THE OPIOID CRISIS IN AMERICA
Domestic and International Dimensions

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Reducing barriers and getting creative

10 federal options to increase treatment access for opioid use disorder and reduce fatal overdoses

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BROOKINGS

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Executive summary

Opioid-related harms in the United States extend far beyond the death toll, but the recent change in the composition of these deaths is shocking. While deaths involving prescription opioids and heroin have stabilized (and may be on the decline), overdose deaths involving much more potent illicitly produced synthetic opioids like fentanyl have skyrocketed—from approximately 3,000 in 2013 to more than 30,000 in 2018 (CDC, 2020).

This paper highlights options for federal decisionmakers seeking to increase access to treatment for opioid use disorder (OUD) and reduce overdose deaths. This is not meant to imply that state and local decisionmakers do not have a significant role to play in these efforts; indeed, state-level Medicaid expansion is "the single most important measure to expand access to mental health and addiction treatment" (Pollack, 2015). Yet 14 states have still not taken this step (Kaiser Family Foundation, 2020).

Although most of these options focus on addressing barriers to treatment and reducing the probability that an overdose is fatal, the first two focus on improving data infrastructure in the U.S. so we have better information about the size of the problem and can get ahead of new threats. This paper does not systematically assess the costs and benefits of these options and it is not an exhaustive list of federal policy options in this space. Further, inclusion on this list should not be seen as a full-throated endorsement. The goal is to expand the menu of options discussed when federal officials have serious conversations about reducing opioid-related harms.

Federal decisionmakers could:

1. Reimagine and reinvest in the Arrestee Drug Abuse Monitoring program.
2. Support large-scale wastewater testing to detect the use of illicitly produced synthetic opioids and other substances.
3. Expand the number of insurers that cover evidence-based treatments.
4. Reduce barriers and increase incentives for practitioners to prescribe FDA-approved treatment medications.
5. Reduce barriers to providing methadone and buprenorphine to incarcerated individuals with OUD.
6. Make it harder for pharmaceutical companies to manipulate FDA processes.
7. Invest in clinical trials of medications not currently used in the U.S. for treatment.
8. Allow jurisdictions to conduct pilot studies of supervised drug consumption sites.
9. Support efforts to monitor drug consumption that don't depend on a physical location.
10. Increase access to naloxone.

Getting those who seek OUD treatment the services they need and reducing the probability that an overdose is fatal are not just about funding. There are laws, policies, and other barriers that make it harder to achieve these goals. If policymakers simply treat the current crisis like a typical drug epidemic and do not think creatively, we will likely condemn thousands of people to early deaths.

Introduction

Opioid-related harms in the United States extend far beyond the death toll, but the recent change in the composition of these deaths is shocking. While deaths involving prescription opioids and heroin have stabilized (and may be on the decline), overdose deaths involving the much more potent illicitly produced synthetic opioids like fentanyl have skyrocketed—from approximately 3,000 in 2013 to more than 30,000 in 2018 (CDC, 2020).[1] In many of these cases, those dying did not ask for synthetic opioids; it was mixed into the drug supply and sold as heroin or counterfeit pills by suppliers looking to cut costs. While there are some people who use opioids who now prefer synthetic opioids because they have built up a tolerance (Karamouzian et al., 2020), this is not a drug epidemic which is *spreading* because of demand (Pardo et al., 2019d).

An obvious approach for reducing opioid-related harms is increasing access to evidence-based treatment for opioid use disorder (OUD). Some examples include reducing barriers to prescribing treatment medications and lowering their costs. But even if these efforts are wildly successful, there will still be people who use drugs obtained on the street. Given that synthetic opioids increase overdose risk and that an overdose is much more likely to be fatal when people consume by themselves, it is also critical that we increase the number of episodes monitored in these markets and that the opioid overdose-reversal medication naloxone is readily available.

This paper discusses options for *federal* decisionmakers seeking to increase access to treatment for OUD and reduce the probability that a drug overdose becomes fatal.[2] This is not meant to imply that state and local decisionmakers do not have a significant role to play in these efforts; indeed, state-level Medicaid expansion is "the single most important measure to expand access to mental health and addiction treatment" (Pollack, 2015). Yet 14 states have still not taken this step (Kaiser Family Foundation, 2020). This emphasis is also not meant to imply that there is no role for drug prevention or supply reduction in reducing deaths from opioids, especially the synthetics (e.g., see Pardo et al., 2019c; Pardo et al., 2019d; Pardo & Reuter, this volume). Indeed, if innovative supply-side interventions can delay the entrenchment of synthetic opioids west of the Mississippi River, they could save thousands of lives over the next few years. The federal government's XPRIZE-type competition for developing new ways to detect fentanyl in international mail packages[3] is one example of the type of innovative approach needed, although the $1.5 million budgeted seems underwhelming given the scale of the problem we are confronting.

This paper is rooted in several collaborations (Kilmer et al., 2018; Caulkins et al., 2019; Kilmer & Pardo, 2019; Pardo et al., 2019d) and offers 10 ideas for federal decisionmakers to consider. It does not systematically assess the costs and benefits of these options and it is not an exhaustive list of federal policy options in this space. Further, the numeric order should not be interpreted as a priority ranking, and inclusion on this list should not be seen as a full-throated endorsement. The goal is to expand the menu of options discussed when federal officials have serious conversations about reducing opioid-related harms.

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[1] So far, deaths involving synthetic opioids have largely been concentrated east of the Mississippi River (Ciccarone et al., 2017; Pardo et al., 2019b; Zoorob, 2019), but they are becoming increasingly common in some areas on the West Coast (e.g., Allday & Fagan, 2019; Fleiz et al., 2019).

[2] While the focus of this paper is on opioids, many of the ideas presented could also be useful for understanding and addressing problems associated with other types of substance use.

[3] See the Opioid Detection Challenge: www.opioiddetectionchallenge.com

10 options for federal decisionmakers

The federal government has helped to massively expand access to OUD treatment over the past decade (largely through passage of the Mental Health Parity and Addiction Equity Act of 2008, the Affordable Care Act, the Comprehensive Addiction and Recovery Act, and the 21st Century Cures Act) and many argue it should provide even more funding to this end (see, for example, Haffajee & Frank, 2018). However, it is not clear what the optimal level of spending would be. We really don't know how many people are seeking treatment or are currently receiving it (National Academies of Science, Engineers, and Medicine, 2019) and not everyone who experiences an opioid use disorder needs treatment to stop using or reduce harms. There is also the uncomfortable fact that public and private funds are being used to pay for low-quality OUD treatment that can sometimes be more harmful than helpful (Lopez, 2019). That said, we do know there are sometimes waiting lists for evidence-based treatments and there is a shortage of methadone and buprenorphine providers for OUD in many parts of the country, especially in rural areas (President's Commission on Combatting Drug Addiction and the Opioid Crisis, 2017; U.S. Department of Health and Human Services, 2020).

Although most options discussed in this section focus on addressing barriers to treatment and reducing the probability that an overdose is fatal, the first two focus on improving our data infrastructure so we have better information about the size of the problem and can get ahead of new threats. Federal decisionmakers could:

1. Reimagine and reinvest in the Arrestee Drug Abuse Monitoring program.

We are now largely flying blind when it comes to tracking the number of people currently using opioids who meet clinical criteria for OUD. This makes it hard to determine whether public policy is changing the share of individuals with OUD, and among those, how many have received evidence-based treatment.[4] This lack of knowledge also makes it difficult to efficiently allocate resources to tackle these problems. While one commonly hears there are approximately 2 million individuals in the U.S. who experienced OUD in the past year (see for example: Substance Abuse and Mental Health Services Administration [SAMHSA], 2018; U.S. Department of Health and Human Services, 2020), this figure is too low. It is based on household surveys such as the National Survey on Drug Use and Health (NSDUH) that miss most heavy heroin users who would meet clinical criteria for OUD (Kilmer et al., 2014; Caulkins et al., 2015).[5] While data from the 2016 NSDUH suggest there were on the order of 200,000 people who used heroin on a daily or near-daily basis (Reuter et al., in progress), the national estimates RAND produced for the White House Office of National Drug Control Policy (ONDCP) put that figure closer to 1.6 million (Midgette et al., 2019).

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[4] But the data issues are not only with respect to tracking people who use opioids and may have OUD: we also have minimal information about the number of people currently receiving substance use disorder treatment and their outcomes. Indeed, in 2019 the National Academy of Sciences, Engineering, and Medicine concluded that we do not have rigorous national estimates of those receiving medications for OUD. This is becoming more difficult as more individuals seek medications outside of the specialty treatment sector which is largely covered by the Treatment Episode Data System and the National Survey of Substance Abuse Treatment Services (N-SSATS). Even with N-SSATS, which is especially useful for tracking how many people are in methadone treatment (but also includes limited information about other medications), it has become increasingly difficult for analysts to get information at the county level which can be useful for assessing treatment gaps and conducting policy analyses. Since SAMHSA is in the process of making the NSDUH with geographic identifiers available for researchers at Federal Statistical Research Data Centers, one could imagine SAMHSA could do something similar with the N-SSATS.

[5] While NSDUH is useful for understanding the number of people who use alcohol, tobacco, and cannabis, it is not very useful for understanding the consumption of more stigmatized substances like heroin, methamphetamine, and crack.

The RAND estimates were based on several data sources, but the most important dataset for these calculations was the Arrestee Drug Abuse Monitoring (ADAM) Program, which no longer exists. ADAM not only collected rich self-reported drug use data and market transaction information from jail inmates, it also included a voluntary urine test that most arrestees agreed to take after completing the interview.[6] The program was active in approximately 40 counties in the early 2000s (costing on the order of $10 million per year) and there were plans to expand it to 75 counties. Unfortunately, the Department of Justice (DOJ) stopped funding the program after 2003. Understanding the value of this data source, ONDCP was able to bring it back in 2007, although only with enough funding for 10 counties. Funding constraints reduced it to five counties in 2012 and, after 2013, ADAM was eliminated again.

Without the ADAM data, or something similar, it will be extremely difficult to credibly estimate the size of drug-using populations, and thus the total number of people with OUD, in the US.[7] There are other benefits of collecting these data as well. For example, the survey questions about the amount spent on illicit drugs were essential for estimating total spending on drugs, and thus, how much money was being earned by drug trafficking organizations (e.g., see Kilmer et al., 2010). Further, the urine test results could also be very useful for monitoring the consumption of novel drugs, such as fentanyl, that individuals may not even know they are using.

It would also be possible to revise the ADAM instrument to collect additional types of data. Obviously, adding questions about non-fatal overdoses and access to naloxone would be important for informing discussions about opioids, but the arrestee population needs a lot of help and has insights that extend far beyond drug policy. Another possibility would be to include rotating panels that cover other topics such as health status, health care utilization, housing and homelessness, police contacts, or firearms,[8] that could be sponsored by the relevant federal agencies.

2. Support large-scale wastewater testing to detect the use of synthetic opioids and other substances.[9]

Novel approaches to measuring drug consumption might be needed, especially given that many fentanyl analogs and other synthetic opioids quickly enter and exit markets (see, for example, MacDonald, 2020). As noted, users themselves might not know that they consumed a synthetic opioid, let alone be able to point to which compound was supplied. Wastewater testing is another approach for monitoring the spread of new psychoactive substances and for measuring consumption (Castiglioni, 2016). This technique, which is used in Europe and Australia—and, to a much lesser extent, in the United States—can supplement traditional epidemiological drug indicators, such as prevalence rates or overdoses. For example, wastewater analysis in Washington state found sharp increases in cannabis consumption after legalization (Burgard et al., 2019) and, in Oregon, it shows that higher concentrations of drug metabolites were found in municipalities that reported higher rates of drug use (Banta-Green et al., 2009). Cities in Europe have been developing and deploying this technique for decades, with demonstrated success in delivering near-real-time information about shifting use patterns in drug markets (Castiglioni, 2016). For example, results from one wastewater examination of eight cities in Europe found high correlations between results from tested water samples and various indicators of local drug markets, including the sales of pharmaceuticals and illicit drug

[6] Participating in the interview and testing did not affect their legal cases; it was for research purposes only.
[7] This is not meant to infer that everyone who uses heroin has an opioid use disorder.
[8] Indeed, at one point there was a module about the acquisition of and attitudes about firearms (Decker et al., 1997).
[9] Part of this section on wastewater testing is excerpted from the RAND Corporation book *The Future of Fentanyl and Other Synthetic Opioids* (Pardo et al., 2019d).

seizure records (Baz-Lomba et al., 2016). A 2018 report from Australia found that fentanyl consumption, although low to begin with, might have doubled outside of capital city jurisdictions from April 2017 to April 2018 (Australian Criminal Intelligence Commission, 2018).

The information used from wastewater testing could be part of an early-warning system to alert people who use drugs as well as health and safety workers when new substances have entered the local market. For example, in places that are not yet swamped with synthetic opioids, a spike in fentanyl levels could trigger public messaging about not using alone and increased deployment of naloxone and fentanyl testing strips (Green et al., 2020). For places that already have entrenched problems, this type of system could provide warnings when more potent synthetics have entered the market. In addition to informing communities and helping them prepare, data obtained from wastewater testing can be used to help evaluate the effectiveness of interventions targeting drug use.

3. Expand the number of insurers that cover evidence-based treatments.

Outlays for treatment are not the only way federal officials can increase treatment utilization and retention; they could also do more to prevent insurers from violating laws as they pertain to Food and Drug Administration (FDA)-approved medications for opioid use disorder (see text box). Together, the Mental Health Parity and Addiction Equity Act of 2008 and the Affordable Care Act (ACA) proscribe group health plans, group health insurance issuers, and individual health providers offering "mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits" (CMS, 2016).

But just because a law is on the books does not mean insurers are complying. Indeed, there are several examples of insurers flouting the laws, particularly using managed care techniques that are difficult to monitor, leading to continued morbidity and in some cases death (see, for example, Harris & Weber, 2018). Federal officials could invest more in working with states to monitor compliance and investigate violations. They could prioritize cases against such violators and/or provide assistance to state attorneys general or insurance commissioners pursuing these cases. Another approach would be for federal officials to hold back some Medicaid funds or exchange subsidies from those who are not complying.[10] Of course, before any coercive action like this is taken, serious thought must be given to the legality and potential drawbacks.

The types of OUD treatment covered by insurers also varies considerably. For example, as of 2017, only seven states and Washington, D.C. explicitly covered all FDA-approved drugs for OUD in their ACA plans; 14 states covered methadone for pain but not for OUD (Vuolo, 2019).[11] Indeed, there is an ongoing discussion about whether plans can legally exclude methadone coverage for OUD. Vuolo et al. (2019) note that, "While plans are not required by the ACA to cover methadone, recently, the federal government clarified that excluding coverage of methadone for OUD may violate federal laws, including the ACA's nondiscrimination provision and the Mental Health Parity and Addiction Equity Act of 2008." Given that we are in the middle

[10] For example, a new Government Accountability Office report (USGAO, 2020) recommends that, "The Administrator of CMS should determine the extent to which state Medicaid programs are in compliance with federal requirements to cover MAT medications in all formats and take actions to ensure compliance, as appropriate."

[11] Another example: It was traditionally difficult for states to use Medicaid funding for some types of inpatient substance use treatment, but an increasing number of states have recently sought and successfully received waivers to overcome this barrier (Musumeci et al., 2019). For more on the debate about the Institution for Mental Diseases (IMD) exclusion, see discussions in Bipartisan Policy Center (2019), Miller and Sandoe (2019), and Musumeci et al. (2019).

of a presidentially-declared public health emergency related to opioid use, the federal government could go further to encourage—and, where appropriate, require—payers to cover evidence-based treatments.[12]

A primer on FDA-approved medications for OUD

The FDA currently authorizes three medications for treating opioid use disorder: methadone, buprenorphine, and naltrexone. Methadone is an opioid agonist (i.e., it activates the opioid receptors in the brain) that is taken daily to reduce opioid cravings and opioid withdrawal while blunting or blocking the effects of other opioids (SAMHSA, 2019a). Buprenorphine is a partial agonist that also reduces withdrawal symptoms while blocking the effects of agonists like heroin. Unlike methadone, which for OUD is largely distributed through designated opioid treatment programs (OTPs), buprenorphine for OUD can also be prescribed by any provider with a Drug Enforcement Administration (DEA) waiver. As SAMHSA (2019b) notes, it also has some other advantages:

> *Buprenorphine's opioid effects increase with each dose until at moderate doses they level off, even with further dose increases. This "ceiling effect" lowers the risk of misuse, dependency, and side effects. Also, because of buprenorphine's long-acting agent, many patients may not have to take it every day.*

Both can also be prescribed for pain relief. Naltrexone, on the other hand, is a long-acting opioid antagonist that binds to opioid receptors without stimulating them.

Methadone and buprenorphine reduce the use of heroin (Mattick et al., 2009; Mattick et al., 2014) and substantially reduce the risk of mortality from overdose and other causes (Sordo et al., 2017; Ma et al., 2018). There is strong evidence suggesting that: 1) providing these medications is cost-effective in terms of quality-adjusted life years (see, e.g., Barnett and Hui, 2000); and 2) the social benefit of providing these medications exceeds the costs (see e.g., Cartwright, 2000). There is less research on the effect of naltrexone for opioid use disorder, but there is evidence indicating that the extended release formulation reduces the use of illicit opioids (Lee et al., 2017; Tanum et al., 2017).

4. Reduce barriers and increase incentives for practitioners to prescribe FDA-approved treatment medications.

While methadone can be prescribed for pain by any doctor and picked up at most pharmacies, methadone for OUD treatment is largely dispensed from 1,600 federally-licensed clinics, mainly in urban areas (Stein et al., 2015; Jones et al., 2019). Because of concerns about methadone being diverted, and the risks of overdose, OUD patients must initially visit the clinic

[12] There is also the separate issue of whether providers will even accept insurance for OUD treatment (see e.g., Geissler & Evans, 2020).

every day for a dose; only after a fixed period of compliance are they eligible for take-home doses.[13]

Given that some parts of the country are essentially experiencing a poisoning outbreak involving illicitly produced synthetic opioids like fentanyl (Pardo et al., 2019a), it may make sense to change regulations to remove these restrictions. In Canada and a number of European countries, methadone for OUD can be dispensed from pharmacies (Government of Canada, 2018). But doing this in the U.S. would not just require a change in regulation: physicians would also need to be educated about how prescribing methadone for pain differs from prescribing maintenance doses for those with OUD.

Unlike methadone, buprenorphine can be prescribed for OUD in the U.S. by physicians and other medical officials outside of opioid treatment programs; however, they must undergo an on-line training to receive a waiver to prescribe it for OUD (sometimes referred to as the "X waiver" because the DEA issues a license number that begins with an X). Practitioners are also limited to prescribing buprenorphine to a maximum number of patients, which may be 30, 100, or 275 depending on various eligibility criteria (SAMHSA, n.d.). Many have argued that eliminating this waiver (i.e., "X the X waiver"; Fiscella et al., 2019) or raising or eliminating the patient cap (see discussion in Knopf, 2019) could increase access and mainstream OUD treatment.

While this would surely increase access, it is unclear by how much. Indeed, most waivered physicians are not close to their patient cap, suggesting there are other issues limiting physician use (Stein et al., 2016; Thomas et al., 2017). In a survey of physicians focused these questions, Huhn and Dunn (2017) concluded:

> *[P]hysicians who have not applied for the buprenorphine prescription waiver expressed negative attitudes toward buprenorphine treatment, including concerns about diversion and managing numerous patient requests for [opioid maintenance treatment]. On the other hand, physicians who had received the waiver but were not prescribing to capacity expressed concern with practical barriers associated with buprenorphine treatment, such as appropriate reimbursement for services and actual time capacity.*

Let me be clear: these are not arguments against eliminating the waiver requirement or patient caps. But they reveal some insights into factors that may influence the overall impact of making it easier for practitioners to prescribe buprenorphine and/or methadone to more patients.

While waivers are required for buprenorphine prescription for OUD, the federal government could take several steps to increase the number of waivered practitioners, such as:

- Make federal funding for medical schools conditional upon making sure all eligible students are waivered within a certain period after graduation (C. Davis, personal communication).
- Require that physicians receiving Medicare-funded residency slots be waivered (Davis and Carr, 2019).
- Allow telemedicine providers to prescribe buprenorphine without performing an in-person examination (Haffajee & Frank, 2018).

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[13] The paper was written before the COVID-19 pandemic. In response to the emergency, federal agencies have temporarily eased some restrictions on in-person visits related to OUD medications. For more information see https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

- Deploy federally funded public health personnel to provide OUD medications (Haffajee & Frank, 2018).
- Continue enticing more medical professionals to work in underserved areas and specialize in addiction through loan forgiveness programs (Haffajee et al., 2018).

5. Reduce barriers to providing methadone and buprenorphine to incarcerated individuals with OUD.

Efforts targeting justice-involved individuals with OUD are particularly important: their risk of overdose is much higher immediately after leaving jail or prison because their tolerance is lower (see, for example, Binswanger et al., 2007). The risk is likely even higher in places swamped in illicitly produced synthetic opioids. One strategy for increasing the probability that those released from incarceration seek treatment is to begin treating them for OUD *while they are behind bars*. A recently published meta-analysis reported that those who received methadone while incarcerated were more likely to engage in community-based substance use treatment compared to those who did not receive methadone (Moore et al., 2019). Another recent systematic review by Sugarman et al. (2020) concluded that, "Evidence supports medication treatment administered throughout the period of criminal justice involvement as an effective method of improving post-release outcomes…."

There are a host of barriers to this continuity of care; most importantly, the vast majority of correctional institutions do not offer medication treatment for OUD to all inmates (Nunn et al., 2009; Vestal, 2016). There are laws requiring correctional institutions to provide these treatments to expecting mothers with OUD, and some facilities will use these drugs to detox individuals undergoing withdrawal when they are first incarcerated, but only for a short period. Thus, most individuals suffering from OUD behind bars are not given access to the best treatment available.

There are several possible reasons for the denial of evidence-based medication treatment. Despite the overwhelming research base supporting the value of their use, some decisionmakers still view methadone and buprenorphine as simply switching one addiction for another and believe abstinence-based treatment is the only approach. This is not unique to correctional settings. Some also have concerns about these drugs being diverted to other inmates, although there are recommended strategies for addressing this (SAMHSA, 2019c). That said, supervising the use of these drugs does require staff and some facilities argue that they don't have the resources.[14]

The federal Bureau of Prisons (BOP) has a policy of only allowing methadone to be used for detoxification or pain relief; inmates cannot receive it for ongoing OUD treatment unless they are pregnant. Thus, one way to increase utilization of these medications, and increase the probability they are used after release, is for the BOP to change this policy and expand access for all.[15] The Bureau has increased efforts to make sure some inmates with OUD receive a naltrexone shot before they leave, but there is far less evidence for this approach compared to the decades of research available for methadone. It also does not address those who need the medications while incarcerated.

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[14] For a point of comparison, Horn et al (2018) report: "The average (per patient) weekly cost of methadone maintenance treatment (MMT) is $115 and the total treatment cost for an average treatment episode is $689. These costs are generally in-line with non-jail-based MMT programs of similar size. Weekly cost estimates range from $86 to $185 depending on the size of the treatment facility, with larger programs exhibiting lower per-patient costs."

[15] The BOP was recently sued for not allowing methadone treatment for those with OUD under its supervision; the case is ongoing (Goonough, 2019).

Let's not forget that the federal system accounts for a very small share of those incarcerated in the U.S.; most inmates are held in state prisons and local jails. Still, the federal government could play a role in increasing access to methadone and buprenorphine in these settings. For example, the DEA could end its moratorium on mobile methadone units; these could serve jails and prisons that, for whatever reason, do not prescribe it to most individuals who would benefit. Such units could increase access for those unable to travel to a clinic each day or who are incarcerated. Jurisdictions in only six states and Puerto Rico offer mobile services, largely because the DEA has not granted any new licenses for mobile units since 2007 (Vestal, 2018). While McBournie et al (2019) report that the DEA Administrator indicated in 2018 that this moratorium would be lifted, as of July 2019 this had not happened.

Some jurisdictions are making progress when it comes to increasing access to OUD medications (see, for example, Connolly, 2019), and the National Institutes of Health should be applauded for allocating over $150 million to the Justice Community Opioid Innovation Network to better understand which approaches are most effective. Yet, more can be done to make sure inmates in jails and state prisons have access. Federal officials could steer additional resources toward setting up corrections-based programs, especially in places flooded with potent synthetic opioids. This is not meant to suggest there is not a place for abstinence-based treatment programs or self-help groups, but given the current public health emergency, increasing access to evidence-based medications must remain a top priority.

6. Make it harder for pharmaceutical companies to manipulate FDA processes.

The federal government could also do more to reduce the costs of these medications. For example, more could be done to prevent pharmaceutical companies from blocking competition when their marketing exclusivity ends. Indeed, to maintain market share and keep prices and profits inflated, some companies attempt to manipulate FDA processes and undercut efforts for other manufacturers to enter the market. There are multiple examples of this. One tactic is "product hopping," whereby a company shifts customers from one branded drug to a very similar drug with a longer patent life; this effectively extends the company's market exclusivity (Rai & Richman, 2018). Another is to secure orphan drug status from the FDA when it is really not warranted.

Haffajee and Frank (2020a; 2020b) argue that the manufacturer of branded Suboxone manipulated FDA processes to keep its market share. They offer a number of congressional actions that could make it harder for pharmaceutical companies to impede the entry of generic competitors and maintain elevated prices for drugs such as updating the Orphan Drug Act and the Hatch–Waxman Act.[16] They also note that Congress could reduce these abuses by modifying filing procedures for those submitting citizen petitions to the FDA, which have been shown to delay new drug entry (Carrier & Wander, 2012; Carrier & Minniti, 2016; Feldman & Wang, 2017). While the FDA is making progress on this front (see, for example, USFDA, 2019), more could be done.

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[16] Specifically, they argue: "Congress could also reform the Orphan Drug Act to prohibit 'grandfathering' of orphan drugs and require the FDA to base qualifying economic-recoupment determinations for orphan drugs on unbiased sales projections and to revoke designations if revenues exceed projected sales. To the FDA's credit, it intends soon to carefully review and possibly revoke the orphan designation for combination buprenorphine–naloxone, after previously revoking buprenorphine's orphan designation. To address product hopping, we suggest that Congress modernize the Hatch–Waxman Act, which provides the framework for FDA regulation of generic-drug entry and for extensions of market exclusivity that are granted when products are reformulated. For example, legislation could define a period before the loss of product exclusivity (e.g., 1 year) and a similar period after generic entry during which new formulations of the existing product wouldn't be granted market exclusivity. This policy would have reduced Reckitt Benckiser's incentive to introduce Suboxone film shortly before the exclusivity for its tablets expired" (Hafajee & Frank, 2020b).

7. Invest in clinical trials of medications not currently used in the U.S. for treatment.

The National Institute on Drug Abuse and the FDA are working together and with private companies to develop new drugs, formulations, and even vaccines to address opioid use disorder (Haffajee et al., 2018). While these efforts to spur innovation should continue, there are medications being used in other countries that are not currently being used in the U.S. for these purposes. For example, in at least seven countries, doctors can prescribe pharmaceutical-grade heroin (diamorphine) for those with OUD; this is commonly referred to as supervised-injectable heroin treatment or heroin-assisted treatment (HAT). HAT is not a first-line treatment and is generally targeted at those with a long use-history who have tried other treatments multiple times but are still using heroin (Strang et al., 2015). The main goals are to reduce patients' use of street-sourced heroin and help stabilize their lives (see, for example, Reuter, 2009).

There have been several randomized controlled-trials (RCTs) of HAT wherein those in the treatment group visit a clinic and inject pharmaceutical-grade heroin under medical supervision two or three times a day; they are also offered a take-home dose of methadone to help mitigate withdrawal symptoms. Those in the control group are given oral methadone. A recent review of nine RCTs found strong evidence that those randomly assigned to supervised HAT were much less likely to use street-based heroin and suggestive evidence that it reduced criminal activity and improved some health outcomes (Smart, 2018).[17] There was also strong evidence that HAT improved treatment retention; however, this result must be considered in the context that some individuals assigned to methadone dropped out of the trial once they realized they would not be receiving free heroin. Finally, while prescribed heroin is safer than what is obtained on the street, it does come with risks (that's why the injections in nearly all places are supervised).[18] The trials found that those assigned to heroin-assisted treatment were more likely to experience adverse medical consequences due to the study medication than those assigned to methadone.

As for the effect of HAT on overdose deaths, it should be noted that the RCTs typically lasted 12 months or less. Over this short period, there were relatively few deaths in the treatment or control groups, meaning these studies really didn't have the statistical power to detect a difference. Reviews of these studies find that HAT may have a protective effect against fatal overdoses, but not surprisingly, these results were not statistically significant (Smart, 2018). Rehm et al. (2005) followed a Swiss cohort of heroin-prescribed clients and found that this group had a higher mortality risk than the general population, but a lower risk compared to other opioid-using populations.

While heroin is a Schedule I drug in the U.S. that cannot be prescribed by doctors, it is legal to conduct RCTs of these substances (Kilmer et al., 2018; Pardo & Reuter, 2018). One reason for conducting trials in the U.S. is that it is unclear whether HAT would produce the same results in the U.S. as it does in Canada and Europe. Those places generally have stronger safety nets, providing more opportunities for patients to utilize additional services once their lives are less hectic. Indeed, by reducing their need to spend significant time finding money for heroin—sometimes risking victimization—this treatment can stabilize the lives of patients and those

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[17] The evidence was considered strong if: 1) all or almost all RCTs assessed the outcome; 2) more than two-thirds of the relevant studies found significant effects in the same direction; and 3) studies of comparable methodological quality did not find significant effects in an opposing direction. The evidence was considered suggestive if the second factor did not hold, but statistically insignificant findings generally supported the same direction of the effect.

[18] The UK started offering unsupervised prescription heroin in 1926 and while there is no national registry of patients receiving this treatment, they are currently estimated to be in the hundreds (Strang & Taylor, 2018).

who care about them, and make it easier for them to utilize health and other social services. Given that such safety nets are severely constrained in many parts of the U.S., one may hypothesize that some of the benefits for American patients may be attenuated.

On the other hand, synthetic opioids were not a problem in the countries where HAT trials were conducted. The Canadian trials, for example, were mostly conducted before fentanyl became an issue. Thus, if U.S. trials were able to get long-time heavy users with health problems to no longer use heroin contaminated with fentanyl, this treatment could significantly reduce the risk of overdose and other harms.[19] In places flooded with fentanyl, HAT may lead to more of an improvement in health outcomes compared to other places.

In the Netherlands and Switzerland, where heroin-assisted treatment has been used the most extensively, only around 10 percent of those receiving medication for OUD currently receive heroin (Kilmer et al., 2018; Nordt et al., 2019). Thus, some may argue that, "Even if the trials are positive and HAT is made more available, evidence from other countries shows that not a lot of people want it." Once again, heroin poisoned with synthetic opioids was not an issue in those places; the uptake rates could be much higher in U.S. settings.

Indeed, in places where synthetic opioids are entrenched, HAT may be such an attractive option that it could increase the number of people seeking medications for OUD. This is especially important to consider given evidence that once synthetics replace street heroin in a market, heroin usually doesn't come back (Pardo et al., 2019d; Taylor & Reuter, 2019). In such places, HAT may eventually be the only option for those who want to use heroin.

There are other novel treatments for OUD to consider. A less-studied option is to prescribe hydromorphone (Dilaudid). The Canadian SALOME trial found that injectable hydromorphone may be as effective as HAT at improving patient-level outcomes (Oviedo-Joekes et al., 2016).[20] Since hydromorphone is a Schedule II drug in the US, there would likely be fewer obstacles to studying this approach. One could easily imagine adding a hydromorphone arm (injectable or oral extended release) to any HAT trials in the U.S., or conducting separate trials that compare its effectiveness to FDA-approved medications. Much could also be learned from studies examining the effects of injectable methadone and slow-release morphine on OUD and overdose deaths in U.S. settings.

While such clinical trials would likely compare the use of these novel medications to more traditional ones, it may be best to think about how these novel treatments compare to the use of street-sourced opioids. With respect to heroin-assisted treatment, Kilmer et al. (2018) note:

> *Clearly, any relative benefits of HAT must be balanced with the risks associated with it. Still, the risk of such adverse events is likely to be much smaller for HAT than with the use of street-sourced heroin or synthetic opioids, whose potency and consistency are virtually unknown to consumers. Since the target audience is those who had already tried traditional treatments, the more relevant comparison may be HAT versus street-sourced opioids.*

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[19] A recently published study of people who inject drugs in Los Angeles and San Francisco found that, "[P]eople reporting perceived illicit fentanyl use had a greater odds of high frequency opioid use (adjusted odds ratio (aOR) = 2.36; 95% CI: 1.43–3.91; p = 0.001), high frequency injection (aOR = 1.84; 95% CI: 1.08–3.13; p = 0.03), and receptive syringe sharing (aOR = 2.16; 95% CI: 1.06–4.36; p = 0.03), as compared to people using heroin and other street drugs but not fentanyl" (Lambdin et al., 2019).

[20] Smart also noted: "Based on the pilot arm of the NAOMI trial, Marchand et al. (2011) found similar rates of client satisfaction among participants receiving injectable hydromorphone or injectable heroin, satisfaction levels which significantly exceeded those expressed by the oral methadone treatment group."

But the discussion must not remain limited to establishing efficacy in the U.S. If heroin-assisted treatment does prove effective, how would such programs be implemented in this country? Is there enough space in existing opioid treatment programs, or would new construction be needed? With HAT requiring multiple supervised injections each day, what would this mean for staffing? Would these novel treatments be allowed outside of OTPs?[21] There are many implementation questions that need to be considered and, once again, much could be learned by examining how these programs have rolled out in other countries.

8. Allow jurisdictions to conduct pilot studies of supervised drug consumption sites.

Supervised drug consumption sites (SCS) are places where people who use drugs can consume them in the presence of trained staff who monitor for overdose or risky injection practices, intervening when necessary. More than 150 sites have been implemented in at least 10 countries, and they are an important component of Canada's response to opioid-involved overdoses (Health Canada, 2018; Kilmer et al., 2018). SCS provide a safe and sanitary environment for those who inject drugs; some sites also have ventilated spaces for people who choose to smoke them. They offer sterile injection and cleaning materials so people who use drugs can wash their injection site; thereby reducing the risk of infection. Some offer drug-checking services, such as fentanyl test strips, and other services such as treatment referrals for those who want them. They also typically serve as a syringe service program where those who consume at the SCS, as well as those who don't, can obtain new injection supplies for use outside of the facility.

The available research on safe consumption sites is overwhelmingly positive (see, for example, Potier et al., 2014; Kennedy et al., 2017), but most published studies do not have credible control groups that allow for strong causal inferences (Pardo et al., 2018). The limited quasi-experimental literature examining what happens in neighborhoods where SCS open, and comparing them to other areas, finds no evidence that the sites increase crime rates; one study in fact suggests it may have led to a decrease (Freeman et al., 2005; Fitzgerald et al., 2010; Donnelly & Mahoney, 2013; Myer & Belisle, 2018). Of the two quasi-experimental studies examining community-level overdose deaths, one in Vancouver found a negative association (Marshall et al., 2011) and one in Sydney found no effect (Salmon et al., 2010); however, the latter study found a negative association with ambulance calls for non-fatal overdoses. While the causal evidence on the population-level effects of these interventions is sparse and largely focused on these two locations, thousands of overdoses have been reversed at these sites around the world and there appears to be little basis for concern about adverse effects in communities where they operate (Caulkins et al., 2019).

In 2017, the American Medical Association (AMA) voted to support the creation of pilot SCS facilities in the United States. In a press release, Dr. Patrice Harris, current president of the AMA and chair of its Opioid Task Force, noted that, "Pilot facilities will help inform U.S. policymakers on the feasibility, effectiveness and legal aspects of supervised injection facilities in reducing harms and health care costs associated with injection drug use" (AMA, 2017).

Despite the nation's oldest and largest medical association calling for pilot studies to learn more about the benefits and costs of safe consumption sites in the U.S. context, the federal government has stifled these efforts. The Department of Justice (DOJ) contends that SCS

[21] For example, there is a new pilot program in Vancouver which distributes hydropmorphone to registered patients with OUD via a biometric vending machine (Crawford, 2020).

violate the "crack house statute" of the Controlled Substances Act (CSA; § 856(a)(2)). Various DOJ officials have written memoranda (e.g., U.S. Attorney's Office, District of Vermont, 2017) or op-eds (Rosenstein, 2018; Lelling, 2019) making this argument, and the U.S. Attorney for the Eastern District of Pennsylvania went as far as to file a preemptive injunction asking a federal judge to declare that Safehouse—the proposed SCS in Philadelphia—was in violation of the CSA. In September 2019, Judge McHugh ruled against the government, noting:

> *[H]aving reviewed materials I consider appropriate in discerning what Congress sought to address in enacting § 856(a)(2), there is no support for the view that Congress meant to criminalize projects such as that proposed by Safehouse. Although the language, taken to its broadest extent, can certainly be interpreted to apply to Safehouse's proposed safe injection site, to attribute such meaning to the legislators who adopted the language is illusory. Safe injection sites were not considered by Congress and could not have been, because their use as a possible harm reduction strategy among opioid users had not yet entered public discourse.*

While the DOJ has indicated its intention to appeal, the efforts to implement an SCS in Philadelphia continue (Estes, 2019). Other jurisdictions are also paying close attention to this ruling (Bogel-Burroghs, 2019; Burris et al., 2020).

One federal option is to pass a law explicitly exempting safe consumption sites from the Controlled Substances Act. Of course, the law would have to be broad enough to make sure those who worked there could not be sanctioned (e.g., lose the ability to prescribe drugs) and that those who entered with drugs would not be arrested. While the federal government typically does not make arrests for possessing small amounts, it is still a possibility.

Another option would be to pass a budget rider prohibiting federal funds from being used to enforce federal laws against those implementing, staffing, or using an SCS (L. Beletsky, personal communication). A recent precedent with respect to the CSA was the budget rider that prohibited federal funds from being used to enforce federal law against those participating in medical cannabis programs that were legal at the state level.

However, Congress does not have to pass legislation to reduce federal barriers to implementing supervised consumption sites. U.S. attorneys have limited resources and discretion about the types of cases they pursue. They could simply decide to not enforce federal laws against those implementing, staffing, or using SCS. They could also issue guidance about the types of cases they will prioritize (Kilmer & Pardo, 2019).

For example, after the voters in Colorado and Washington passed cannabis legalization for nonmedical purposes in 2012, it was not clear what the federal government would do. The following year, the Department of Justice released a memorandum making it clear that cannabis activities in these states violated federal law, but as long as a state has a strict enforcement and regulatory system, and those participating in the market do not violate eight explicit guidelines, the federal government would consider it a low enforcement priority. The Obama administration did not interfere and while the Trump administration eventually rescinded the memorandum, enforcement activities did not noticeably change.

The DOJ could take a similar approach to SCS. They could publish guidance indicating that they are not "legalizing" these sites but will not make it an enforcement priority to target sites that are consistent with state and local laws. Additional guidelines could be added, for example, requiring that any sites opening have a robust evaluation plan with a credible control groups and disinterested evaluator, such as the General Accounting Office. While such guidance could always be overturned, it would allow local governments to experiment with an

intervention that may help reduce some of the harms associated with unsupervised consumption.

As noted, there is much to learn about the community-level outcomes associated with implementing safe consumption sites. While no jurisdictions in the U.S. have opened a sanctioned site yet, a number seem poised for this and now is the time to start collecting pre-implementation data and thinking critically about possible control jurisdictions for pilot studies. While an RCT at the individual-level would likely raise ethical concerns,[22] other research designs could be implemented.[23]

9. Support efforts to monitor drug consumption that don't depend on a physical location.

Like the NIMBYism sometimes expressed during discussions of potential sites for drug treatment centers, some of the resistance to SCS comes from the fact that some residents and businesses do not want to see a bricks-and-mortar facility in their neighborhood. Thus, it is imperative that we not limit our thinking about supervising consumption to fixed sites. Some SCS are mobile and there has been a proliferation of less structured and less resource-intensive "overdose prevention sites" in Canada. Additionally, "don't use alone" education campaigns and hotlines—which provide people with someone to listen on the phone while they inject and summon medical assistance if an overdose is suspected—can also reduce unsupervised consumption.

But what about new technologies and approaches to supervising consumption? Innovation is desperately needed here (Pardo et al., 2019d) and government-sponsored competitions could inspire new ideas. Indeed, there are precedents for this in the synthetic-opioid space. For example, Impact Canada (2020) is currently sponsoring a competition to improve drug-checking technology to help people who use drugs verify what they are consuming; this could be useful for sellers as well. And as noted in the introduction, ONDCP, the Department of Homeland Security, and other federal agencies in the U.S. are sponsoring a competition for detecting synthetic opioids in international mail.

10. Increase access to naloxone.

Naloxone is a medication that can rapidly reverse an opioid overdose. It even works for those who overdosed after using fentanyl and other potent synthetic opioids, but may require a higher dose (Moe et al., 2020). Government agencies, non-profit organizations, and people who use opioids have worked tirelessly to distribute naloxone throughout the country. While more funding is needed for naloxone (Haffajee & Frank, 2018), the federal government could do even more to increase access. One idea offered by Wang and Kesselheim (2018) is for the federal government to invoke its authority under the government use provision (U.S.C. § 1498)

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[22] For more discussion about the ethics and feasibility of conducting RCTs with SCS, see Christie et al. (2004) and May et al. (2019).

[23] Kilmer et al. (2019) argue: "A less controversial approach would be a multisite stepped-wedge cluster randomized trial, which is sometimes used to evaluate service delivery interventions (Hemming et al., 2015). With this approach, all sites will eventually get the treatment—in this case, an SCS—but the treatment is phased in over time. In some ways, this is similar to a wait-list design, but it is neighborhoods or communities, not individuals, that wait for a facility to be available. Even if randomization is not possible, much can be learned from rigorous quasi-experimental studies that compare neighborhood-level outcomes in places with and without an SCS. Regardless of whether an RCT or quasi-experimental approach is employed, it would also be extremely useful to collect individual-level data on people who use opioids (PWUO) in the treatment and control regions before and after the SCS opens. One approach could use respondent-driven sampling to approximate a random sample of PWUO in each area (Heckathorn, 1997; Heckathorn and Cameron, 2017) and then follow them over time."

to address the high price of some forms of naloxone. They note that this approach is not entirely new:

> *While the government use provision has not been invoked to reduce brand-name drug costs in recent decades, this proposal is consistent with past experience in which §1498 was invoked to address high costs of necessary antibiotics for military uses in the 1960s, and was threatened to be invoked in 2001 to stockpile drug treatment in response to the anthrax threat.*

Another idea being floated is to have the FDA move naloxone from prescription-only to over-the-counter (OTC) status. Davis and Carr (2020) acknowledge that this move will likely reduce insurance coverage for the medication and increase costs for some people, but they cite a modelling study (Murphy et al., 2019) suggesting this would likely lead to a total increase in pharmacy sales. Murphy et al. note that the public health impact of such a move "will depend on how likely the new population of OTC naloxone consumers are to encounter an overdose and use the product relative to the population of existing naloxone consumers." The overall impact will also depend on whether this change influences the consumption behaviors of people who use opioids.

Brief thoughts about criticisms of making drug use less risky

Interventions that reduce the risks associated with using illicit drugs are sometimes criticized for extending duration of use, increasing risky use, and "sending the wrong message" to youth about substance use (MacCoun & Reuter, 2001; MacCoun, 2009). We should fully evaluate the intended and unintended consequences of drug policy options, but we must not forget that we are dealing with a public health emergency and time is of the essence.

By design, some of the interventions discussed in this paper will extend duration of use by reducing the probability that an overdose becomes fatal. What is less certain is how some of these interventions influence *those who are contemplating reducing or stopping their use of heroin and other opioids*. Would some of those who would have taken steps to get out of the illicit market because of the dangers associated with fentanyl now continue to use since the risk of dying conditional upon overdosing seems smaller? On the other hand, are those in the contemplation phase now more likely to enter treatment because of a referral from first responders or SCS staff? The net effect of operating a SCS on treatment *entry* in a community has not been addressed in the quasi-experimental literature and should be incorporated into future evaluations.

If the probability of fatally overdosing is smaller because of these interventions, one could hypothesize that some people who use opioids will, on occasion, be more likely to take a bigger dose or a pill of unknown origin; however, these hypotheses must also account for consequences associated with surviving an overdose. Having naloxone administered—aka getting "Narcanned"—can be a very unpleasant experience and there can be significant costs to people who use opioids, their families, and their communities associated with non-fatal overdoses (see, for example, Wall et al., 2000).

Finally, the messages that these interventions send to youth and other community members are worth considering, but this factor seems to play an outsized role in policy discussions. Some argue that interventions not purely focused on abstinence send a message to youth that

"it's OK to use drugs." But it seems tenuous whether this is the message youth receive (one typically hears this argument only from adults), and if so, whether this contributes to them using heroin. Indeed, one could also argue that these interventions send a different message to youth: "it's OK to be compassionate to individuals who need help in our communities—especially when they are at a heightened risk of being poisoned." Communities contemplating safe consumption sites or heroin-assisted treatment will want to seriously consider public engagement and messaging strategies, including information about how parents, teachers, and community members should talk to youth about these interventions.

Conclusion

With some estimates projecting that the social burden of the opioid crisis could be in the ballpark of $200 billion in 2020 (Altarum, 2018), a significant treatment expansion would be a relative drop in the bucket (see Appendix). But getting people the treatment that works best for them and reducing the probability that an overdose is fatal aren't just about funding. There are laws, regulations, and other barriers that make it harder to achieve these goals. Thus, the federal government has many other levers it could pull.

The primary goal of this paper has been to expand the number of policy options that federal decision makers consider when trying to increase treatment access and reduce the probability that an overdose is fatal. While some of these 10 ideas would require federal expenditures, many do not. Some would require congressional approval, but others could be implemented by those working in federal agencies.

There may be some good ideas that can only be implemented at the state level. If the federal government wanted to make sure that states adopted, changed, or removed certain laws, federal policymakers could publicly encourage states to make these changes or offer incentives to those who enact them. One example would be to get more states to increase reimbursement rates for OUD treatment (Hinde et al., 2017) Another measure specific to reducing opioid overdose deaths would be to change state laws that make it difficult to distribute and use fentanyl test strips and other drug-checking technologies (Davis et al., 2019; Glick et al., 2019; Pieper et al., 2019).

For some of the options discussed in this paper, we do not have enough evidence to determine which are more cost-effective at reducing morbidity and mortality. But it is not enough to consider costs and benefits—one also needs to have a sense of scale and political feasibility when thinking about possible interventions. For example, Kilmer et al. (2018) estimate that one would need to build the equivalent of roughly 7,000 supervised consumption sites like Vancouver's Insite to cover all the opioid injections in the U.S. Does this mean that calls for SCS should be automatically dismissed? Not at all, but it does suggest that we need to be realistic about the magnitude of impact these interventions can have and appreciate that they may be more politically acceptable in some places than others: urban areas overwhelmed with fentanyl, for example, will likely be more open to implementing them than rural places where methadone is not readily available.

Finally, it should also be stressed that policy changes do not have to be permanent. Since some parts of the country are experiencing a poisoning outbreak, it may be prudent for federal policymakers to make it easier for these jurisdictions to experiment with alternative approaches like SCS that could be reconsidered in the future (e.g., include a sunset clause). Indeed, if policymakers simply treat the current crisis like a typical drug epidemic and do not

think creatively, we will likely condemn thousands of people to early deaths (Pardo et al., 2019d).

Appendix: Rough estimates on the potential cost of expanding treatment

Estimating the cost of providing high-quality OUD treatment to everyone who wants is difficult: we do not know the underlying demand, and the cost of treatment can depend on who is paying (e.g., government versus private insurer versus individuals paying out of pocket) and the perspective being considered (e.g., taxpayer versus societal). To help put this in perspective, here is a back-of-the-envelope calculation to help get a sense of the order of magnitude.

In 2017, there were probably on the order of 3 million individuals suffering from OUD in the US.[24] We do not have rigorous evidence on the *total* number of patients receiving medication (NASEM, 2019), but we do know that on March 31, 2017, there were nearly 400,000 patients receiving methadone at opioid treatment programs (NSSATS, 2018). If one sought to *increase* the number of people receiving medications for OUD by 750,000 (i.e., 25% of the 3 million suffering from OUD), under current policies and an assumption that the annual cost per patient was in the ballpark of $4,000 per year, this additional cost would be in the single-digit billions per year.[25]

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[24] Using round numbers given the amount of uncertainty surrounding these figures, on any given day there were about 2 million people who used heroin on 10 or more days in the past month in 2016 (Midgette et al., 2019). Data from NSDUH suggests there were nearly 700,000 people with OUD still actively using opioid analgesics and not using heroin in 2017 (SAMHSA on-line analysis). Since we know there are significant underreporting problems with NSDUH—even for cannabis (Harrison et al., 2007)—we need to inflate the 700,000 figure. If one assumes: a) that everyone who uses heroin on 10+ days a month likely meets criteria for OUD (the vast majority are daily/near-daily users); b) the figures for 2017 were the same or larger for 2016; and c) that we should inflate the NSDUH figure by 50%, we would estimate that there were approximately 3 million active opioid users meeting OUD criteria on any given day. There are also may people who suffer from OUD who are no longer actively using.

[25] To help put this in perspective, the Washington State Institute for Public Policy puts the annual per participant costs of methadone and buprenorphine at $3,827 (+/- 20%) and $4,689 (+/- 60%), respectively (WSIPP, 2018a; 2018b). Some of the estimates appear to include some fixed costs and differ depending on services provided (see Kilmer et al., 2018, footnote 37). For rough calculations, at an annual cost of $4,000, getting 750,000 more people into medication treatment with additional services for a year would cost in the ballpark of $3 billion annually. While buprenorphine can be prescribed in regular office settings, massively increasing the number of methadone clients would likely require building several new facilities that should also be factored into these calculations. In addition, one should also factor in the funds devoted to increasing outreach to those with OUD as well as increasing incentives to physicians to treat these patients.

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