THE OVERDOSE CRISIS

Congress should

- repeal 21 U.S.C. Section 856, known as the "crack house statute";
- permit health care practitioners to prescribe methadone for medication-assisted treatment (MAT) of addiction to patients on an outpatient basis in lieu of their having to visit methadone clinics regulated by the Drug Enforcement Administration;
- repeal the so-called X-waiver required of licensed health care practitioners who wish to prescribe buprenorphine as MAT of addiction on an outpatient basis and eliminate restrictions on the number of patients they may treat;
- reschedule diamorphine from Schedule I to Schedule II of the Controlled Substances Act to allow for its use in MAT of addiction; and
- reclassify the opioid overdose antidote naloxone from prescription-only to over the counter.

States should

- repeal drug paraphernalia laws so that harm-reduction strategies, such as syringe services programs, can develop and function efficiently.

Fifty-one years after President Richard M. Nixon declared a “war on drugs,” overdose deaths from illicit drug use have climbed to record levels. Last November, the Centers for Disease Control and Prevention reported 100,000 overdose deaths for the 12-month period ending in April 2021, a 28.5 percent increase over the year before. Nearly 76,000 of those deaths were opioid related, and 83 percent of opioid-related deaths involved illicit fentanyl.

Fentanyl is a highly potent opioid—about 50 times stronger than heroin—that can easily cause overdoses, particularly if users don’t know if it is in their drug supply or how much. Over the past decade, drug traffickers have

increasingly preferred fentanyl because of its compact size. The smuggler's preference for higher potency drugs is a manifestation of the "iron law of prohibition," and it is almost the entire reason fentanyl has poisoned the American drug supply. The iron law of prohibition states that, all things being equal, as enforcement ramps up, smugglers prefer higher potency forms of a drug for the same reason those who sneak alcohol into a football game prefer hard alcohol in flasks to 12-packs of beer. The lethal logic of the iron law of prohibition means that we cannot enforce our way out of the opioid crisis. And if fentanyl smugglers bexcome somehow easy to catch, there's always carfentanil, which is about 100 times more potent than fentanyl and has already been showing up in America's drug supply.

In 2018, researchers at the Centers for Disease Control and Prevention and the University of Pittsburgh Graduate School of Public Health reported, "The U.S. drug overdose epidemic has inexorably been tracking along an exponential growth curve since at least 1979." A September 2019 report by the Joint Economic Committee of Congress places the trend's start in 1959. Policymakers from across the political spectrum have grown more receptive to adopting harm-reduction strategies that have worked for decades in Europe, Canada, Australia, and much of the developed world to reduce deaths and the spread of communicable diseases. The harm-reduction strategy is based on the realistic understanding that a drug-free society is unattainable and focuses nonjudgmentally on reducing the harms that come from using prohibited drugs obtained in the dangerous black market. Unfortunately, in the United States federal and state laws block harm-reduction organizations—many of which are privately funded nonprofit concerns—from fulfilling their missions.

The ultimate solution to the overdose crisis is to legalize and regulate currently illegal drugs, as was done after alcohol prohibition. "Legal" can mean many things, from prescriptions to over the counter (OTC). How that looks in practice can vary between states, just as with alcohol. Yet some sort of safe supply of opioids is needed to prevent deaths resulting from the adulteration of black-market drugs, which are most of them. In the meantime, government should get out of the way of harm-reduction organizations that want to save lives.

Safe Consumption Sites and the "Crack House" Statute

Safe consumption sites (also called "safe injection sites" and "overdose prevention sites") have established a track record of saving lives and preventing the spread of HIV, hepatitis, and other infectious diseases since the late 1980s. This harm-reduction strategy is used throughout Europe, Canada (which now has 38 sites), and Australia. In fact, the United States is an outlier among

developed countries—federal law, 21 U.S.C. Section 856, dubbed the "crack house statute," outlaws knowingly maintaining premises where controlled substances are used or stored.

Since 2014, a safe consumption site has been secretly saving lives in the United States while being monitored by researchers at an independent nonprofit research institute based in North Carolina. The researchers provide data in the peer-reviewed medical literature that they update regularly, while keeping the name and location of the site confidential. To avoid interdiction, the site is only able to operate part-time.

In July 2020, the researchers provided five years (2014–2019) of data in the *New England Journal of Medicine*. There were 10,514 injections through 2019, with 33 overdoses during the five-year period—all of which were reversed. They reported that the types of drugs changed over that period, with combinations of opioids and stimulants composing 5 percent of injections in 2014 and 60 percent of injections in 2019.

In January 2022, these researchers reported in the *Journal of General Internal Medicine* that facility users were 27 percent less likely to visit emergency departments, had 54 percent fewer emergency department visits, and were 32 percent less likely to be hospitalized. Those who were hospitalized spent 50 percent fewer nights in the hospital. Therefore, in addition to saving the lives of people who inject drugs, safe consumption sites can reduce stress on the health care system.

When a private, self-funded organization in Philadelphia sought, with the city council's endorsement, to open Safehouse in the city's Kensington district, it was thwarted by the Trump administration's Department of Justice (DOJ). Under the DOJ's interpretation of the statute, Safehouse was no different than a crack house operating under a different name. After Safehouse's principals lost in the Third Circuit, the Supreme Court refused to hear their case. In July 2021, defying federal law, the governor of Rhode Island signed a bill permitting privately funded safe consumption sites beginning in the spring of 2022. New York City opened two safe consumption sites in November 2021 and plans to open others. The California legislature is entertaining a bill to legalize safe consumption sites statewide starting in 2023. The Biden administration's DOJ is seeking a way to accommodate the demand for safe consumption sites when they have been held to violate 21 U.S.C. Section 856.

But selective nonenforcement is a tenuous thing for safe consumption organizations to depend on. Congress should repeal or amend the crack house statute. Short of outright repeal, the statute can be amended to explicitly exempt safe consumption sites that have clear medical and harm-reduction purposes and to get the federal government out of the way of state and local organizations that, unconditionally, want to save their neighbors' lives.

Medication-Assisted Treatment with Methadone

Researchers at Harvard University Medical School recently published comparative effectiveness data finding medication-assisted treatment with either methadone or buprenorphine the only addiction treatments "associated with reduced overdose and opioid-related morbidity." The study evaluated methadone and buprenorphine MAT against five other mutually exclusive treatment pathways: no treatment, inpatient detox or residential services, intensive behavioral health, naltrexone, and nonintensive behavioral health. Unfortunately, federal law prevents addiction therapists from using MAT to its full potential.

Even though doctors in Canada, the United Kingdom, and Australia have been prescribing their clinic patients methadone to take home and use as directed since the late 1960s, the Drug Enforcement Administration (DEA) places very severe restrictions on methadone treatment, regulating and licensing stationary clinics called narcotics treatment programs (NTPs). Under DEA rules, patients must visit the NTPs daily to take their methadone in the presence of designated NTP staff. These onerous requirements hinder patient compliance and reduce access to treatment. In some cases, patients are expected to travel several miles every day to receive their dose of methadone. Yet the DEA permits health care practitioners to prescribe take-home buprenorphine as MAT.

The DEA temporarily relaxed some of these regulations for the duration of the COVID-19 public health emergency, allowing "stable" patients a 28-day take-home supply of methadone—a tacit admission that it is possible to successfully administer a take-home methadone program. Research published in early 2021 showed no evidence of increased methadone diversion to the black market because of the relaxed rules.

A Boston-area pilot program in which primary care practitioners prescribed take-home methadone—reported in the *New England Journal of Medicine* in 2018—proved successful. Last year, the National Academies of Sciences, Engineering, and Medicine urged policymakers to allow primary care practitioners to prescribe take-home methadone to patients in their clinics.

Congress should enact legislation allowing health care practitioners to prescribe methadone to patients to take home, as was allowed during the public health emergency and is permitted when buprenorphine is used for MAT.

Medication-Assisted Treatment with Buprenorphine

The so-called X-waiver is part of the Drug Addiction Treatment Act of 2000. It requires doctors who want to prescribe buprenorphine for opioid use disorder to take an eight-hour training course. It is a needless requirement that is unique to buprenorphine. Physicians can freely prescribe hundreds of more dangerous drugs without supplemental training.

In the closing days of the Trump administration, the Department of Health and Human Services (HHS) announced that it was relaxing the X-waiver as an emergency action to address the worsening drug overdose rate. The action applied only to physicians and limited them to 30 patients at any given time. In late January 2021, the Biden administration rescinded the order.

In April 2021, the secretary of HHS announced new guidelines that again suspend the X-waiver requirement for physicians treating up to 30 patients within their states. The guidelines go a step further by also permitting physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives to use buprenorphine for MAT as well, without having to go through the ordeal of qualifying for an X-waiver on their narcotics prescribing license from the DEA. Providers who wish to take on more than 30 patients must go through the onerous waiver process.

The American Medical Association, the National Academies of Sciences, Engineering, and Medicine, and many addiction specialists have called for eliminating the X-waiver program entirely.

There has been bipartisan support for eliminating the X-waiver requirement for health care practitioners in previous sessions of Congress. Congress should seize the momentum from the new HHS guidance and end the X-waiver program for good, as well as the 30-patient cap on prescriptions.

Reschedule Diamorphine to Schedule II

Diamorphine is a semi-synthetic opioid that was developed in the 1890s as a slightly more potent form of morphine that takes effect more rapidly. It was manufactured by Bayer under the brand name Heroin. It is roughly two and a half times more potent than morphine, one-half as potent as legal hydromorphone (Dilaudid), and one-fiftieth the potency of legal fentanyl. It was fully banned in the United States in 1924 despite protests from the medical professional community and, pursuant to the Controlled Substances Act of 1970, is classified by the DEA as a Schedule I drug (highly addictive with no known medical use). Diamorphine remains on the formularies of many developed countries, including Switzerland, Germany, the UK, the Netherlands, and Canada.

Moving a drug from Schedule I to Schedule II is a form of "legalization," but for those concerned about having "legal heroin," it's an innocuous one. Fentanyl is a Schedule II drug that is prescribed by physicians thousands of times a day. Cocaine and methamphetamine are also Schedule II drugs. Both are more legal than heroin, which only researchers can possess legally. Moving a drug to Schedule II simply acknowledges that it has legitimate medical uses,

which heroin unquestionably does, either as a pain killer or as a useful treatment for opioid use disorder.

Although it might seem crazy to prescribe heroin to those who compulsively use heroin, that view misunderstands drug addiction and the dangers that users face from the black market. Many compulsive users of heroin spend their days searching for a fix and then experience great relief when they find it. That search-and-relief process can make the dependency even stronger. Additionally, users have no idea what is in black-market drugs. The heroin can be highly variable in strength and, as discussed, is often tainted with fentanyl, which can easily cause overdoses.

Moreover, legal access to a safe supply of heroin for compulsive users can help drug users do other things with their lives—things that might have been crowded out by the search-and-relief process of the black market. It becomes easier to attend counseling, keep a job, and associate positively with loved ones when a safe supply of heroin is available. Finding other sources of happiness is one of the best ways to help compulsive users.

Diamorphine has been used since the 1920s in the UK, and since the 1990s in Switzerland, Germany, and other European countries as a form of MAT for patients who have not responded well to methadone or buprenorphine MAT. Canada began heroin MAT pilot programs in the cities of Vancouver and Montreal in 2009. A 2011 Cochrane systematic review concluded:

> The available evidence suggests an added value of heroin prescribed alongside flexible doses of methadone for long-term, treatment refractory, opioid users, to reach a decrease in the use of illicit substances, involvement in criminal activity and incarceration, a possible reduction in mortality; and an increase in retention in treatment.

Congress should reschedule diamorphine to Schedule II, because it is less potent than several legal semi-synthetic and synthetic opioids, is used widely in developed countries for medicinal purposes, and can make a vital contribution to addiction treatment. Rescheduling will allow harm-reduction organizations to develop pilot diamorphine MAT programs and study their effectiveness as an addiction treatment tool.

Reclassify Naloxone to Over the Counter

The opioid overdose antidote naloxone is still classified by the Food and Drug Administration (FDA) as "prescription-only." States have developed workarounds to make it easier for patients to obtain the lifesaving drug without going to a doctor for a prescription. In many states, the state director of health is a licensed physician who issues a "standing order" and assumes responsibility

as the prescriber. In states where the director of health is not a licensed physician, pharmacists are granted authorization to prescribe naloxone. Therefore, in most states, patients can get naloxone by going up to the counter and asking the pharmacist. However, some states prohibit third parties from obtaining a prescription for another person. People in those states who wish to have naloxone available because they have a friend or relative who uses opioids cannot obtain it. Experience also shows that many pharmacists choose not to stock naloxone or participate in any distribution program. Some fear they are condoning or enabling opioid use. Furthermore, the stigma now attached to opioid use has deterred many patients from going up to the pharmacy counter and explaining to a pharmacist why they need naloxone.

To get around such obstacles, Australia and Italy have designated naloxone as a truly over-the-counter drug. People can discreetly buy it off the shelf and check out at the cash register. If naloxone were available OTC in the United States, it could be marketed in convenience stores and vending machines, making acquisition more accessible and private.

The FDA is on record since at least 2016 as believing that it is probably appropriate for naloxone to be rescheduled as OTC and has encouraged manufacturers to petition the FDA to that end. In January 2019, then FDA commissioner Scott Gottlieb announced that the FDA had even gone to the trouble of designing Drug Facts labels required of manufacturers for their products to be sold OTC, and had even tested those labels for "consumer comprehension" in front of focus groups. The commissioner stated in the announcement that this represented an unprecedented effort to facilitate and accelerate the reclassification of naloxone from prescription-only to OTC.

The FDA commissioner does not have to wait for manufacturers, who may lack the incentive, to request the move to OTC. Under FDA regulations, the FDA can undertake reclassification review at the request of "any interested person," or the commissioner may act unilaterally. The FDA should no longer wait for manufacturers to ask them to make this lifesaving drug more accessible to those in need. If all else fails, Congress should order the reclassification.

State Lawmakers Should Repeal Drug Paraphernalia Laws

State-level drug paraphernalia laws prevent people who use drugs from doing so safely. They prevent individuals from defending themselves against many of the risks of State-level drug paraphernalia laws prevent people who use drugs from doing so safely. They prevent individuals from defending themselves against many of the risks of using drugs obtained in the black market. Some paraphernalia laws deny drug users access to fentanyl test strips, a vital means of screening drugs for contamination with the dangerous opioid responsible

for the great majority of opioid-related overdose deaths. Some paraphernalia laws restrict people from purchasing or possessing clean needles and syringes. Drug paraphernalia laws also threaten to punish others involved in harm reduction, such as those attempting to help people who use illicit drugs. People risk incarceration if they give out or obtain clean needles and syringes, test strips to check for dangerous additives or contaminants in drugs obtained on the black market, or materials used to clean drug use equipment. Several paraphernalia laws prevent governmental and nongovernmental organizations from creating syringe services programs (SSPs), which some call "needle exchange" programs. These programs reduce the spread of HIV, hepatitis, other blood-borne infectious diseases, and soft tissue infections. More recently, they have proved helpful in reducing drug overdoses.

Federal law does not interfere with states' operating or permitting privately run SSPs. However, many state drug paraphernalia laws prohibit them. Most states have carve-outs in their drug paraphernalia laws that authorize SSPs. Many of those carve-outs place restrictions on their number, the entities allowed to operate them, and conditions they must meet. Alaska is the only state without drug paraphernalia laws.

The Centers for Disease Control and Prevention endorses and promotes the implementation of syringe services programs with guidance and, in some cases, provides financial assistance to local jurisdictions. The World Health Organization, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, and the American Psychiatric Association all support and encourage SSPs. The Substance Abuse and Mental Health Services Administration and the National Academies of Sciences, Engineering, and Medicine endorse SSPs. Former U.S. surgeon general Jerome Adams, who served during the Trump administration, gave many public presentations in support of SSPs.

State lawmakers should emulate Alaska and eliminate their states' drug paraphernalia laws so that harm-reduction organizations can effectively implement lifesaving measures.

Conclusion

For over 100 years, our drug laws surrounding opioids have pushed users to consume more dangerous drugs and have denied them the harm-reduction goods and programs that could not only save their lives but help them recover. It's time to treat opioid use disorder like alcoholism, with care rather than neglect and callousness.

Suggested Readings

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