

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 JOSE A. BENITEZ, as
President and Treasurer of Safehouse, *Appellees*.

SAFEHOUSE, a Pennsylvania nonprofit Corporation, *Appellee*,

v.

UNITED STATES OF AMERICA; 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, *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
CALIFORNIA, DELAWARE, ILLINOIS, MICHIGAN, MINNESOTA, NEW
MEXICO, OREGON, VERMONT, AND VIRGINIA AS *AMICI CURIAE* IN
SUPPORT OF BRIEF FOR APPELLEE SAFEHOUSE AND AFFIRMANCE**

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GLOSSARY

App.	Joint Appendix
CDC	Centers for Disease Control and Prevention
CSA	Controlled Substances Act
HHS	U.S. Department of Health and Human Services
MAT	Medication-Assisted Treatment
SIS	Safe Injection Site
SEP	Syringe Exchange Programs

INTEREST OF AMICI CURIAE

The District of Columbia and the States of California, 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 under Rule 29(a)(2) of the Federal Rules of Appellate Procedure. The *Amici States* are battling a nationwide opioid crisis that claims 128 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 (“SIS”) are emerging as a measure designed 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 (“CSA”), however, threatens 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. Every day, Americans die 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 significant increase 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.

The *Amici* States are on the front lines of this crisis, battling each day to save their citizens from the deadly effects of opioids. But states' significant efforts have not ended this epidemic. As fentanyl and heroin use increases, states need the freedom to implement innovative treatment programs to save lives.

2. States have a traditional and well-established role in protecting the health and welfare of their citizens. The opioid crisis, like so many other public health issues, is a matter of local concern. The causes and characteristics of the crisis in each state differ. Rural areas may lack substance abuse and medical programs,

whereas metropolitan areas face different challenges. As laboratories of democracy, states must be able to use their broad powers to develop the tailored interventions needed to save lives.

States on the forefront of public health crises often develop successful, novel interventions that later become nationwide standards. For example, Good Samaritan laws that offer limited legal immunity to encourage bystanders to seek help for overdose victims began in New Mexico in 2007; as of May 2018, similar laws have been enacted in 45 states. Similarly, states have eliminated barriers for Medicaid recipients who need medication-assisted treatment to treat opioid use disorder. Syringe exchange programs were also 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.

Operating or regulating SISs falls within the states' power to implement public health measures. Although the sites have not yet opened in the United States, about 100 sites operate in 60 different cities in Canada, Australia, and many European nations. After studying SIS interventions in other countries, many states and cities are considering them as a means of saving lives. The studies predict that the sites will reduce deaths, the spread of blood borne diseases, and costs. And they

are a unique solution to the common problem in many urban areas of rapid, unintended overdoses of heroin or fentanyl.

3. The CSA should not be interpreted to prevent states from exercising their police powers to develop innovative public health solutions. Section 856 of the CSA was developed to shut down “crack houses,” not community health clinics. SISs, unlike crack houses, do not distribute, manufacture, or facilitate drug possession. The purpose of an SIS is to prevent death and provide medical care along with substance abuse and other medical and social services.

Moreover, the federal government’s interpretation of Section 856 raises constitutional questions about Congress’s ability to intrude on traditional state police powers. The states have authority to regulate the practice of medicine, and SISs are medical interventions. Reading Section 856 to limit a state’s traditional authority to address overdose deaths raises significant federalism concerns. Courts are obligated to avoid serious constitutional questions where an alternative interpretation is fairly possible. Safehouse has provided a fair interpretation that allows states to retain their traditional role in protecting the public health and safety. The Court should embrace that reasonable interpretation.

ARGUMENT

I. The Opioid Crisis Profoundly Affects The States, And They Must Be At The Forefront Of Any Solution.

A. Opioid abuse is a problem on a national scale that affects every state.

The nationwide opioid crisis affects all the *Amici* States, taking a daily, devastating toll on their citizens.¹ States have reported staggering numbers of overdose deaths and other dire consequences stemming from the crisis. In Maryland, opioid-related deaths increased from 504 in 2010 to 2,090 in 2019. Opioid Operational Command Ctr., *Annual Report: Before It's Too Late* 7 (2020).² In 2018 alone, Michigan reported 2,011 overdose deaths involving opioids. Nat'l Inst. on Drug Abuse, *Michigan Opioid Summary*.³ On a nationwide scale, the opioid crisis

¹ This nationwide crisis has been studied by the Centers for Disease Control and Prevention ("CDC") and covered in a variety of news outlets. *See, e.g.*, Ctrs. for Disease Control & Prevention, *Drug Overdose Deaths*, www.cdc.gov/drugoverdose/data/statedeaths.html; James Nachtwey et al., *The Opioid Diaries*, Special Report, Time, <https://time.com/james-nachtwey-opioid-addiction-america>; Joel Achenbach and Dan Keating, *Unnatural Causes: Sick and Dying in Small-town America*, Series, Wash. Post (Apr. 10, 2016) <https://www.washingtonpost.com/unnatural-causes>; Scott Glover et al., *Dying for Relief: A Times Investigation* L.A. Times (Nov.-Dec. 2012) <http://graphics.latimes.com/prescription-drugs-part-one>.

² <https://beforeitstoolate.maryland.gov/wp-content/uploads/sites/34/2020/03/2019-ANNUAL-FINAL-3.24.20.pdf>.

³ <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/michigan-opioid-involved-deaths-related-harms>. *See generally* Nat'l Inst. on Drug Abuse, *Opioid Summaries by State*, <https://www.drugabuse.gov/drugs->

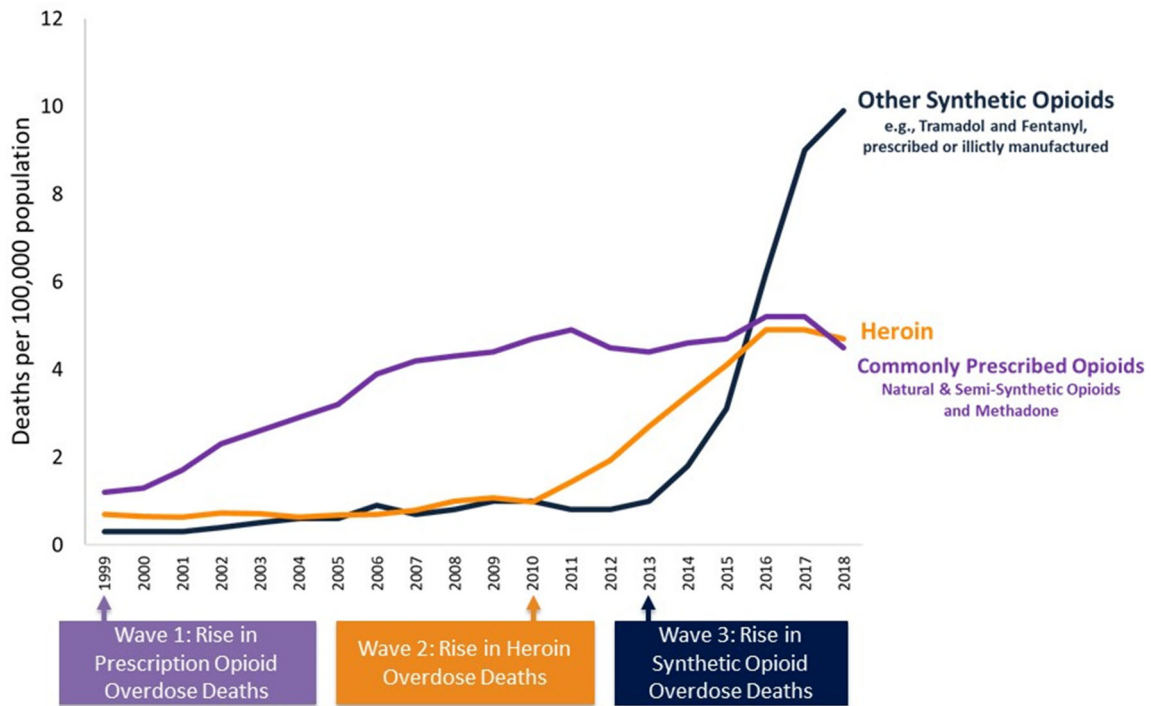
claims 128 lives each day. *See* Ctrs. for Disease Control & Prevention, *Understanding the Epidemic*.⁴ Nearly 450,000 people have died from opioid-related overdoses from 1999 to 2018. *Id.*

The nature of the crisis has evolved over time, making it increasingly difficult to engineer an enduring solution. The Centers for Disease Control and Prevention (“CDC”) explains the opioid crisis as comprising three waves: the first involving primarily prescription opioids, the second indicating increased heroin use, and the third heralding an uptick in synthetic opioid use, such as fentanyl. *Id.* Those waves are depicted in the chart below:

abuse/opioids/opioid-summaries-by-state (Ohio’s overdose deaths increased from fewer than 500 in 1999 to 2,783 in 2018; Minnesota’s overdose deaths increased from approximately 50 in 1999 to 343 in 2018; Oregon’s overdose deaths increased from under 150 in 1999 to 339 in 2018; and New Mexico’s overdose deaths increased from fewer than 200 in 1999 to 338 in 2018).

⁴ <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

Id.

Since the start of the first wave, which began around 1999, more than 232,000 people have died from an overdose related to prescription opioids. Ctrs. for Disease Control & Prevention, *Prescription Opioids Data Overview*.⁵ 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-*

⁵ <https://www.cdc.gov/drugoverdose/data/prescribing/overview.html>.

Related Risks and Outcomes 6 (2018).⁶ The prescription-based crisis affected regions across the country. *Id.* at 67-68, tbl. 4; Ctrs. for Disease Control & Prevention, *Prescription Opioids Data Overdose Death Maps*.⁷

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. Ctrs. for Disease Control & Prevention, *Opioid Basics: Heroin*.⁸ Heroin carries unique risks: it is commonly injected, and the use and disposal of syringes increases the risk of blood-borne illnesses such as HIV and Hepatitis B and C. *Id.* While there was a slight decrease in overdose deaths involving heroin from 2017 to 2018, the number of deaths remains disturbingly high—7 times higher than in 1999. Ctrs. for Disease Control & Prevention, *Heroin Overdose Data*.⁹ Although heroin is used everywhere, it has a concentrated impact on cities. *Id.*

During the third wave, which began around 2013, the use of synthetic opioids added additional fuel to the fire. *Understanding the Epidemic, supra.* In 2018, more

⁶ <https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf>.

⁷ <https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html>.

⁸ <https://www.cdc.gov/drugoverdose/opioids/heroin.html>.

⁹ <https://www.cdc.gov/drugoverdose/data/heroin.html>.

than 31,000 deaths involved a synthetic opioid. Ctrs. for Disease Control & Prevention, *Synthetic Opioid Overdose Data*.¹⁰ Deaths involving synthetic opioids increased from 2017 to 2018, and in 2018 accounted for 67% of opioid-related deaths. *Id.* Even in relation to heroin, synthetic opioids pose a serious problem. Fentanyl is 50 times more potent than heroin and 100 times more potent than morphine. *Id.* Illegally sold fentanyl is often mixed with heroin and other drugs, thereby increasing the risk of overdose for an already potent drug. Ctrs. for Disease Control & Prevention, *Opioid Basics: Fentanyl*.¹¹ Large metropolitan areas have borne the brunt of this third wave of the crisis. *Synthetic Opioid Overdose Data, supra.*

Particularly with fentanyl, overdose deaths can occur within minutes. Joint Appendix (“App.”) 361-62 (testimony of Dr. Jean Marie Perrone). Quick action is essential to prevent death. *See* Ctrs. for Disease Control & Prevention, *Preventing Opioid Overdose: Know the Signs. Save a Life 2* (“It’s important to recognize the signs [of overdoses] and *act fast*.” (emphasis added)).¹² Naloxone is among the best life-saving interventions. It acts to block and reverse the effects of an opioid and

¹⁰ <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

¹¹ <https://www.cdc.gov/drugoverdose/opioids/fentanyl.html>.

¹² <https://www.cdc.gov/drugoverdose/pdf/patients/Preventing-an-Opioid-Overdose-Tip-Card-a.pdf>.

“very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing.” Nat’l Inst. on Drug Abuse, *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)*.¹³ Multiple doses of naloxone may be required to restore breathing during an overdose. *Id.* And all patients “given naloxone *should be observed constantly . . . and for at least 2 hours by medical personnel after the last dose of naloxone to make sure breathing does not slow or stop.*” *Id.* (emphasis added).

Although opioid abuse is a massive national problem, given the different forms and changing “waves” of opioid abuse, effective solutions are varied—and often implemented locally.

B. States and localities are instrumental to solving the problem.

States and localities are on the front lines of addressing this crisis. Acknowledging this reality, the federal government has declared the “deadly opioid crisis” a nationwide public emergency with a “call to action . . . which empowers the real heroes of this fight: the communities on the frontlines of the epidemic.” Press Release, U.S. Dep’t of Health & Human Servs., *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis* (Oct. 26, 2017)

¹³ <https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio>.

(quoting Eric D. Hargan, Acting Sec’y, Health & Human Servs.).¹⁴ 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.” *Combatting the Opioid Epidemic: 2019 Budget Fact Sheet*, Exec. Office of the President.¹⁵

Because there is no one-size-fits-all solution, state and local governments and non-profit 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

¹⁴ <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

¹⁵ https://www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Combatting-the-Opioid-Epidemic.pdf. See U.S. Dep’t of Health & Human Servs., *Fact Sheet: Combating the Opioid Crisis* 1 (Apr. 2019), <https://www.hhs.gov/sites/default/files/opioids-fact-sheet-april-2019.pdf> (noting that “the most effective responses to this crisis are when entire communities come together—doctors, nurses, cops, courts, teachers, mayors, employers, parents, coaches, young people, social workers, faith leaders—everybody”); see also Press Release, U.S. Dep’t of Health & Human Servs., *Secretary Azar Statement on 2018 Provisional Drug Overdose Death Data* (Jul. 17, 2019), <https://www.hhs.gov/about/news/2019/07/17/secretary-azar-statement-on-2018-provisional-drug-overdose-death-data.html> (“While the declining trend of overdose deaths is an encouraging sign, by no means have we declared victory against the epidemic or addiction in general.” (quoting Alex Azar, Sec’y, Health & Human Servs.)).

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).¹⁶

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.

One thing, however, is certain regardless of geography: As states and localities work to create tailored solutions, lives hang in the balance. And the nature of the crisis continues to morph in ways that require room for innovation.

II. The Controlled Substances Act Should Not Be Interpreted To Criminalize Public Health And Safety Interventions, Which Are Traditionally The Subject Of State Regulation.

A. Medical care and issues of public health and safety are areas of traditional state police power.

It is well established that states have wide latitude to address problems concerning “the protection of the lives, limbs, health, comfort, and quiet of all persons.” *Medtronic Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)). This latitude permits states to experiment to solve problems of social policy. *See New State Ice Co. v. Lienmann*,

¹⁶ <https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf>.

285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“[A] state may . . . serve as a laboratory.”). In particular, “a vital part of a state’s police power” is to regulate medicine and public health. *Barsky v. Bd. of Regents of the State Univ. of N.Y.*, 347 U.S. 442, 449 (1954); see *Great Atl. & Pac. Tea Co., Inc. v. Cottrell*, 424 U.S. 366, 371 (1976) (“[U]nder our constitutional scheme the States retain broad power to legislate protection for their citizens in matters of local concern such as public health.” (internal quotation marks omitted)). States must be able to respond creatively to public health crises because the effectiveness of an intervention will unquestionably depend on the specific needs of the state. Indeed, “the essence of federalism is that states must be free to develop a variety of solutions to problems and not be forced into a common, uniform mold.” *Addington v. Texas*, 441 U.S. 418, 431 (1979). Especially in the case of an ever-changing epidemic that persists despite extensive and costly interventions, states must be able to use their broad power to implement new programs in their role as “laboratories for experimentation.” *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring).

To implement effective interventions, states must have “a clear understanding of the causes and characteristics of local public health problems.” Carroll et al., *supra*, at 3. Substance abuse interventions are most effective when programs are centered on “the needs and concerns specific to the local drug using community.”

Id. at 27. In rural areas of the country, the opioid crisis is exacerbated by a lack of substance abuse treatment infrastructure, few physicians providing medication-assisted treatment (“MAT”),¹⁷ and insufficient regional coordination of treatment resources. *National Rural Health Association Policy Brief: Treating the Rural Opioid Epidemic*, Nat’l Rural Health Assoc. 1 (Feb. 2017).¹⁸ Rural terrain makes for longer ambulance transit time, which increases the likelihood of overdose deaths; lack of public transportation hinders access to treatment; and there is often significant social stigma around addiction in small communities. Chiara Corso & Charles Townley, Nat’l Acad. for State Health Pol’y, *Intervention, Treatment, and Prevention Strategies to Address Opioid Use Disorders in Rural Areas: A Primer on Opportunities for Medicaid-Safety Net Collaboration* 14 (Sept. 2016).¹⁹

In contrast, urban areas face challenges related to high-density populations and racial disparities in healthcare. In the District of Columbia—an exclusively urban jurisdiction—the opioid epidemic does not “fit squarely into the public

¹⁷ Medication-assisted treatment is the use of behavioral and pharmacological therapy to treat opioid use disorder. Carroll et al., *supra*, at 10. The medications used are approved by the Federal Drug Administration and treat withdrawal symptoms, block the effect of opioids, and reduce cravings. *Id.* The treatment usually requires frequent visits to the administering physician or clinic. *Id.*

¹⁸ https://www.ruralhealthweb.org/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/2019-NRHA-Policy-Document-Treating-the-Rural-Opioid-Epidemic.pdf.

¹⁹ <https://nashp.org/wp-content/uploads/2016/09/Rural-Opioid-Primer.pdf>.

narrative of the modern opioid crisis” because the majority of overdose victims are not “member[s] of the white, rural working class.” Swathi Srinivasan, *Hidden Faces of the Opioid Epidemic*, Harv. Pol. Rev. (Feb. 25, 2019).²⁰ Overdose victims in the District are overwhelmingly Black and those who are long-term users of heroin. Peter Jamison, *An Opioid Epidemic That Nobody Talks About*, Wash. Post (Dec. 18, 2018).²¹ Effective interventions in the District must both reduce the harm from the rise in fentanyl use and provide treatment for decades-long heroin dependency. *Id.* Additionally, to be effective, local interventions must combat discrimination that Black Americans face in both research and treatment for substance use disorder. Marisa Peña, *The Opioid Crisis is Surging in Black, Urban Communities*, NPR (Mar. 8, 2018) (“[The Black] population has been totally ignored. They are invisible.” (quoting Dr. Edwin Chapman, who specializes in drug addiction in Washington, D.C.)).²²

California also has a host of urban communities struggling with the opioid epidemic, and those communities face their own unique challenges. In San Francisco, for example, approximately 69 percent of people who inject drugs have

²⁰ <https://www.harvardpolitics.com/united-states/hidden-faces-of-the-opioid-epidemic>.

²¹ <https://wapo.st/national-opioids>.

²² <https://www.npr.org/2018/03/08/579193399/the-opioid-crisis-frightening-jump-to-black-urban-areas>.

“reported living on the street, using homeless shelters, or living in [hotels].” San Francisco Safe Injection Servs. Task Force, *2017 Final Report* 5, 7 (2017).²³ This results in widespread public injection, which leads to both unsafe disposal of drug paraphernalia and creates “dangerous and alarming conditions in public spaces for residents, visitors, and [drug users] themselves.” *Id.* at App. A (Board of Supervisor’s Resolution).²⁴ Because “prevention strategies need to take into account the realities, experiences, and perspectives of those at risk of overdose,” public health officials must consider the high-poverty, densely populated nature of urban neighborhoods in order to be “responsive to local realities.” Carroll et al., *supra*, at 3.

As with many public health issues, then, the opioid crisis is in many ways highly localized. Accordingly, states need leeway to “develop a variety of solutions to problems and not be forced into a common, uniform mold.” *Addington*, 441 U.S. at 431.

²³ <https://www.sfdph.org/dph/files/SISTaskforce/SIS-Task-Force-Final-Report-2017.pdf>.

²⁴ New York City faces similar issues. *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, NYC Health 10-11, <https://www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report.pdf?mccid=2a562844de&mceid=fec6ed8b11>.

B. Acting as laboratories, many states have implemented and spread successful interventions.

Some of the most successful and widely used opioid interventions originated because a state was empowered to “try novel and social experiments without risk to the rest of the country.” *New State Ice Co.*, 285 U.S. at 311. 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, 45 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.* (“An evaluation of 911 Good Samaritan Law education efforts in New York City found that awareness of this law statistically increased the likelihood that a bystander would call 911 in the event of an overdose.”).

States have also engaged in meaningful research and creative regulation. A 2016 New York examination of obstacles to opioid use disorder treatment “prompted [major insurance companies] to remove all prior authorization requirements for [patients] seeking [MAT],” an insurance formality that leads to unnecessary delay in treatment. *Id.* at 15. Multiple states have since eliminated that requirement for Medicaid recipients and collaborated with insurance companies to

do the same, preventing patients from self-medicating with opioids or illegal drugs when faced with delays in treatment.²⁵

Syringe exchange programs (“SEPs”) too were once limited to a single city in Washington state—Tacoma. Melissa Vallejo, Note, *Safer Bathrooms in Syringe Exchange Programs: Injecting Progress into the Harm Reduction Movement*, 118 Colum. L. Rev. 1185, 1195 (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 B and C, and other blood-borne diseases. Carroll et al., *supra*, at 26. SEPs have been controversial because they have been mistakenly viewed as “feeding an

²⁵ Carroll et al., *supra*, at 15 (Rhode Island); Press Release, N.J. Dep’t of Human Servs., New Jersey Medicaid Removes Prior Authorization Requirements for Opioid Addiction Treatment Medication (Apr. 1, 2019), <https://www.nj.gov/humanservices/news/press/2019/approved/20190401.html> (New Jersey); Press Release, Am. Med. Ass’n, Arkansas Sets Standard for States by Removing Prior Authorization for Treatment of Opioid Use Disorder (Apr. 22, 2019), <https://www.ama-assn.org/press-center/press-releases/arkansas-sets-standard-states-removing-prior-authorization-treatment> (Arkansas); Press Release, Am. Med. Ass’n, Pennsylvania Removes Prior Authorization for Opioid Treatment (Oct. 12, 2018), <https://www.ama-assn.org/press-center/press-releases/pennsylvania-removes-prior-authorization-opioid-treatment> (Pennsylvania); Press Release, Am. Med. Ass’n, District of Columbia Takes Important Step to Reverse Opioid Epidemic (Apr. 5, 2019), <https://www.ama-assn.org/press-center/press-releases/district-columbia-takes-important-step-reverse-opioid-epidemic> (District), Press Release, Am. Med. Ass’n, Iowa Removes Barriers to Treatment of Opioid Use Disorder (May 6, 2019), <https://www.ama-assn.org/press-center/press-releases/iowa-removes-barriers-treatment-opioid-use-disorder> (Iowa).

addiction,” *Needle Exchange Programs: Consideration for Criminal Justice* 1,²⁶ yet their effectiveness in preventing the spread of disease is well-documented and they now operate as an important harm-reduction approach in most states. *Id.* at 1; *id.* at 3 (SEPs “have com[e] into being [as the result of] civil disobedience; gradual community acceptance and legitimization; and local community or foundation funding and support.”). Many states have legalized SEPs by permitting state and local health departments or nonprofits to provide SEP services. *See, e.g.*, Md. Code Ann., Health-Gen. § 24-903 (2016); N.C. Gen. Stat. § 90-113.27 (2017); N.M. Stat. Ann. § 24-2C-1 to 24-2C-6; Tenn. Code Ann. § 68-1-136 (2017). For example, California has over 40 sites that offer an array of health and social services in addition to syringe exchange and disposal. Cal. Dep’t of Pub. Health, Office of AIDS, *Syringe Exchange Programs in California: An Overview* (updated Apr. 2018).²⁷ And in 2016, Congress passed legislation that gives states and localities the ability to use federal funds provided through the Department of Health and Human Services for certain costs of operating SEPs. Consolidated Appropriations Act of

²⁶ <https://harmreduction.org/wp-content/uploads/2012/01/NEPcriminaljusticeCIPP.pdf>.

²⁷ https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/Overview%20SEPs%20in%20CA_2017.pdf. *See* Cal. Dep’t of Pub. Health, Office of AIDS, *California Legal Code Related to Access to Sterile Syringes* (updated Apr. 2020), https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CA%20Legal%20Code_Final.pdf.

2016, Pub. L. No. 114-113, § 52, 129 Stat. 2242, 2652 (2015). Once a harm-reduction strategy limited to a single city in a single state, SEPs now help to prevent the spread of disease nationwide.

To be sure, many of the interventions implemented to date focus on the first phase of the opioid crisis—opioid use disorder tied to prescription opioids.²⁸ Those interventions include regulating and monitoring prescription opioids to reduce the number of prescriptions. For example, Oregon developed a prescription drug monitoring program to better regulate the distribution of narcotic pain relievers. Oregon Health Auth., *Prescription Drug Monitoring Program*, Oregon.gov²⁹; cf. New Mexico Bd. of Pharm., *What Is the New Mexico Prescription Monitoring Program?*³⁰ States are also working with medical professionals on alternatives for chronic pain management. See, e.g., TN Dep't of Health, TN Opioid Epidemic Response, *Turning the Tide: Collaborating to Prevent Opioid Abuse*.³¹ For persons

²⁸ Twenty-nine states receive funding from the CDC specifically related to preventing overdose deaths from prescription opioids. Ctrs. for Disease Control & Prevention, *State Information: Prevention for States*, CDC.gov, https://www.cdc.gov/drugoverdose/states/state_prevention.html.

²⁹ <https://www.oregon.gov/oha/ph/preventionwellness/safeliving/pdmp/pages/index.aspx>.

³⁰ <http://nmpmp.org/Default.aspx>.

³¹ <https://www.tn.gov/health/health-program-areas/tdh-opioid-coalition/redirect-tn-opioid-epidemic-response/turning-the-tide-collaborating-to-prevent-opioid-abuse.html> (detailing efforts by Tennessee).

with opioid use disorder, states are increasing access to substance abuse treatment services, including MAT. *See* Cal. Dep't of Health Care Servs, *The California MAT Expansion Project Overview*³²; Oregon Health Auth., *Medication-Assisted Treatment and Recovery*.³³ And states are pursuing opioid drug manufacturers for their deceptive marketing practices. *See, e.g.*, Lenny Bernstein & Katie Zezima, *Purdue Pharma, State of Oklahoma Reach Settlement in Landmark Opioid Lawsuit*, Wash. Post (Mar. 26, 2019) (detailing \$270 million settlement obtained by Oklahoma).³⁴

To stem the tide of overdose deaths, many states are also expanding first responder access to naloxone.³⁵ *See, e.g.*, Md. Code Ann., Health-Gen. § 13-3101 to 13-3109 (making naloxone available); Mich. Comp. Laws. Ann. § 333.17701 *et seq.* (same); Or. Rev. Stat. § 689.681 (2017) (same); N.M. Stat. Ann. § 24-23-1

³² <https://www.dhcs.ca.gov/individuals/Pages/State-Targeted-Response-to-Opioid-Crisis-Grant.aspx>.

³³ <https://www.oregon.gov/oha/HSD/AMH/Pages/UMATR.aspx> (detailing Oregon's efforts).

³⁴ https://www.washingtonpost.com/national/health-science/purdue-pharma-state-of-oklahoma-reach-settlement-in-landmark-opioid-lawsuit/2019/03/26/69aa5cda-4f11-11e9-a3f7-78b7525a8d5f_story.html.

³⁵ Network for Pub. Health, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws 2*, <https://www.networkforphl.org/resources/legal-interventions-to-reduce-overdose-mortality-naloxone-access-and-good-samaritan-laws>.

(2016) (same). Indeed, 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-002-2018: Naloxone Prescription for Overdose Prevention 2 (2018)³⁶; see Cal. Dep't of Health Care Servs., *Naloxone Distribution Project*.³⁷

Many states expanded their Medicaid programs to include treatment for substance use disorder. U.S. Dep't of Health & Human Servs., *Resources for States, Substance Use Disorders*.³⁸ And under the Affordable Care Act several states are addressing the opioid epidemic through insurance coverage expansions, regulatory insurance reforms that require inclusion of substance use disorder treatments, enhanced mental health parity, and opportunities to integrate substance use disorder treatment and mainstream healthcare. Amanda J. Abraham et al., *The Affordable Care Act Transformation of Substance Use Disorder Treatment*, Am. Journal of Pub. Health (Jan. 2017).³⁹

³⁶ <https://www.health.pa.gov/topics/Documents/Opioids/General%20Public%20Standing%20Order.pdf>.

³⁷ https://www.dhcs.ca.gov/individuals/Pages/Naloxone_Distribution_Project.aspx.

³⁸ <https://www.medicaid.gov/resources-for-states/innovation-accelerator-program/program-areas/substance-use-disorders/1115-substance-use-disorder-demonstrations/index.html>.

³⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5308192>.

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.

C. Despite substantial efforts from multiple states, new and innovative interventions are needed.

As noted, although there has been incremental progress in reducing overdose deaths related to prescription opioids, there were still 46,802 opioid-involved overdose deaths in 2018 in the United States. Nana Wilson et al., Ctrs. for Disease Control & Prevention, *Drug and Opioid-Involved Overdose Deaths—United States, 2017-2018*, Morbidity and Mortality Weekly Report (Mar. 20, 2020).⁴⁰ And synthetic opioids are now at the forefront of the problem—death rates involving synthetic opioids increased ten percent from the year before. *Id.*

Many states and localities that are experiencing overdose deaths due to synthetic opioids are considering SISs, similar to the sites proposed by Safehouse. On June 23, 2020, the San Francisco Board of Supervisors unanimously approved legislation that would allow safe injection sites to open in San Francisco city. CBS News SF Bay Area, *San Francisco Officials Approve Controversial Safe Injection*

⁴⁰ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6911a4.htm>.

Sites; Await State Approval (June 24, 2020).⁴¹ And a bill is currently pending before the California legislature to authorize the City and County of San Francisco to approve entities to operate SISs. Assemb. B. 362, 2019 Reg. Sess. (Cal. 2019).⁴² The author of the bill explained that California “must . . . look for innovative strategies for addressing this epidemic.” *Id.*, Analysis.⁴³ The proposal would enable San Francisco to approve SISs to allow for rapid intervention for overdoses and to connect people with a host of medical and social services, “reduce public nuisance and safety concerns,” and extend “the harm reduction strategies” already adopted by California. *Id.*

New York City published a report in 2018 on SISs and acknowledged that “[t]he opioid overdose epidemic . . . persists despite current efforts, which include availability of treatment services, collaborative interventions between public health and law enforcement, and increased access to the emergency overdose rescue medication naloxone.” *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection, supra*, at 3. Similarly, Maryland has been considering developing SISs on a pilot basis, and a

⁴¹ <https://sanfrancisco.cbslocal.com/2020/06/24/sf-supes-approve-safe-injection-sites-rehiring-city-workers-laid-off-due-to-pandemic>.

⁴² https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB362.

⁴³ <https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml> (Mar. 15, 2019).

Johns Hopkins study 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.” News Release, Johns Hopkins Bloomberg Sch. of Pub. Health, *Safe Consumption Spaces Would Be Welcomed By High-Risk Opioid Users* (June 5, 2019).⁴⁴

States and localities considering employing SISs should not be hindered by Section 856 from doing so. They would join an international community that has successfully been operating these facilities to save lives. Approximately 100 SISs operate across 60 different cities in Australia, Canada, Denmark, France, Germany, Luxembourg, the Netherlands, Norway, Spain, and Switzerland. Alex Kreit, *Safe Injection Sites and the Federal “Crack House” Statute*, 60 B.C. L. Rev. 413, 415 n.2 (2019). In Vancouver, Canada, SIS professionals intervened in over 300 overdoses during the site’s first five years of operation. Amber A. Leary, Note, *A Safe Harbor in the Opioid Crisis: How the Federal Government Should Allow States to Legislate for Safe Injection Facilities in Light of the Opioid Public Health Emergency*, 84 Brook. L. Rev. 635, 660 (2019). The site also saw “no evidence of increases in drug-related loitering, drug dealing, or petty crimes” near the facility. *Id.* Numerous studies from other countries report that no deaths have occurred at

⁴⁴ <https://www.jhsph.edu/news/news-releases/2019/safe-consumption-spaces-would-be-welcomed-by-high-risk-opioid-users.html>.

safe injection sites. *Id.*; *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, *supra*, at 20.

Like Philadelphia, the states and localities in the United States that are considering SISs contain densely populated urban areas where public injections frequently occur due to elevated rates of homelessness. The New York City Department of Health and Mental Hygiene investigated both the feasibility and potential benefits of creating SISs, paying special attention to “neighborhood-specific estimates” for overdose deaths given the “variation in mortality among different neighborhoods.” *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*, *supra*, at 33. In New York City, people who are homeless die from overdoses at more than six times the rate of the general population. *Id.* 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-saving benefits and cost savings. *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*, 29 *Abell Rep.* 11 (2017).⁴⁵ A Johns Hopkins-led study therefore urged opening two

⁴⁵ <https://www.abell.org/sites/default/files/files/Safe%20Drug%20Consumption%20Spaces%20final.pdf>.

SISs based on these unique conditions, one on the east side of the city and one on the west side, to maximize accessibility. *Id.* Additionally, many states—including California, Colorado, Maryland, Maine, Massachusetts, New Jersey, Vermont, and Washington—have introduced bills in their state legislatures to create safe consumption sites based on their track record of success elsewhere in the world.⁴⁶

As these examples demonstrate, solutions to the opioid crisis—including ones targeted at reducing deaths from fentanyl—are highly localized. Evidence from international SISs show they are among the more promising interventions in urban areas to address widespread public injection and overdose. States that are home to metropolitan areas should be free to experiment with this potentially lifesaving intervention, as well as others, without fear that public health nonprofits or doctors in their jurisdictions will be subject to criminal prosecution.⁴⁷

⁴⁶ See, e.g., Assemb. B. 362, 2019 Reg. Sess. (Cal. 2019); S.B. 18-040, 71st Gen. Assemb. (Co. 2018); Leg. Doc. 949, 129th Leg., First Reg. Sess. (Me. 2019); H.B. 139, 2019 Reg. Sess. (Md. 2019); S.B. 1081, 191st Gen. Court (Mass. 2018); S.B. 3293, 218th Leg. (N.J. 2019); S.B. 107, 2017 Gen. Assemb. (Vt. 2017); S.B. 5380, 2019 Legis., Reg. Sess. (Wash. 2019).

⁴⁷ The U.S. Attorney for Northern California threatened legal action in response to California Assembly Bill No. 362. Shannon Lin, *US Attorney Threatens Legal Action if San Francisco Opens Supervised Injection Sites*, KQED (Mar. 4, 2019), <https://www.kqed.org/news/11804290/us-attorney-threatens-legal-action-if-san-francisco-opens-supervised-injection-sites>.

III. The Controlled Substances Act Should Not Be Interpreted To Prevent States From Embracing Innovative Public Health Solutions.

The *Amici* States can continue to experiment with promising and life-saving solutions like SISs only if federal law is read sensibly, to accord states their traditional power over public health policy. The CSA should not be read to prohibit medical interventions like SISs, when those interventions are affirmatively authorized or regulated by states.

Congress enacted Section 856 of the CSA to target crack houses, not community health clinics.

[I]t shall be unlawful to . . . 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)(2); *United States v. Safehouse*, 408 F. Supp. 3d 583, 613 (E.D. Pa. 2019) (noting that “the section-by-section description read: ‘Outlaws operation of houses or buildings, so-called “crack houses,” where “crack” cocaine and other drugs are manufactured and used.’” (quoting 132 Cong. Rec. 26474)). The statute originated from an “explosion of public concern about crack cocaine use in the mid-1980s” and was subsequently amended to prevent “the use of ‘ecstasy’ by young people at ‘rave’ parties.” Scott Burris et al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 St.

Louis U. L.J. 1089, 1117-18 (2009). The purpose of the statute was to aid law enforcement in arresting drug dealers and users—not to prohibit life-saving public health interventions. *See* 132 Cong. Rec. 26447 (daily ed. Sept 26, 1986) (“When police raid these crack houses, the dealers and users can easily dispose of the drugs, thus avoiding arrest. [Section 856] makes it a felony to operate such a house.” (statement of Sen. Chiles)).

Although Section 856 has been applied beyond crack houses, none of the cases cited by the United States applied to medical facilities with the sole purpose of preventing overdose deaths. U.S. Br. at 22-27. Indeed, unlike crack houses or raves, SISs do not distribute, manufacture, or encourage drug possession, but rather “serve a medical purpose by providing counseling to people with a substance use disorder, preventing overdoses, and stopping the use of dirty needles.” *Kreit, supra*, at 432. SISs thus do not present the identified dangers that Congress feared when Section 856 was enacted. *See* Office of Nat’l Drug Control Pol’y, *National Drug Control Strategy: A Nation Responds to Drug Use* 6 (1992) (identifying “open-air drug markets, crack houses, drug-exposed infants, abused and neglected children, gang violence, decaying neighborhoods, and drive-by shootings” as significant concerns surrounding the drug epidemic).⁴⁸ And contrary to the concern behind the

⁴⁸ <https://www.ncjrs.gov/pdffiles1/ondcp/134372.pdf>.

2003 amendments to the CSA targeting rave parties, SISs do not initiate young people “into the drug culture.” *See* Reducing Americans’ Vulnerability to Ecstasy Act of 2002: Hearing on H.R. 5519 Before the H. Subcomm. on Crime, Terrorism, and Homeland Sec. of the H. Comm. on the Judiciary, 107th Cong. 2 (2002). Instead, SISs may be able to provide potentially life-saving treatments for Americans experiencing the effects of a nationwide epidemic. *See* App. 684-85 (Stipulation of Facts) (describing services to be available at Safehouse, including medical services, wound care, on-site initiation of MAT, recovery counseling, HIV and Hepatitis C counseling, testing and treatment, referral to primary care, and referrals to social, legal, and housing services). To employ the federal government’s proposed application of Section 856 would be to misconstrue its intended reach.

SISs should thus be considered in the same vein as Good Samaritan laws, which also stem from the idea that public health objectives should sometimes defeat an interest in criminal prosecution. *See, e.g., Noble v. State*, 189 A.3d 807, 810 (Md. Ct. Spec. App. 2018). Possession of illicit substances is unquestionably a federal offense, *see* 21 U.S.C. § 844, yet the federal government does not claim that the scores of states with Good Samaritan immunity should cease prioritizing the public health of their citizens above criminal prosecutions. Quite to the contrary, the federal government encourages the enactment of these laws. *Carroll et al., supra*, at 18.

What is more, the federal government’s understanding of Section 856 would raise significant constitutional questions about Congress’s ability to intrude on state police powers. The federal government “can exercise only the powers granted to it” and “[f]or nearly two centuries it has been ‘clear’” that the federal government lacks “a police power.” *Bond v. United States*, 572 U.S. 844, 854 (2014) (“The States have broad authority to enact legislation for the public good—what we have often called a “police power.” (quoting *United States v. Lopez*, 514 U.S. 549, 567 (1995)).

As the Court explained in *Gonzales v. Oregon*, 546 U.S. 243 (2006), “[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States’ police powers.” *Id.* at 270; *see id.* (“[T]he structure and limitations of federalism . . . 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.” (internal quotation marks omitted)). SISs are medical facilities that provide critical interventions and fall comfortably within the State’s powers to regulate. *Id.* The CSA therefore should be read—as it has been in cases like *Gonzales*—to leave room for states to make judgments about how best to meet the medical needs of its residents. *See id.* (“the background principles of our federal system also belie the notion that Congress would use such an obscure grant of authority to regulate areas traditionally supervised by the States’ police power”). Stripping states of that authority raises concerns of constitutional dimension.

However, “[t]he court need not reach” constitutional questions regarding powers reserved to the states, but should instead construe the CSA to avoid constitutional doubt. *INS v. St. Cyr*, 533 U.S. 289, 300 (2001) (“[W]here an alternative interpretation of the statute is fairly possible, [courts] are obligated to construe the statute to avoid [constitutional] problems.” (internal quotation marks and citation omitted)); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (“[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.”). That is especially true where, as here, there is an alternative application that is more consistent with congressional purpose and statutory text, and respectful to state sovereignty.

CONCLUSION

The district court’s judgment should be affirmed.

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CERTIFICATE OF SERVICE

I certify that on July 6, 2020, 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
LOREN L. ALIKHAN

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/s/ Loren L. AliKhan
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