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# EVALUATING PUBLIC POLICY RESPONSES TO OPIOID ABUSE AND MARYLAND'S PROPOSED AND EXISTING INITIATIVES

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## INTRODUCTION

If you open a local newspaper or watch the evening news, you'll be hard pressed to find a state in the union that's not struggling with opioid abuse—and trying to implement policies to solve it. Drug overdose deaths are on the rise and opioids are largely to blame. Opioids include illicit drugs like heroin, but also powerful legal painkillers such as oxycodone, hydrocodone, morphine, and fentanyl, among others.

The rate of fatal drug overdoses in the United States is now higher than deaths from car accidents, firearms, and suicides.[1] Overdose deaths involving opioids increased 200 percent between 2000 and 2014.[2] Overall, opioids were a factor in 63.1 percent of the 52,404 fatal overdoses that occurred in 2015, though many involved other drugs as well.[3] While alcohol, marijuana, and cocaine abuse are all more common than heroin abuse, and most people who are prescribed opioid painkillers do not become addicted or misuse them, the overdose rate demonstrates what an alarming problem opioid abuse has become. Policymakers are increasingly determined to act and address it.

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One study placed the total societal cost for prescription opioid abuse at $55.7 billion for one year.[4] When the negatives associated with illicit drug abuse are also considered, the overall costs for opioid addiction and misuse are likely significantly higher. There are also costs involved with trying to solve the problem, both in direct expenditures and unintended consequences for pain sufferers. The epidemic's far-reaching effect on multiple policy areas, primarily health and criminal justice, further complicates political responses. In addition, because the problem involves alleged abuse of both prescription pain medication and illegal drugs, it requires coordinated responses from numerous public agencies and private entities.

As is happening in other state governments, Maryland lawmakers are looking for ways to address the issue at home. They have implemented some reforms and are considering several others. Examining Maryland's action on opioid use and abuse to date, and how well it reflects historical lessons and best practices, provides an opportunity to assess whether the state's response will succeed and if it can or should be replicated elsewhere.

## ILLICIT DRUG ABUSE

Heroin is a Schedule I controlled substance, and has no accepted medical use. It is typically injected, but is also snorted or smoked, and works by binding to the opioid receptors in the brain that control feelings of pain and pleasure.

Both heroin use and heroin-related overdoses have increased in recent years. The United Nations reported about one million heroin users in the United States as of 2014—almost three times as many as 2003.[5] During the same time, heroin deaths have skyrocketed. The National Institute on Drug Abuse reported a 6.2-fold increase in heroin overdose deaths from 2002 to 2015.[6] In addition to the obvious harm caused by fatal overdoses, heroin use is associated with a variety of negative health effects such as collapsed veins, damage to the heart and lungs, and liver or kidney disease, which all place added strain on health care systems. Moreover, even though most people who misuse prescription opioids do not progress to heroin use, nearly 80 percent of heroin users reported misusing prescription opioids at some point prior to using heroin.[7]

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It's also impossible not to consider heroin use within the broader context of the war on drugs—an entrenched nationwide policy dating to the Nixon administration. The aggressive campaign to combat drug abuse has used paramilitary style police raids and lengthy prison sentences that have failed to produce significant results. Instead, it has created a host of other social and economic ills. Much of the crime and devastation associated with illegal drug use is a consequence of prohibitive policies.[8] Similar effects were observed during alcohol Prohibition during the 1920s, when the homicide rate increased from 6 per 100,000 before Prohibition to almost 10 per 100,000 by the time it was repealed in 1933, and organized crime fueled by black-market alcohol sales took off.[9] [10] History reinforces the need to look at growing heroin use as a health problem rather than simply as a criminal justice issue.

## PRESCRIPTION OPIOID ABUSE

The most powerful and effective painkillers—opioids—are typically those derived from the opium plant or their synthetic counterparts, and are potentially addictive. Unlike heroin, the growth trend for deaths associated with prescription opioid abuse has seemingly flatlined, and even declined slightly from the 2011 peak.[11]

Many of those abusing opioids never intended to do so, which is why solutions are not easy to come by. With 9 million to 12 million Americans suffering chronic pain—many of them combat veterans—and as many as 100 million Americans suffering from pain at some point in a given year, there are legitimate reasons for widespread use of opioid medications. There is also a case to be made that the fear of causing an addiction or being punished by law enforcement has resulted in doctors under-prescribing opioid painkillers. There is even a word for this phenomenon: opiophobia.[12] Balancing the competing interests of treating patients with chronic or severe pain and reducing overdose deaths and drug abuse is understandably difficult for doctors.

Some who start taking opioids with a prescription to treat a legitimate condition become addicted, while others sell some or all of their prescribed medication on the black market for a lucrative return. Unfortunately, policies that seek to restrict access to prescription opioids can further compound the problem by driving addicts to heroin and the even more dangerous world of illegal substance abuse as an alternative. Instead of simply turning away those seeking prescription drugs to feed their addiction, the better alternative is to treat addicts in a safe and controlled environment and wean them from their reliance on prescription painkillers.

## TREATING OPIOID ADDICTION

In 2002 the Food and Drug Administration (FDA) approved the use of buprenorphine, in addition to the name brand drug Suboxone, as a way to medically treat opioid addiction. Buprenorphine is a partial opioid agonist, which means it stimulates the opioid receptors, but because Suboxone combines bupreorphine with naloxone (an opiate blocker), it largely prevents the patient from getting high.

Therefore, it doesn't lead to tolerance, an ever-growing need for higher doses, or addiction.

Medication-based treatment of opioid addiction works. A U.K.-based study found that patients treated with medication were half as likely to die from an overdose within four years as those treated only with counseling.[13] Similar findings were reported in Australia, where opioid-addicted patients leaving prison saw their risk of overdose death reduced by 75 percent with pharmacological treatment.[14]

Unfortunately, the best approach for treating opioid addiction has long been underutilized.[15] There's a stigma to treating addiction with pharmacology that does not exist for other medical interventions, and confusion between physical dependence and addiction often muddies the waters.[16] Relying on an external source of opioids as a solution to prevent withdrawal and physical dependence is different than addiction where uncontrollable cravings lead to destructive behavior. Only the latter is a legitimate issue of public health and safety.

Other factors identified as contributing to underuse of opioid painkillers for chronic sufferers and others in need include limited availability, lack of behavioral health services support such as abuse counseling and mental health services, and concerns about reimbursement.[17] These problems can be mitigated, if not resolved, through creative public policy solutions. Alternatively, a continued pursuit of aggressive drug war policies, which make buprenorphine harder to acquire, will continue to cause additional death, disease, and crime.[18]

Adding to the problem is the behavior of Reckitt-Benckiser, Suboxone's manufacturer. When its patent for Suboxone tablets expired in 2009, the company transitioned away from the tablet form of the drug to filmstrips, which are patent-protected until 2024. The company also engaged in a self-serving campaign to paint the tablet version, which they enthusiastically sold when it was under monopoly protection, as dangerous to children in an effort to force regulators to prevent competition from other tablets potentially entering the market.

Based on this behavior, the FDA referred Reckitt-Benckiser to the Federal Trade Commission (FTC) for investigation, and a coalition of 42 attorneys general are suing the company for anticompetitive behavior. George Jepsen, the attorney general of Connecticut, observed: "The circumstances alleged in this case are particularly egregious in that, in the midst of an epidemic of opioid abuse and addiction…consumers and taxpayers have had to pay more for a drug that may help to mitigate some of the problem."

U.S. Senator Ed Markey of Massachusetts wrote in a letter that the manufacturer has "significantly impeded the FTC investigation by attempting to deny the FTC access to thousands of pages of documents that are integral to the investigation."[19]

Ironically, the filmstrips have been proven riskier and less effective than the tablets. For example, they are easier to smuggle into prisons as contraband and pose a greater threat of diversion.[20] And Suboxone is available in fewer dosage amounts than alternatives, making it harder to customize treatment plans based on individual patient needs.

Thanks to the large scope of the federal Medicaid program, the government's purchasing power gives it significant say in the market success or failure of drug treatments. Convincing officials to keep Suboxone Film on the preferred drug list by demonizing potential tablet competitors would perhaps have been a smart business strategy if they had not been caught, but is clearly bad for patients who would benefit from greater competition, as well as the communities that suffer when opioid addiction goes untreated.

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The continued preference for Suboxone in some states is preventing market competition that leads to the emergence of alternatives that are less vulnerable to abuse. In 2002, when treatments for opioid addiction were first emerging and underutilized, and Suboxone's makers could have worked with medical professionals to expand access and help solve an emerging health crisis, they instead chose to manipulate the intellectual property system to extend their exclusive control over the market. Both patients and taxpayers have suffered as a result.

## COMPARING POLICY RESPONSES

The predominant policy responses to the opioid abuse problem tend to fall within a narrow range of approaches. They either focus on tightening controls over access to opioids and punishing illegal drug users, or on expanding access to treatment programs for addicts. Often the two are presented hand in hand, though only one is actually beneficial. The evidence shows that attempting to control supply and fighting an aggressive war on drugs does not work, while treating addicts has demonstrated results.

Policies that push more consumers seeking pain relief into the black market only exacerbate the problem. Being at the forefront of the war on drugs, the Drug Enforcement Administration (DEA) has made it risky for doctors to treat pain.[21] New reporting requirements after the Nixon era convinced many doctors to stop prescribing painkillers,

such as when the DEA sent armed men after Ronald Blum, associate director of New York University's Kaplan Comprehensive Cancer Center, for not filling out a form correctly.

The DEA later shifted from focusing primarily on illegal black market drugs after facing heavy criticism from Congress in 1999 for failing to provide any "measurable proof" that its efforts to reduce the illegal drug supply were working.[22] The Controlled Substances Act empowered the agency to regulate all pharmaceuticals, and following their Congressional rebuke the DEA began listing pain medication like OxyContin alongside drugs like heroin or cocaine as serious threats in need of DEA action, and manipulated statistics to make it appear that OxyContin was a factor in more deaths than was really the case.[23] Overall, the new campaign against "diversion" of prescription pain medication was based largely on alarmist media coverage, misleading analysis, and political overreaction. Based on current trends, the DEA's approach has also clearly accomplished little.

Prosecution of doctors for opioid deaths is not unusual, and is often done without consultation with state medical boards before indictment.[24] Dr. Frank Fisher, for instance, was charged by the California state attorney general's office with drug trafficking and murder when five of his patients treated with opioid pain relievers died. Only after five months in prison and the loss of his home and medical practice was it discovered that the patients died from other medical illnesses or accidents and not from the pain relievers he prescribed. Dr. Fisher believes he was targeted for prescribing high-dose opioids to low-income pain sufferers, who he said then suffered when other doctors were too scared to treat them.[25]

**While bad actors no doubt exist and need to be policed, the heavy focus on punishing suppliers will inevitably ensnare those acting in good faith to treat pain and scare away others from doing so in the future.**

Given this environment, it is little wonder that the Association of American Physicians and Surgeons once warned: "If you're thinking about getting into pain management using opioids as appropriate—DON'T. Forget what you learned in medical school—drug agents now set medical standards. Or if you do, first discuss the risks with your family."[26]

Unfortunately, past mistakes are being repeated. The Centers for Disease Control (CDC) issued guidelines in March 2016 aimed at reducing use of opioids for treating chronic pain.[27] Reports have since indicated patients are losing access to their medications, even those who have successfully used opioids for decades without becoming addicted or misusing their prescriptions. The DEA is also still pursuing an aggressive campaign targeting drug manufacturers, pharmacies, and doctors.[28] While bad actors no doubt exist and need to be policed, the heavy focus on punishing suppliers will inevitably ensnare those acting in good faith to treat pain and scare away others from doing so in the future. The DEA also reduced the amount of almost every Schedule II opiate and opioid medication to be manufactured by at least 25 percent.[29] Limiting the supply of medication that is already under-prescribed will lead to more suffering and higher medical costs.

## CASE STUDY: MARYLAND'S APPROACH

Maryland Governor Larry Hogan campaigned on addressing the growing heroin problem, citing the loss of his cousin to overdose as motivation. After winning election, he quickly established a Heroin and Opioid Emergency Task Force to look at the problem. The committee's membership commendably featured not just the typical law enforcement voices, but also a variety of medical professionals.

In March 2017, he signed an executive order declaring a state of emergency and promised to commit $50 million over the next five years to enforcement, prevention, and treatment.[30] Thus far, it is unclear what precisely this means. The executive order follows his January announcement of the 2017 Heroin and Opioid Prevention, Treatment, and Enforcement Initiative, which consists of several pieces of proposed legislation involving both new enforcement efforts and treatment programs. Assuming the legislative package is adopted, the initiative is likely to produce mixed results.

The initiative includes the Prescriber Limits Act, which would prevent more than seven days' worth of opioid painkillers from being prescribed during a patient's first visit. This sort of interference in medical practice has plagued drug policy in the past, serving only to reduce access to those in need while failing to significantly impact drug abuse. Dr. Patrice Harris, chairwoman of the American Medical Association's committee on opioid abuse, said, "Arbitrary pill limits or dosage limits are not the way to go. They are one-size-fits-all, blunt approaches."[31]

The Distribution of Opioids Resulting in Death Act similarly involves a drug war-style new felony charge for selling opioids that result in the death of a user. Laws like this are bad at reducing drug abuse or illegal sales, but good at filling prisons. The latter comes with heavy costs for the government, which will house these offenders, but also for communities that lose members of society who could otherwise be rehabilitated. This is a reversal from other recent policies, where Maryland prioritized health outcomes over outdated tough-on-crime attitudes, like the 2015 Good Samaritan Law that protected individuals reporting

an overdose of themselves or another from prosecution for drug violations. Finally, the Overdose Prevention Act would authorize collection of new overdose data and expand access to naloxone for overdose treatment, both of which should prove beneficial.

The administration has also enacted recommendations from its 2015 task force. These include the positive change of increasing the number of patients that a physician qualified to prescribe buprenorphine can treat, but also a registration and monitoring program for licensed providers that at best will force abusers to seek more dangerous alternatives, while reducing access for those with legitimate medical need. The Governor's proposed budget also includes $4 million in new spending to support those struggling with opioid addiction, and $1.3 billion for mental health and substance use disorders, including $159 million for existing non-Medicaid treatment programs.[32] These investments will lead to cost savings down the road, as treatment reduces illegal substance abuse and related crimes.

**"Arbitrary pill limits or dosage limits are not the way to go. They are one-size-fits-all, blunt approaches."** — DR. PATRICE HARRIS

Another change already paying dividends is the Pharmacy and Therapy (P&T) Committee's move to replace Suboxone Film on the Medicaid preferred drug list with Zubsolv, a more efficient and less easily smuggled buprenorphrine/naloxone tablet. The P&T Committee cited "extensive clinical and financial data to assist in the deliberations."[33] Due to its delivery method, Zubsolv requires 30 percent less of the active ingredient buprenorphine, which makes it less desirable for abuse. Its tablets are also more difficult to divert and smuggle into prisons. Six months after the change, the Department of Public Safety and Correctional Services reported "a decline in comparison to last year's figures" of Suboxone Film, which it described as "by far the most prevalent form of contraband found in Maryland State Correctional Facilities since the drug is easily concealed and easy to transfer to other mediums."[34]

## CONCLUSIONS

While overdose deaths involving prescription opioids have increased in recent years, they still represent only a fraction of overall prescriptions. Evidence even suggests that more Americans are still in need of pain treatment. Cracking down on prescription opioids will likely have little impact on overall opioid deaths and do great harm to the vast majority who need them. It can also backfire by funneling more abusers into the black market where drugs are stronger and deadlier. In contrast to drug war-style control efforts that create as many or more problems than they solve, a public health-minded approach that holistically treats opioid addicts is much more likely to produce positive results.

Governor Hogan has given heroin abuse his full attention—a necessity given its wide scope. He is commendably putting significant resources toward addressing the root problem of addiction. Unfortunately, some of the proposals represent a return to the 20th-century drug war mindset that focuses on symptoms, while ignoring that many of the ills associated with heroin abuse are themselves exacerbated by the decades-long war on drugs and its legacy.

Maryland's establishment of coordinated task forces to overcome bureaucratic barriers and mobilize resources for targeted interventions is commendable and should be replicated elsewhere. The switch made to a more efficient state-preferred buprenorphine treatment is just one example of this positive action, but it's an important one, which should be replicated by other states seeking commonsense steps towards progress. Maryland has also committed substantial funding for mental health treatment, a crucial step as federal funding for similar programs is expected to decline. Other states should look at expanding access to medication that can treat addiction, and consider how incentives created by other government programs like the Medicaid preferred drug lists may be contributing to the problem.

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