No. 20-1422

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA, *Appellant*,

v.

SAFEHOUSE, a Pennsylvania nonprofit corporation, and JOSÉ BENITEZ, as President and Treasurer of Safehouse, *Appellees*.

SAFEHOUSE, a Pennsylvania nonprofit corporation, *Appellee*,

v.

U.S. DEPARTMENT OF JUSTICE; MONTY WILKINSON, in his official capacity as Acting Attorney General of the United States; and JENNIFER ARBITTIER WILLIAMS, in her official capacity as Acting U.S. Attorney for the Eastern District of Pennsylvania, *Appellants*.

ON APPEAL FROM A JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT PENNSYLVANIA (No. 19-cv-519)

BRIEF OF THE DISTRICT OF COLUMBIA AND THE STATES OF DELAWARE, ILLINOIS, MICHIGAN, MINNESOTA, NEW MEXICO, OREGON, VERMONT, AND VIRGINIA AS AMICI CURIAE IN SUPPORT OF THE PETITION FOR REHEARING EN BANC

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GLOSSARY

SIS	Safe Injection Site
SEP	Syringe Exchange Programs

INTEREST OF AMICI CURIAE

The District of Columbia and the States of Delaware, Illinois, Michigan, Minnesota, New Mexico, Oregon, Vermont, and Virginia (collectively "the Amici States") file this brief as amici curiae in support of appellee Safehouse's petition for rehearing en banc under Rule 29(b)(2) of the Federal Rules of Appellate Procedure. The Amici States are battling a nationwide opioid crisis that claims over 100 lives every day. States are working to address this epidemic, develop interventions to prevent opioid use disorder, and treat those suffering from opioid dependence. But, as the data demonstrate, neither states nor the federal government have solved this crisis yet. The Amici States share a goal of preventing overdose deaths, but the means of achieving that important goal must vary based on the nature of the epidemic on a local level.

State-sanctioned safe injection sites ("SISs") are emerging as a promising measure to save lives and to fill a time-sensitive gap in medical care. Some states and localities are considering implementing SISs, relying on empirical evidence of their effectiveness. As laboratories of experimentation and the primary regulators of public health, states should be free to adopt cutting-edge medical interventions. The federal government's opposition to SISs and the prospect of criminal prosecution under the Controlled Substances Act, 21 U.S.C. § 856, however, threaten to interfere with states' power to implement SISs and other innovative

strategies. The Amici States have a strong interest in preserving their traditional authority over public health and safety, and in ensuring that the federal government does not undermine their crucial work in addressing the opioid crisis.

SUMMARY OF ARGUMENT

1. At least 128 Americans die every day from overdoses caused by opioids. The deaths are widespread, and each state feels the sting of losing its citizens to these highly addictive drugs. The crisis is not new. Opioid death rates have risen starkly since 1999, based initially on the proliferation of opioid prescriptions. But as the use of opioids has evolved, there has been a surge in overdose deaths due to heroin and synthetic opioids such as fentanyl. Death can occur within minutes of heroin or fentanyl use—too rapidly for emergency personnel to be called to the scene before lives are lost.

2. The Amici States are on the front lines of this crisis, battling each day to save their citizens from the deadly effects of opioids. And states on the forefront of public health crises have a track record of developing successful, novel interventions that become nationwide standards. For example, Good Samaritan laws that offer limited legal immunity to encourage bystanders to seek help for overdose victims originated in New Mexico in 2007; as of 2018, 44 additional states had enacted similar laws. Syringe exchange programs ("SEPs") were once limited to a single locale but are now viewed as a standard harm-reduction approach to prevent the

spread of disease. And many more interventions that are now commonplace were initially pioneered by states and localities.

But states' significant efforts have not yet ended this epidemic. As fentanyl and heroin use increases, states need the freedom to implement innovative treatment programs to save lives. After studying SIS interventions, many states and cities are considering them as a means of preventing harm. The studies predict that the sites will reduce both deaths and costs. And they are a unique solution to the common problem in many urban areas of rapid, unintended overdoses of heroin or fentanyl. The panel's interpretation of the Controlled Substances Act stands as an obstacle to this innovation and should be reconsidered by the Court en banc.

ARGUMENT

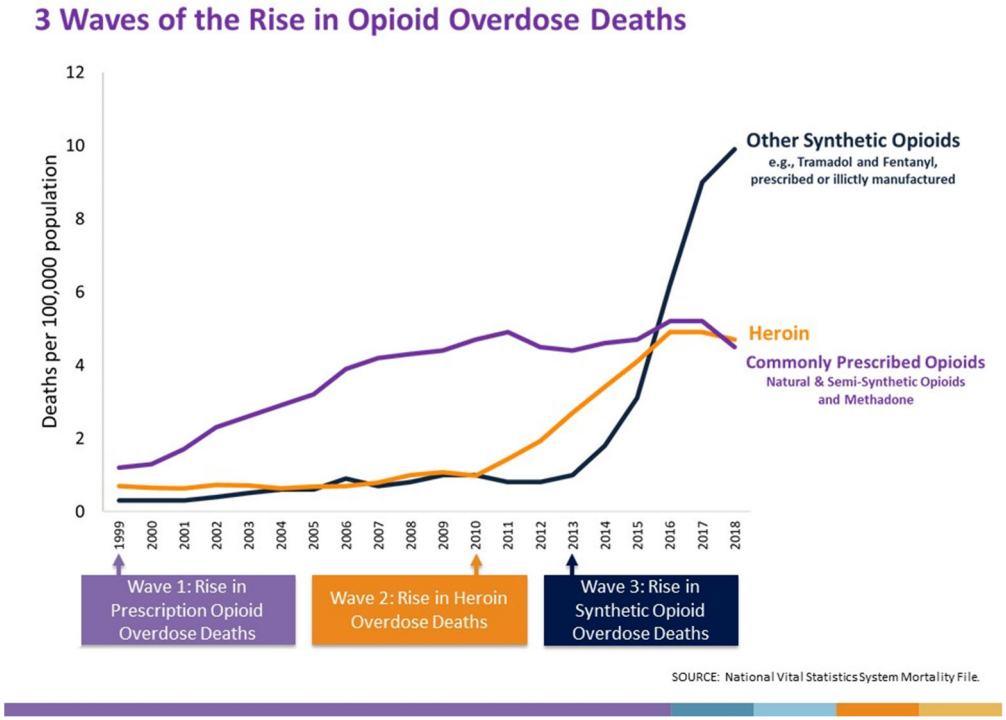
I. Opioid Abuse Is An Evolving, National Problem That Affects Every State.

The nationwide opioid crisis affects all the Amici States, taking a daily, devastating toll on their citizens. States have reported staggering numbers of overdose deaths and other dire consequences stemming from the crisis. For example, opioid-related deaths in Maryland skyrocketed from 504 in 2010 to approximately 2,090 in 2019. Md. Opioid Operational Command Ctr., *Annual Report* 7 (2020).[1] Nationwide, the opioid crisis has claimed more than 450,000 lives,

[1] *Available at* https://bit.ly/3dC6lPR.

and currently takes the lives of around 128 people each day. *See* Ctrs. for Disease Control & Prevention, *Understanding the Epidemic*;[2] Ctrs. for Disease Control & Prevention, *Overdose Deaths Accelerating During COVID-19*.[3]

The nature of the crisis has evolved over time—unfolding over three waves—making it increasingly difficult to engineer an enduring solution. The first wave involved primarily prescription opioids; the second was characterized by increased heroin use; and the third related to an uptick in the use of synthetic opioids like fentanyl. *Understanding the Epidemic*, *supra.* Those waves are depicted in the chart below:



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2 *Available at* https://bit.ly/2OEzzCX (last visited Mar. 5, 2021).

3 *Available at* https://bit.ly/3k75Oqk (last visited Mar. 5, 2021).

Id.

Since the first wave began around 1999, more than 232,000 people have died from overdoses related to prescription opioids. Ctrs. for Disease Control & Prevention, *Prescription Opioids Overview*.[4] These fatalities correlated with "dramatic increases in [the] prescribing of opioids for chronic pain." Ctrs. for Disease Control & Prevention, *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes* 6 (2018).[5]

During the second wave, starting in 2010, overdose deaths due to heroin began to increase. *Understanding the Epidemic*, *supra*. From 1999 to 2018, more than 115,000 people died from overdoses related to heroin use, with a large concentration in cities. Ctrs. for Disease Control & Prevention, *Heroin Overdose Data*.[6]

During the third wave, which began around 2013, the use of synthetic opioids added additional fuel to the fire. *Understanding the Epidemic*, *supra*. In 2019, more than 36,000 deaths—73 percent of *all* opioid-related overdose fatalities—involved a synthetic opioid. *See* Nat'l Inst. on Drug Abuse, *Overdose Death Rates* (Jan. 29, 2021).[7]

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4 *Available at* https://bit.ly/3atyruv (last visited Mar. 5, 2021).

5 *Available at* https://bit.ly/3awqO6D.

6 *Available at* https://bit.ly/3azppfE (last visited Mar. 5, 2021).

7 *Available at* https://bit.ly/3pySqMq.

Even compared to heroin, synthetic opioids pose a serious problem. Fentanyl is up to 50 times more potent than heroin and 50 to 100 times more potent than morphine. Drug Enf't Admin., *Alarming Spike in Fentanyl-Related Overdose Deaths Leads Officials to Issue Public Warning* (Aug. 6, 2020).[8] Illegally sold fentanyl is often mixed with heroin and other drugs, increasing the risk of overdose for an already potent drug. *See* Ctrs. for Disease Control & Prevention, *Fentanyl*.[9] And overdose deaths can occur within minutes—so quick action is essential to prevent a fatality. *See* Ctrs. for Disease Control & Prevention, *Save a Life from Prescription Opioid Overdose*.[10]

II. States Are Critical Laboratories Of Health Policy And Must Be Afforded The Freedom To Enact Innovative Solutions.

A. Many states have already implemented and spread successful opioid interventions.

States and localities are on the front lines of addressing the ever-evolving opioid crisis. As the federal government observed: "Ending the epidemic will require mobilization of government, local communities, and private organizations. It will require the resolve of our entire country." President Donald J. Trump,

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8 *Available at* https://bit.ly/3udAhaz.

9 *Available at* https://bit.ly/3qzDG1c (last visited Mar. 5, 2021).

10 *Available at* https://bit.ly/3kbX421 (last visited Mar. 5, 2021).

Remarks by President Trump on Combatting Drug Demand and the Opioid Crisis (Oct. 26, 2017).[11]

Because there is no one-size-fits-all solution, state and local governments and nonprofit organizations must develop strategies "driven by evidence and data" rooted in their communities and "must remain vigilant in maintaining a holistic and grounded understanding of who is at risk of fatal overdose, how that risk is constructed, and what can be done to reduce that risk as much as possible." Jennifer J. Carroll et al., Ctrs. for Disease Control & Prevention, *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States* 3 (2018).[12] For example, states still struggling with the first wave of the crisis may continue to spend the bulk of their resources combating prescription opioid abuse. By contrast, states with large urban populations must also contend with the explosion of fentanyl and heroin use and its consequences, including blood-borne diseases and frighteningly rapid overdoses.

Some of the most successful and widely used opioid interventions originated because a state was empowered to "try novel social . . . experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting); *see* Carroll et al., *supra*, at 8-28 (describing ten evidence-

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11 *Available at* https://bit.ly/3keHq6c.

12 *Available at* https://bit.ly/3dtySH5.

based strategies for combatting opioid overdoses, most of which have been pioneered by state and local governments). For example, Good Samaritan legislation, which encourages bystanders and fellow users to seek help for those suffering from a drug overdose by offering limited immunity from drug-related charges, was an effort originally pioneered by the states. New Mexico was the first state to pass Good Samaritan laws for overdose prevention in 2007; by May 2018, 44 additional states had enacted similar laws. Carroll et al., *supra*, at 19. These laws have effectively addressed the fear that many overdose bystanders have of arrest or criminal charges. *See id.*

SEPs first originated in Tacoma, Washington. Melissa Vallejo, Note, *Safer Bathrooms in Syringe Exchange Programs: Injecting Progress into the Harm Reduction Movement*, 118 Colum. L. Rev. 1185, 1194-95 (2018). A harm-reduction approach that provides people who inject drugs with clean needles at no cost, SEPs help prevent the spread of HIV, Hepatitis C, and other blood-borne diseases. Carroll et al., *supra*, at 26. They now operate as an important harm-reduction approach in most states. *See* Victoria Knight, *Needle Exchanges Find New Champions Among Republicans*, KHN (May 9, 2019).[13]

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[13] *Available at* https://bit.ly/3pOmG6n.

To stem the tide of overdose deaths, many states are also expanding first responder access to naloxone, a drug that quickly reverses an opioid's effects. *See* Network for Pub. Health L., *Legal Interventions to Reduce Overdose Mortality: Naloxone Access Laws* 1-10 (2021).[14] In Pennsylvania, the Physician General has issued a standing order that constitutes a statewide prescription for eligible persons to obtain naloxone. Pa. Dep't of Health, Standing Order DOH-005-2021: Naloxone Prescription for Overdose Prevention 2 (2021).[15] And California has created a "Naloxone Distribution Project," which uses federal funds to provide the drug for free to entities like law enforcement and homeless aid programs. Cal. Dep't of Health Care Servs., *Naloxone Distribution Project*.[16] The project has recorded over 27,750 overdose reversals. *Id.*

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

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14 *Available at* https://bit.ly/3aKvTsa.

15 *Available at* https://bit.ly/3dCLY4T.

16 *Available at* https://bit.ly/2NHkC2J (last visited Mar. 5, 2021).

B. Despite substantial efforts from multiple states, the crisis demands new and innovative interventions.

Although there has been incremental progress in reducing overdose deaths related to prescription opioids, there were still 49,860 opioid-involved overdose deaths in 2019 in the United States. *Overdose Death Rates*, *supra*. Synthetic opioids are now at the forefront of the problem—death rates involving synthetic opioids increased 14-fold from 2012 to 2019. *Id.* And the ongoing COVID-19 pandemic appears to be only intensifying the crisis. Deaths involving synthetic opioids increased 38.4 percent in the 12 months leading up to May 2020 compared to the 12 months leading up to June 2019. *Overdose Deaths Accelerating During COVID-19*, *supra*. *See generally* Valerie Bauman & Ian Lopez, *The Opioid Crisis, Fueled by Covid, Is Worse than Ever*, Bloomberg Businessweek (Feb. 20, 2021).[17] Opioid-related deaths in the District of Columbia increased from a record 281 in 2019 to 377 in 2020—without including December 2020. D.C. Off. of the Chief Med. Exam'r, *Opioid-Related Fatal Overdoses: January 1, 2016 to November 30, 2020* 1 (2021).[18]

To combat the skyrocketing synthetic opioid epidemic, many states are considering SISs like those proposed by Safehouse. These sites have a global record

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17 *Available at* https://bloom.bg/3bq6O4U.

18 *Available at* https://bit.ly/3qAQRiE.

of success, with around 100 different locations across 66 cities. Alex H. Kral & Peter J. Davidson, *Addressing the Nation's Opioid Epidemic: Lessons from an Unsanctioned Supervised Injection Site in the U.S.*, 53 Am. J. Preventative Med. 919, 919 (2017).[19] One SIS in Vancouver recorded over 8,000 visits over a five-year span—and no deaths. Health Can., *Vancouver's INSITE Service and Other Supervised Injection Sites: What Has Been Learned from Research?* (Mar. 31, 2008) ("Executive Summary" subheading).[20] Following this worldwide success, a state senator in California recently introduced a bill that would allow three cities to open SISs, S.B. 57, 2021-2022 Reg. Sess. (Cal. 2020),[21] a proposal that Governor Gavin Newsom said he is "very, very open" to supporting, Trisha Thadani, *Scott Wiener Tries—Again—to Allow S.F., Oakland and L.A. to Open a Safe Drug Use Site*, S.F. Chron. (Dec. 8, 2020).[22] New Mexico and Utah have also introduced bills in their state legislatures to create similar sites. H.B. 123, 2021 Reg. Sess. (N.M. 2021);[23] H.B. 146, 2021 Gen. Sess. (Utah 2021).[24]

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19 *Available at* https://bit.ly/3kBTsXl.

20 *Available at* https://bit.ly/3kIBDGf.

21 *Available at* https://bit.ly/3seMb2n.

22 *Available at* https://bit.ly/3pC4Fry.

23 *Available at* https://bit.ly/3uUY6EI.

24 *Available at* https://bit.ly/309TVqd.

City governments are likewise considering SISs as evidence-based tools to address the crisis. In a 2018 report assessing the sites' feasibility and efficacy, the New York City Department of Health and Mental Hygiene recommended piloting four SISs, finding that doing so could prevent up to 130 deaths and save up to $7 million per year. *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, N.Y.C. Dep't of Health & Mental Hygiene 5 (2018).[25] Baltimore has also been considering SISs, and a Johns Hopkins study of cities including Baltimore revealed that a "large majority of people who use heroin and fentanyl would be willing to use safe consumption spaces where they could obtain sterile syringes and have medical support in case of overdose." Johns Hopkins Bloomberg Sch. of Pub. Health, *Safe Consumption Spaces Would Be Welcomed by High-Risk Opioid Users* (June 5, 2019);[26] *see* Meredith Cohn, *Supporters Push Safe Injection Sites to Stem Overdose Deaths in Maryland, but Legal Questions Unresolved*, Balt. Sun (Sept. 25, 2019).[27]

California, New Mexico, Utah, New York City, Baltimore—and indeed, Philadelphia—each have distinct demographic features that contribute to the crisis, and cities and states must have the freedom to tailor their responses accordingly. For

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25 *Available at* https://on.nyc.gov/3unWIdx.

26 *Available at* https://bit.ly/2P4XuvP.

27 *Available at* https://bit.ly/3sioxC8.

example, in New York City, people who are homeless die from overdoses at more than six times the rate of the general population. *Overdose Prevention in New York City*, *supra*, at 34. The city found that SISs would address the problem that "homeless or unstably housed [individuals] may be most likely to inject in public or semi-public settings," and that the facilities would have both life- and cost-saving benefits. *Id.* In Baltimore, opioid and drug use is "dispersed throughout the city." Susan Sherman et al., *Safe Drug Consumption Spaces: A Strategy for Baltimore City*, Abell Rep., Feb. 2017, at 1, 11.[28] Another Johns Hopkins-led study urged opening two SISs based on these unique conditions to maximize accessibility. *Id.*

As these examples demonstrate, solutions to the opioid crisis—including those targeted at reducing deaths from fentanyl—are highly localized. States that are home to metropolitan areas should be free to experiment with this lifesaving intervention without fear that public health nonprofits or doctors in their jurisdictions will be subject to criminal prosecution. Because the panel's ruling threatens to take this option away from state and local governments, the Amici States urge the Court to grant rehearing en banc.

CONCLUSION

This Court should grant appellees' petition for rehearing en banc.

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[28] *Available at* https://bit.ly/302bA35.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 5, 2021, I electronically filed this brief with the Clerk of the Court of the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Loren L. AliKhan
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CERTIFICATE OF COMPLIANCE AND BAR MEMBERSHIP

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2. I certify that this brief complies with the type-volume limitation in Federal Rule of Appellate Procedure 29(b)(4) because the brief contains 2,581 words, excluding exempted parts.

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4. Pursuant to the Third Circuit Local Appellate Rule 31.1(c), I certify that a virus detection program was performed on this electronic brief/file using McAfee Endpoint Security (version 10.6), and that no virus was detected.

5. Pursuant to Third Circuit Local Appellate Rule 28.8(d), I certify that I am a member of the bar of this Court.

/s/ Loren L. AliKhan
LOREN L. ALIKHAN