what Safehouse, its employees, or volunteers would do with respect to illegal narcotics inside its facility. The allegations contained in those sentences are therefore denied. As to the final sentence, the United States admits that Safehouse proposes to "supervise consumption" of illegal drug use within its facility, but denies that such conduct is legal or authorized under the Controlled Substances Act. Therefore, the remainder of the final sentence of paragraph 52 is denied.
- 53. Admitted in part and denied in part. The United States admits that Safehouse purportedly would provide services including medical care, provision of sterile consumption equipment, education, counseling, and "wraparound services" to its clients, but denies the remainder of the allegations of this paragraph. By way of further answer, Safehouse's operation of Consumption Rooms would violate the Controlled Substances Act.
- 54. Denied as stated. The allegations contained in this paragraph consist of conclusions of law to which no response is required under the Federal Rules of Civil Procedure. By way of further answer, Safehouse's operation of Consumption Rooms would violate the Controlled Substances Act.
 - 55. Denied.
- 56. Denied as stated. Notwithstanding any "changes in federal law" and approval of certain "strategies to address the opioid crisis," Safehouse's operation of Consumption Rooms would violate the Controlled Substances Act.

- 57. Admitted in part and denied in part. The United States admits that, in 2011, the United States Surgeon General issued a determination regarding needle exchange programs. The remainder of the allegations contained in this paragraph summarize the content of a writing, the content of which speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 58. Denied as stated. The allegations contained in this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 59. Admitted in part and denied in part. The United States admits that, in 2012, the Centers for Disease Control issued a report regarding prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis in illicit drug users. The remaining allegations of this paragraph summarize the content of a writing that speaks for itself. Any attempt by Safehouse to characterize or interpret that content is denied.
- 60. Denied as stated. This paragraph constitutes conclusions of law to which no response is required under the Federal Rules of Civil Procedure, and therefore are denied. By way of further answer, the allegations summarize the content of legal and policy provisions that speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied. By way of further answer, the 2016 Appropriations Act provides that no appropriated funds shall be used to purchase sterile syringes, but that federal funds may be used for other elements of a drug-treatment program if the CDC and local health authorities determine that a locality is experiencing a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and provided that such program is otherwise operating in accordance with law. See 114 P.L. No. 113 at § 520.

- 61. Admitted in part and denied in part. The United States admits that Safehouse purportedly would provide services including sterile syringe distribution, syringe disposal, distribution and administration of Naloxone, and primary care services, but lacks knowledge or information sufficient to form a response as to the remaining allegations contained in this paragraph, which are therefore denied. By way of further answer, Safehouse's "comprehensive overdose protection services" includes operation of Consumption Rooms, which would violate the Controlled Substances Act.
- 62. Denied as stated. By way of further answer, it is the determination of the United States Congress not "the DOJ's rationale" that would make Safehouse's operation of "consumption rooms" unlawful. Safehouse's Consumption Rooms would violate the Controlled Substances Act.
 - 63. Denied.
 - 64. Denied.
- 65. Denied. By way of further answer, Safehouse's proposed Consumption Rooms would not be a "modest extension" of existing law.
- 66. Denied as stated. The United States lacks knowledge or information sufficient to form a response as to the allegations contained in this paragraph, which are therefore denied. By way of further answer, Safehouse's proposed operation of Consumption Rooms would violate the Controlled Substances Act.
- 67. Denied as stated. By way of further answer, Safehouse's "overdose prevention model" includes operation of Consumption Rooms, which would violate the Controlled Substances Act. There are no Pennsylvania state laws authorizing such conduct; in fact,

Safehouse's proposed model has been denounced by Pennsylvania's Governor, General Assembly, and Attorney General.

- 68. Admitted in part and denied in part. The United States admits that timely administration of Naloxone or similar opioid receptor antagonists can reverse the effects of an opioid overdose, but denies that it can do so in all circumstances and specifically denies that it will "reverse an otherwise fatal overdose with medical certainty."
- 69. Admitted in part and denied as stated in part. The United States lacks knowledge or information sufficient to form a response as to whether "Naloxone can only work if someone is close by to administer it," which is therefore denied as stated. The remaining allegations contained in this paragraph are admitted.
- 70. Admitted in part and denied in part. The United States lacks knowledge or information sufficient to form a response as to whether "first responders, family members, and Good Samaritans sometimes lack sufficient doses of Naloxone or lack training in other respiratory support requires to resuscitate" a person suffering an opioid overdose, which is therefore denied. The remaining allegations contained in this paragraph are admitted.
- 71. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required under the Federal Rules of Civil Procedure and are therefore denied. The allegations cite legal provisions which speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.
- 72. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required under the Federal Rules of Civil Procedure and are therefore denied. The allegations cite legal provisions which speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.

- 73. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required under the Federal Rules of Civil Procedure and are therefore denied. The allegations cite legal provisions which speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.
- 74. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required under the Federal Rules of Civil Procedure and are therefore denied. The allegations cite legal provisions which speak for themselves. Any attempt by Safehouse to characterize or interpret that content is denied.
- 75. Admitted in part, denied in part. It is admitted that the Pennsylvania Secretary of Health issued Standing Order DOH-002-2018 on or about April 18, 2018, concerning Naloxone. The Standing Order speaks for itself and any characterization of it is denied.
- 76. Admitted in part, denied in part. It is admitted that Naloxone can help reverse the effects of an opioid overdose. The United States is without sufficient information to admit or deny the remaining allegations in this paragraph, and they are therefore denied.
 - 77. Denied.
- 78. Admitted in part, denied in part. It is admitted that the United States supports a multifaceted strategy to combat the opioid crisis. It is admitted that the United States brought this case seeking a declaration that Safehouse's proposed supervised injection site will violate 21 U.S.C. § 856. The remaining allegations in this paragraph are denied.
 - 79. Denied.
- 80. Denied as stated. It is admitted that § 856 applies to drug dealers and party promoters that establish locations for the purpose of unlawfully manufacturing, storing,

distributing, or using a controlled substance. It is denied that § 856 applies only to drug dealers and party promoters. The remaining allegations in this paragraph are denied.

- 81. Denied as stated. It is admitted only that this is the first case in which the United States has sought to use § 856 to block a supervised injection site. By way of further response, Safehouse is the first supervised injection site planned to open in the United States.
- 82. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the quoted legislative history speaks for itself and any characterization of it is denied.
- 83. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the quoted legislative history speaks for itself and any characterization of it is denied.
- 84. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the quoted legislative history speaks for itself and any characterization of it is denied.
- 85. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the referenced legislative history speaks for itself and any characterization of it is denied.

- 86. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 87. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, this paragraph accurately quotes 21 C.F.R. § 1306.04 as it relates to prescriptions.
- 88. Denied as stated. Public statements by the listed organizations regarding Safehouse speak for themselves and any characterization of them is denied. It is admitted that various organizations support Safehouse's proposed site and that other organizations oppose it. By way of example, the U.S. Surgeon General does not support Consumption Rooms. *See* "Surgeon General urges ER docs to advocate for evidence-based opioid treatment," Steven Ross Johnson, Modern Healthcare (May 23, 2018). The proposed Consumption Rooms would violate § 856 and therefore the United States denies the characterization of Safehouse's Consumption Room as "legitimate." The remaining allegations in this paragraph are denied.
- 89. Denied as stated. Public statements by the listed Philadelphia officials speak for themselves and any characterization of them is denied.
- 90. Denied as stated. By way of further answer, Safehouse's "overdose prevention services" include operating Consumption Rooms, which would violate the Controlled Substances Act. In addition, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

¹ Available at https://www.modernhealthcare.com/article/20180523/NEWS/180529976/surgeongeneral-urges-er-docs-to-advocate-for-evidence-based-opioid-treatment.

- 91. Admitted.
- 92. Denied as stated. By way of further response, Safehouse's operation of Consumption Rooms would violate the Controlled Substances Act.
- 93. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 94. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 95. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the United States states that § 856(a)(2) applies to Safehouse's proposed Consumption Rooms and denies that the phrase "unlawful ... use" is unclear or ambiguous.
- 96. Denied. The United States lacks knowledge or information sufficient to form a response as to the allegation that Safehouse will not manufacture, store, or distribute any controlled substances, and this allegation is therefore denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied. By way of further answer, the United States states that § 856(a)(2) applies to Safehouse's proposed Consumption Rooms and denies that the phrase "unlawful ... use" is unclear or ambiguous.

- 97. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 98. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 99. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 100. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 101. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 102. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 103. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

- 104. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 105. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
 - 106. Denied.
- 107. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 108. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 109. Denied. The allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
 - 110. Denied.
 - 111. Denied.
- 112. Denied. The United States is without knowledge to form a response as to the full totality of what Safehouse, its employees, or volunteers plan to do within its facility, and therefore those allegations are denied. By way of further answer, the proposed actions of Safehouse fall within interstate commerce. *See Gonzalez v. Raich*, 545 U.S. 1 (2005).
 - 113. Denied.

- 114. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 115. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 116. Denied as stated. While state and local government may be "laboratories of experimentation," there is no legislative action by either the Commonwealth of Pennsylvania or the City of Philadelphia authorizing supervised injection sites. Furthermore, Safehouse is not allowed to violate the Controlled Substances Act.
- 117. Denied as stated. While some local officials support Safehouse's proposed Consumption Rooms, numerous other public officials do not.
 - 118. Denied.
 - 119. Denied.
- 120. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 121. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 122. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.

- 123. Denied. By way of further answer, the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, and are therefore denied.
- 124. Denied. The United States is without knowledge sufficient to form a response as to whether the board members, founders, or employees of Safehouse are adherents of religions in the Judeo-Christian tradition. The allegations contained in those sentences are therefore denied.
- 125. Denied. The United States is without knowledge sufficient to form a response as to how the board members, founders, or employees of Safehouse became adherents of religions in the Judeo-Christian tradition. The allegations contained in those sentences are therefore denied.
- 126. Denied. The United States is without knowledge to form a response as to the allegations in this paragraph, and therefore denies them.
- 127. The allegations contained in this paragraph and sub-paragraphs are derived from the writings in the Old and New Testament and therefore speak for themselves. No additional response is necessary.
- 128. Denied. The United States is without knowledge sufficient to form a response as to whether or how the religious beliefs of Safehouse's board members, founders, or employees obligate them to take action, and therefore denies these allegations.
 - 129. Denied.
 - 130. Denied.
 - 131. Denied.
 - 132. Denied.
 - 133. Denied.

CAUSES OF ACTION

COUNT I

- 134. This is an incorporation paragraph to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the United States incorporates its previous responses as though set forth here in full.
- 135. Denied. The allegations contained in this paragraph refer to sections of the Controlled Substances Act, which speak for themselves. Any attempt by Safehouse to characterize that content is denied. To the extent the allegations contained in this paragraph constitute conclusions of law to which no response is required by the Federal Rules of Civil Procedure, they are denied.
 - 136. Denied.
 - 137. Denied.
- 138. Denied. The Controlled Substances Act prohibits Safehouse's proposed operation of Consumption Rooms.
 - 139. Denied.
 - 140. Denied.

COUNT II

- 141. This is an incorporation paragraph to which no response is required under the Federal Rules of Civil Procedure. To the extent a response is required, the United States incorporates its previous responses as though set forth here in full.
 - 142. Denied.
 - 143. Denied.
 - 144. Denied.

- 145. Denied.
- 146. Denied.
- 147. Denied.
- 148. Denied.
- 149. Denied.

PRAYER FOR RELIEF

The United States denies that Safehouse is entitled to any relief in connection with the allegations set forth in its counterclaims to the United States' complaint, nor Safehouse's Third-Party Complaint, including, but not limited to, the allegations set forth in Safehouse's Prayer for Relief.

AFFIRMATIVE DEFENSES

- 1. Pursuant to the United States' Motion under Federal Rule of Civil Procedure 12(c), Safehouse's counterclaim and third-party complaint are without legal merit and should be dismissed.
- 2. Not only is Safehouse's request for injunctive relief barring the United States from enforcing 21 U.S.C. § 856 invalid for the reasons set forth in the United States' Rule 12(c) motion, but this request is further impermissible because it seeks to enjoin proper prosecution under federal criminal law.

Dated: June 10, 2019

JOSEPH H. HUNT Assistant Attorney General

Civil Division

GUSTAV W. EYLER
Acting Director

Consumer Protection Branch

JAMES J. GILLIGAN Acting Director Federal Programs Branch

ANDREW E. CLARK Assistant Director Consumer Protection Branch

JACQUELINE COLEMAN SNEAD Assistant Director Federal Programs Branch

DANIEL K. CRANE-HIRSCH Trial Attorney Consumer Protection Branch

TAMRA T. MOORE Senior Counsel Federal Programs Branch

Co-Counsel for the United States

Respectfully submitted,

WILLIAM M. McSWAIN United States Attorney

/s/

GREGORY B. DAVID

Assistant United States Attorney

Chief, Civil Division

 $/_{\rm S}/$

JOHN T. CRUTCHLOW

ERIC D. GILL

BRYAN C. HUGHES

ERIN E. LINDGREN

Assistant United States Attorneys Eastern District of Pennsylvania 615 Chestnut Street, Suite 1250 Philadelphia, PA 19106-4476

TEL: (215) 861-8200 FAX: (215) 861-8618

Counsel for the United States

CERTIFICATE OF SERVICE

I hereby certify that, on this date, I caused a true and correct copy of the foregoing Answer and Affirmative Defenses, which was filed electronically and is available for viewing and download from the court's CM/ECF system, to be served upon all counsel of record.

Gregory B. David
Assistant United States Attorney

Assistant United States Attorney Chief, Civil Division

Dated: June 10, 2019