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## The Misguided War on Painkillers

BY JEFFREY MIRON, PEDRO BRAGA SOARES, AND JEFFREY SINGER

he Centers for Disease Control and Prevention (CDC) estimates 75,673 people died of opioid overdoses in 2021 in the United States. Just two years before, in 2019, the CDC had recorded 49,860 opioidrelated deaths, which implies a staggering 50 percent increase over the two-year period. Between 1990 and 2020, the opioid overdose death rate rose almost twentyfold in the United States. Most observers assumed that this explosion resulted from a surge in opioid prescribing, spurred especially by Purdue Pharma's promotion of OxyContin, a slowrelease version of oxycodone that allegedly carries a lower risk of addiction. In response to the rise in overdoses, the United States has imposed substantial new restrictions on opioid prescribing.

But that widespread assumption is incorrect: the rise in opioid deaths did not result mainly from the increase in opioid prescribing. And whatever caused the initial increase in

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overdoses, new restrictions have exacerbated rather than ameliorated the upward trend. In addition, these new restrictions have harmed those who use opioids to alleviate pain, a legitimate and undervalued need, even precipitating suicides in many cases. The right policy response is to reduce restrictions on opioid prescribing, perhaps to the point of ending the requirement to get a prescription altogether.

### MORE PRESCRIBING, MORE DEATHS?

Beginning in the 1990s, physicians expanded opioid prescribing substantially. Doctors had previously prescribed opioid painkillers for short-term pain and for palliative care in terminally ill cancer patients but generally not for chronic conditions such as back pain, osteoarthritis, fibromyalgia, or headaches *Continued on page 6* 



PHILIPPE ÉTIENNE, French ambassador to the United States, participates in a discussion with Cato senior fellow JUSTIN LOGAN at a policy forum in December on how increasing European defense capabilities could reduce reliance on the United States.

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due to fear of patient addiction or abuse.

New research in the 1980s, however, suggested that long-term medical use of opioids posed little risk of addiction. This evidence led the medical community to treat chronic pain more aggressively starting in the 1990s. Pharmaceutical companies supported this change and argued that new slow-release opioids such as OxyContin had particularly low risks of addiction.

Critics say this optimism about long-term prescribing, combined with aggressive marketing campaigns, led to widespread abuse of prescription opioids followed by increased overdoses and deaths. These critics successfully pushed for additional restrictions on opioid prescribing.

But this "more prescribing, more deaths" perspective on the opioid crisis is flawed. To begin, numerous studies in subsequent decades have confirmed the 1980s findings that medical opioid use generates minimal addiction (or overdoses). (Addiction and dependence are often mistakenly conflated. Dependence refers to the physiological adaptation to a drug after prolonged use, such that abrupt cessation causes acute withdrawal. This is seen with many drugs, including beta blockers, anti-epileptics, anti-depressants, and opioids. Addiction, on the other hand, is defined as compulsive use despite negative consequences.) Survey data on drug use show that nonmedical use of pain relievers remained stable or declined from 2002 onward. Since 2011, rapidly increasing deaths from heroin and synthetic opioids such as fentanyl have driven up the opioid overdose death rate, even though high-dosage opioid prescriptions have fallen by almost half since 2006. And total drug overdoses have been rising in the United States since 1959, albeit at a slower rate but still suggesting that broader factors might be contributing to the recent spike in opioid deaths.

Perhaps most importantly, the policy

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# Regulations have potentially caused physicians to undertreat pain.

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implication of and increased restrictions from the view that more prescribing is the problem are fundamentally misguided.

### MORE RESTRICTIONS, MORE OVERDOSES

In response to the rising rate of opioid deaths, state and federal governments enacted numerous additional restrictions on opioid access, including state prescription drug monitoring programs (PDMPs), tighter federal guidelines on prescribing, and increased federal monitoring of prescribers. This approach assumes that reducing prescription access will reduce opioid use and overdoses overall.

Restricting access to prescription opioids, however, mainly pushes users to obtain prescription opioids in other ways: stealing them from a parent or friend's medicine cabinet, for example, or illicitly diverting them from pharmacies, or purchasing them in underground markets. Worse, increasing restrictions on the legal supply can push users to more-dangerous synthetic opioids, such as fentanyl, or banned opioids, such as heroin. In 2015, the CDC reported that declining availability of prescription opioids, and an abuse-deterrent reformulation of Oxy-Contin, had led nonmedical users of prescription opioids to switch to heroin. Many young heroin users say they transitioned from prescription opioids when those became scarce due to decreased physician willingness to prescribe them and increased police monitoring of the pill market; the

Drug Enforcement Administration (DEA) sets quotas on the manufacture of prescription opioids and has been ratcheting down those quotas year after year.

Shifting the supply underground increases the frequency of overdoses. The underground drug trade incentivizes trafficking in high-purity products to facilitate evasion, a phenomenon known as the Iron Law of Prohibition. Quality control is poor in underground markets because reliable suppliers cannot legally advertise their goods and because consumers cannot sue for damages caused by faulty or mislabeled products. Also, consumers cannot easily assess the purity of the products they consume, so they accidentally take high-dose drugs or versions laced with more potent opioids like fentanyl.

Consistent with this reasoning, through 2012, natural or semisynthetic opioids such as OxyContin and Vicodin accounted for more than half of opioid deaths. Since 2010, heroin and synthetic opioids such as fentanyl have accounted for a growing share of deaths, with nearly 80 percent attributed to these two drug categories in 2020.

Abundant evidence confirms that increased restrictions have had adverse impacts. State PDMPs are now in effect in all states except Missouri. These programs require doctors who prescribe opioids (and other controlled substances) to enter these prescriptions in a database that allows or requires other prescribers to check a patient's history before writing prescriptions. The goal is to identify high-risk prescribing patterns and so-called doctor shopping.

A recent paper finds that PDMPs indeed curtail consumption of prescription opioids, but users cut off from opioid prescriptions partially switch to heroin as a substitute, fully offsetting the reductions in hospitalizations and deaths from the decline in prescription opioids. Other studies suggest that PDMPs might have even increased overdoses and heroin-related crime.

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Relatedly, federal and state crackdowns on "pill mills," networks of doctors and pain clinics that prescribe high quantities of opioids, have further reduced the availability of prescription opioids. In 2011, for example, Florida banned pain management clinics from dispensing drugs and required extensive medical examinations before and after prescribing opioids for chronic pain. In 2017, the Department of Justice created the Opioid Fraud and Abuse Detection Unit to increase monitoring of physicians and pharmacies deemed to be dispensing "disproportionately large amounts of opioids." Media coverage of these crackdowns has increased physicians' fears of disciplinary action or prosecution, reducing opioid prescribing. Surveys indicate that these regulations have decreased physicians' willingness to prescribe opioids, potentially causing them to undertreat pain. Public pressure also led Purdue Pharmaceuticals to introduce an abuse-deterrent version of OxyContin in 2010. This reformulation, which completely replaced previous versions, makes the pill hard to crush or dissolve. As a result, opioid abusers could not access the full oxycodone content of pills by snorting or injecting them, causing many to turn to heroin. The reformulation of OxyContin led to an estimated one-to-one substitution of heroin overdoses for pharmaceutical opioid overdoses, so deaths did not decrease as a result.

In 2018, Congress passed the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), which increased federal assistance for state PDMPs, expanded access to opioid-use-disorder treatment, expanded efforts to identify overprescribing, and granted funding to hospitals that limit the use of prescription opioids. The act's expansion of opioid-use-disorder treatment was a positive step, but its attempts to limit prescribing again pushed users to illicit opioids, offsetting the effects of reduced

The overdose risk of increased heroin use far outweighs that of prescription opioids.

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access to prescription opioids. And this federal monitoring of prescribers likely contributes to undertreatment of pain by exacerbating fear of regulatory sanctions.

Proponents of opioid-prescribing regulations argue that while decreased prescribing may harm people who switch to more dangerous drugs, it will also reduce creation of new addicts by limiting exposure to opioids. But, as even National Institute on Drug Abuse Director Nora Volkow concedes, addiction occurs in only a small percentage of patients exposed to opioids. Moreover, so long as heroin is illegal, the overdose risk of increased heroin use far outweighs that of prescription opioids. In 2019, roughly 10 times as many people had used nonheroin opioids than heroin in the past year, yet overdoses from heroin and nonheroin opioids were approximately equal. Furthermore, a smaller share of prescription users would switch to heroin if they had easy access to prescription opioids. Troublingly, an increasing number of nonmedical drug users are starting with heroin. Research shows that among heroin addicts admitted for rehab in 2015, 33.3 percent stated that their drug use started with heroin, compared with 8.7 percent in a survey taken 10 years earlier. And if reducing access to opioids restricts the creation of new addicts, we should see deaths from other opioids and heroin decrease as prescription opioid deaths and misuse rates fall, even with a lag. The data, however, show a persistent decline in overdose deaths from prescription opioids alone (not mixed with other substances) since 2011.

### HARM REDUCTION MEASURES HINDERED BY REGULATION

An important component of government limits on prescribing includes restrictions on treating opioid use disorder with opioid replacements such as methadone and buprenorphine. Because of cumbersome regulation, only 5 percent of physicians are licensed to prescribe buprenorphine, and few licensed prescribers treat the maximum permitted number of patients. Surveys of physicians indicate that the main impediments to buprenorphine prescribing include a lack of knowledge about how to acquire a DEA license and fear of buprenorphine diversion. The scarcity of buprenorphine and methadone treatment may have pushed opioid users to underground markets, thereby increasing overdoses.

In fact, recent research suggests that, on average, adding one extra regulation for physical facility management—a category that includes requirements on facility cleanliness, layout, and number of resting rooms—to opioid treatment programs at the state level is associated with an increase of 1.31 opioid-related deaths per 100,000 people. Restrictions on opioid maintenance contradict decades of evidence that shows medically assisted treatments using buprenorphine and methadone mitigate heroin and opioid dependence, reduce drug overdose deaths, and decrease the mortality rate from opioid use. A comparative study of six different treatment pathways for opioid use disorder shows that only treatment with buprenorphine and methadone is associated with reduced risk of overdose. The U.S. Code of Federal Regulations also acknowledges that the use of methadone "has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts."

Evidence from other countries also suggests that increased legal access to replacement opioids reduces deaths and improves health outcomes, such as lower HIV infection rates. In the United Kingdom, Germany, Switzerland, and Canada, physicians can prescribe heroin for the treatment of severe dependence on heroin and other opioids, which has led to positive therapeutic outcomes and reduced illicit heroin use in these countries. In 1995, France allowed physicians to prescribe buprenorphine for maintenance treatment without patient caps or special licensing requirements, leading to a fivefold reduction in heroin deaths and an estimated 3,900 lives saved. In Hong Kong, early programs in the 1970s to expand access to medically assisted treatments for opioid dependence were linked to a low prevalence of HIV among drug users decades later.

Safe consumption sites, which allow users of opioids and other drugs to access clean needles in a supervised and controlled setting, have become common in cities across Europe and Canada. The sites reduce the use of contaminated needles and the pressure to consume drugs in a solitary or unfamiliar setting. Opponents fear that such sites will increase drug use, but safe injection sites are associated with lower overdose mortality, fewer ambulance calls for treating overdoses, and a decrease in HIV infections. Yet such sites

Prohibition is unlikely to succeed.

remain illegal under federal law. Some local governments have authorized such sites, but they still rely on lack of federal enforcement to keep operating.

#### **POLICY IMPLICATIONS**

A simple first step toward decreasing the risks associated with the consumption of opioids is to ensure legal access to harm reduction treatments. For example, the federal government could end or at leastdecrease the restrictive regulation of methadone and buprenorphine and even morphine- or heroin-maintenance treatment for opioid dependence and remove rules that limit prescribing for that purpose. A concrete proposal with bipartisan support would end the DEA X-waiver requirement, which makes it harder for physicians to prescribe buprenorphine to outpatients. Federal and state governments could also end the war on pill mills. Pain patients are the unintended casualties in this war, as it intimidates health care practitioners into underprescribing pain killers. Safe consumption sites could be made legal under federal and state law.

In addition, the United States should consider making all opioids more legal by shifting them to less regulated schedules of the Controlled Substances Act or even to over-thecounter status. In the most radical case, opioids would be legally available for purchase by adults without a prescription. While modest reforms to regulation can decrease the prevalence of underground opioid consumption, outright legalization would eliminate the underground market. Individuals who choose to purchase and consume opioids would have access to labeled products and proper advice, reducing the dangers of use. In our view, this would counteract the recent increase in opioid overdose deaths.

Beyond any implications for overdose deaths, advocates of restrictions on legal access to opioids should consider all their costs and benefits. Prohibition is unlikely to succeed in preventing individuals from using drugs or opioids. While increased opioid access may heighten the risk of opioid dependence, prescribing them also improves the quality of life for patients who suffer severe or chronic pain. We have focused here on overdose deaths, but a complete analysis would also suggest that the harms of regulation outweigh the risk of increasing opioid dependence.

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top spot, followed by New Zealand, Denmark, Estonia, and Ireland. The United States has seen its scores decline, having ranked 7th in 2008 but falling to 15th place in this year's report, tied with Germany and Japan.

The correlation between personal freedom and economic freedom is strong, but sometimes there is a gap where a country does notably better on one than the other. Singapore, for example, has long been noted for its robustly free-market economic policies, ranking 2nd in economic freedom, but an authoritarian political structure with little respect for civil liberties places the island city-state much further down, in 88th place, for personal freedom. On the other hand, Sweden was ranked 1st in the personal freedom category but 37th for economic freedom.

The data behind the scores in the *Human* Freedom Index are potentially useful for a wide range of research. They can be used to study the correlation between different

kinds of freedom, as a way to track the increase or decrease of freedoms over time, to study the correlation between freedom and well-being metrics (such as income or reported happiness), and to tease out hidden trends that indicate whether certain kinds of freedom are more conducive to the spread of other freedoms.

THE HUMAN FREEDOM INDEX, INCLUDING THE FULL REPORT AND DOWNLOADABLE DATA SETS, CAN BE FOUND AT CATO.ORG/HUMAN-FREEDOM-INDEX/2021.