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### INTENSIVE CARE FOR PAIN AS AN OVERDOSE PREVENTION TOOL: LEGAL CONSIDERATIONS AND POLICY IMPERATIVES

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## I. ADDRESSING OVERDOSE AND ASSOCIATED DRUG HARMS: MORE TOOLS NEEDED

The United States is experiencing a historic crisis of opioid-related harms.<sup>1</sup> The rate of fatal overdoses has tripled since 1999, driven primarily by opioids.<sup>2</sup> Spurred by large numbers of new initiates, the incidence of injection-related infections like HIV is now rapidly rising.<sup>3</sup> Despite concerted policymaker attention and the investment of more than ten billion dollars from all levels of government and civil society,<sup>4</sup> the rate of opioid-related harms remains at astronomically high levels.<sup>5</sup> With

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<sup>1</sup> See David C. Perlman & Ashley E. Jordan, *The Syndemic of Opioid Misuse, Overdose, HCV, and HIV: Structural-Level Causes and Interventions*, 15 CURRENT HIV/AIDS REP. 96, 96 (2018) (describing the opioid crisis as a syndemic of interrelated epidemics of opioid use, overdose, and opioid-related disease transmission occurring within communities already struggling with structural conditions of inequality).

<sup>2</sup> See HOLLY HEDEGAARD, MARGARET WARNER & ARIALDI M. MINIÑO, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1999–2016, at 1 (2017) (noting increases in drug overdose deaths involving natural and semisynthetic opioids in recent years).

<sup>3</sup> In 2015, new HIV diagnoses attributed to injection drug use increased for the first time in two decades. *HIV Diagnoses*, CDC NCHHSTP ATLASPLUS, <https://gis.cdc.gov/grasp/nchhstpatlas/charts.html> [<https://perma.cc/K7PB-U6FC>] (change the Year field to “2015” and the Transmission Category field to “Injection drug use”). Rates returned to lower levels in 2016 and 2017, but dramatic increases are emerging in specific settings. See, e.g., Health Advisory, Phila. Dep’t. of Pub. Health, HIV Outbreak Among People Who Inject Drugs (PWID) (Oct. 16, 2019) (reporting a 115% increase in new HIV diagnoses among people who inject drugs from 2016 to 2018); see also Philip J. Peters et al., *HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014–2015*, 375 NEW ENG. J. MED. 229, 230–38 (describing an HIV epidemic in Indiana caused by high-risk use of injectable oxymorphone). The number of new HCV infections reported to the Centers for Disease Control and Prevention (CDC) has tripled in the last five years. See U.S. DEP’T OF HEALTH & HUM. SERVS., NATIONAL VIRAL HEPATITIS ACTION PLAN 2017–2020 (2017) (noting that hepatitis C infections increased nearly 300% from 2010 to 2015).

<sup>4</sup> See BIPARTISAN POL’Y CTR., TRACKING FEDERAL FUNDING TO COMBAT THE OPIOID CRISIS 5 (2019), <https://bipartisanpolicy.org/wp-content/uploads/2019/03/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf> [<https://perma.cc/E3LB-L8LU>] (estimating that nearly \$11 billion in federal funding has been directed to the opioid crisis in 2017 and 2018).

<sup>5</sup> The rate of overdose deaths related to heroin or other commonly prescribed opioids reached and then stabilized at 5.2 deaths per 100,000 individuals between 2015 and 2017. *Overdose Death Rates*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> [<https://perma.cc/FM5P-REYL>] (last updated Jan. 2019). The rate for fentanyl-related overdoses continues to rise with the most recent data suggesting 9.0 deaths per 100,000 individuals. *Id.*

nearly 200 people in the United States dying of overdose every day, hundreds of preventable HIV infections, and countless other avoidable harms,<sup>6</sup> progress is far too slow.

There have been both successes and failures in prevention measures deployed to date. Broadening access to naloxone, lowering barriers to Opioid Agonist Therapy (OAT), and adopting 911 Good Samaritan Laws have contributed to declines in overdoses and other opioid-related harms.<sup>7</sup> Broader structural interventions to improve overall access to health care, including Medicaid expansion, have also helped.<sup>8</sup> Evidence of the benefits of supply-reduction efforts, including prescription

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<sup>6</sup> Every day, over 130 people die in the United States due to opioid overdose. *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis [https://perma.cc/T9VF-3B6Z] (last updated Jan. 2019). With increased injection drug use comes increased spread of infections like HIV and hepatitis C. *Id.*

<sup>7</sup> See Rahi Abouk, Rosalie Liccardo Pacula & David Powell, *Association Between State Laws Facilitating Pharmacy Distribution of Naloxone and Risk of Fatal Overdose*, 179 [J]AMA INTERNAL MED. 805, 809 (2019) (finding that states adopting naloxone access laws granting direct authority to pharmacists experienced statistically significant declines in fatal opioid-related overdoses); Lisa Chimbar & Yvette Moleta, *Naloxone Effectiveness A Systematic Review*, 29 J. ADDICTIONS NURSING 167, 167 (2018) (“[T]here is overwhelming support of [sic] take-home naloxone programs being effective in preventing fatal opioid overdoses.”); Christopher Keane, James E. Egan & Mary Hawk, *Effects of Naloxone Distribution to Likely Bystanders: Results of an Agent-Based Model*, 55 INT'L J. DRUG POL'Y 61, 61 (2018) (“Community-based naloxone distribution to reverse opioid overdose may significantly reduce deaths.”); Chandler McClellan et al., *Opioid-Overdose Laws Association with Opioid Use and Overdose Mortality*, 86 J. ADDICTIVE BEHAVS. 90, 90 (2018) (“[L]aws designed to increase layperson engagement in opioid-overdose reversal were associated with reduced opioid-overdose mortality.”); Holly Nguyen & Brandy R. Parker, *Assessing the Effectiveness of New York's 911 Good Samaritan Law—Evidence from a Natural Experiment*, 58 INT'L J. DRUG POL'Y 149, 149 (2018) (“Accidental heroin overdose emergency department visits and inpatient hospital admissions increased in New York State after the enactment of the 911 GSL, consistent with the intended effect of the GSL.”); Daniel I. Rees et al., *With a Little Help from My Friends: The Effects of Good Samaritan and Naloxone Access Laws on Opioid-Related Deaths*, 62 J. L. & ECON. 1, 1 (2019) (“[T]he estimated effects of GSLs on opioid-related mortality are consistently negative but not statistically significant[, and] adoption of an NAL is associated with a statistically significant 9–10 percent reduction in opioid-related mortality.”); Robert P. Schwartz et al., *Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009*, 103 AM. J. PUB. HEALTH 917, 917 (2013) (“[S]tarting in 2000 expansion of opioid agonist treatment was associated with a decline in overdose deaths. Adjusting for heroin purity and the number of methadone patients, there was a statistically significant inverse relationship between heroin overdose deaths and patients treated with buprenorphine.”).

<sup>8</sup> See Alana Sharp et al., *Impact of Medicaid Expansion on Access to Opioid Analgesic Medications and Medication-Assisted Treatment*, 108 AM. J. PUB. HEALTH 642, 642–46 (2018) (finding that “per-enrollee rates of buprenorphine and naltrexone prescribing increased more than 200% after states expanded eligibility, while increasing by less than 50% in states that

limits, Prescription Drug Monitoring Program (PDMP) authorizations and mandates, and drug interdiction enforcement is far less clear.<sup>9</sup>

Legal barriers—or politico-legal barriers<sup>10</sup>—have stymied adoption of additional measures that have successfully reduced opioid-related harms, like fatal overdose, in other countries. These include Safe Consumption Facilities (SCF), Injectable Opioid Agonist Therapy (iOAT), rapid access to agonist therapy in pharmacies, correctional programs, and prescription status of essential medicines.<sup>11</sup> Efforts to make these measures

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did not expand . . . [and] per-enrollee rates of Medicaid-reimbursed MAT increased significantly more in expansion states.”); *see also* Hefei Wen et al., *Impact of Medicaid Expansion on Medicaid-covered Utilization of Buprenorphine for Opioid Use Disorder Treatment*, 55 J. MED. CARE 336, 336 (2017) (“State implementation of Medicaid expansions in 2014 was associated with a 70% increase in Medicaid-covered buprenorphine prescriptions and a 50% increase . . . in buprenorphine spending.”).

<sup>9</sup> *See, e.g.*, Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 140-78 (2018) (providing a narrative review of the evidence on prescription drug monitoring programs (PDMPs)); S.C. Brighthaupt et al., *Effect of Pill Mill Laws on Opioid Overdose Deaths in Ohio & Tennessee: A Mixed-Methods Case Study*, 126 PREVENTIVE MED. 1, 3 (2019) (suggesting that pill mill laws had no effect on overdose rates in Ohio or Tennessee); *see also* Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 1, 3 (2019) (suggesting that pill mill laws had no effect on overdose rates in Ohio or Tennessee); *see also* Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 182–83 (2018) (noting that supply-side interventions have had small, if any, effects on population-level opioid-related harms).

<sup>10</sup> *See, e.g.*, Scott Burris et al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 ST. LOUIS L. REV. 1089, 1121–24 (2009) (noting that the decision to rely on drug control statutes in frustrating evidence-based public health interventions like Supervised Consumption Facilities is inflected by politics and not driven by the underlying intent of legislators who crafted the statutes).

<sup>11</sup> *See, e.g.*, Kevin Fiscella, Sarah E. Wakeman & Leo Beletsky, *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder, X the X-Waiver*, 76 [J]AMA PSYCHIATRY 229, 229-30 (2019) (describing the decline in death from opioid overdoses following deregulation of the prescription of buprenorphine in France and advocating for deregulation in the United States); Kevin Fiscella, Sarah E. Wakeman & Leo Beletsky, *Implementing Opioid Agonist Treatment in Correctional Facilities*, 178 [J]AMA INTERNAL MED. 1153, 1153-54 (2018) (describing positive outcomes following introduction of opioid treatments in correctional facilities).

available in the United States are gathering momentum,<sup>12</sup> but progress has been dismally slow.<sup>13</sup>

Compared with the current roster of interventions in the United States, these neglected tools reflect a more complete appreciation for the root causes of the crisis. At its core, the overdose crisis is symptomatic of a crisis of undertreated pain—physical, emotional, and economic. The structural drivers of this crisis include factors outside of the healthcare system like financial stress, isolation, and occupational injury,<sup>14</sup> as well as factors within the healthcare system like fragmented insurance coverage and healthcare financing that privileges surgical countermeasures and skimps on preventative and “incremental” care.<sup>15</sup> The very same structural factors have also complicated the response to overdose and other opioid-related harms.<sup>16</sup>

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<sup>12</sup> For example, *United States v. Safehouse* held that, because Congress was not aware of the existence of SCFs when it drafted the relevant section of the CSA, “no credible argument can be made that facilities such as safe injection sites were within the contemplation of Congress.” No. 19-0519, 2019 WL 4858266, at \*1 (E.D. Pa. Oct. 2, 2019). The *Safehouse* judge also acknowledged that, “[v]iewed objectively, what Safehouse proposes is far closer to the harm reduction strategies expressly endorsed by Congress than the dangerous conduct § 856(a) seeks to prohibit.” *Id.* at \*76. There have been some ambitious bills introduced like the Mainstreaming Addiction Treatment Act, which would remove restrictions on healthcare providers to prescribe buprenorphine. Mainstreaming Addition Treatment Act, H.R. 2482, 116th Cong. (2019). Although positive, these developments are unlikely to produce immediate relief for those most in need because of the slow pace of litigation and legislation. In addition, two Democratic presidential candidates explicitly support implementation of Supervised Consumption Sites. See Bernie Sanders, *Justice and Safety for All*, BERNIE, <https://berniesanders.com/justice-and-safety-for-all/> [<https://perma.cc/KYM5-DD52>] (last visited Oct. 15, 2019); Elizabeth Warren, *Rethinking Public Safety to Reduce Mass Incarceration and Strengthen Communities*, MEDIUM (Aug. 20, 2019), <https://medium.com/@teamwarren/rethinking-public-safety-to-reduce-mass-incarceration-and-strengthen-communities-90e8591c6255> [<https://perma.cc/G44P-KDBM>].

<sup>13</sup> See, e.g., Leo Beletsky et al., *The Law (and Politics) of Safe Injection Facilities in the United States*, 98 AM. J. PUB. HEALTH 231, 232-37 (2008) (making the legal case for safe consumption facilities over a decade ago).

<sup>14</sup> See, e.g., Anne Case & Angus Deaton, *Mortality and Morbidity in the 21st Century*, BROOKINGS PAPERS ON ECON. ACTIVITY, SPRING 2017, at 397, 438 (noting that the rise of “deaths of despair” is a social phenomenon associated with decreased levels of individual and collective participation in thick social networks including activities like church and unions).

<sup>15</sup> See, e.g., T.R. REID, *THE HEALING OF AMERICA: A GLOBAL QUEST FOR BETTER, CHEAPER, AND FAIRER HEALTH CARE* 6-8 (Penguin Books Ltd. ed., Reprint ed. 2009) (describing the author’s experience seeking care for a shoulder injury in multiple countries with American physicians suggesting a much more invasive and heroic surgical approach and with physicians from other countries suggesting less invasive action); Atul Gawande, *The Heroism of Incremental Care*, NEW YORKER, Jan. 15, 2017, at 36, 45 (noting devotion to intensive, heroic procedures, while diminishing incremental care that often provides more benefits, and suggesting a shift in focus from rescue medicine to more gradual and deliberate care).

<sup>16</sup> See *infra* Part III.

This Article focuses on the nexus between pain treatment, addiction, and overdose. It argues that much more proactive measures to better control pain among people at high overdose risk are an important but overlooked strategy for reducing opioid-related morbidity and mortality. The social and political terrain for this argument is tricky. Pain management is commonly identified as a key cause of the current crisis, and opioids have been deployed without evidence establishing their safety and efficacy in many instances.<sup>17</sup> Pain is also a complex, ambiguous, and poorly-understood phenomenon,<sup>18</sup> making it hard to quantify and easy to dismiss. But the crisis of pain that spurred the proliferation of opioid analgesics is undeniable.<sup>19</sup> As it progressed, many of those who were managing pain through opioid pharmacotherapy moved on to street drugs because of supply-side policy measures, reformulations, cost, availability, and other factors.<sup>20</sup> Their pain—physical or otherwise—has

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<sup>17</sup> An increasing reliance on opioids to treat pain has been associated with a rising opioid crisis in the United States. *See, e.g.,* NAT'L ACADS. OF SCIS., ENG'G & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 1-2 (Nat'l Acads. Press ed. 2017) (ebook) (asserting that the “increase in opioid-related deaths has occurred in tandem with an equally unprecedented increase in prescribing of opioid medications for purposes of pain management”). A three-paper series in *Lancet* documents the role of inappropriate opioid prescribing after surgery as a major cause of the opioid epidemic. *See* Lesley A. Colvin et al., *Perioperative Opioid Analgesia—When Is Enough Too Much? A Review of Opioid-induced Tolerance and Hyperalgesia*, 393 LANCET 1558, 1568 (2019) (discussing “tolerance and opioid-induced hyperalgesia”); Paul Glare et al., *Transition from Acute to Chronic Pain After Surgery*, 393 LANCET 1537, 1537 (2019) (documenting the “epidemiology and societal effect, basic science, and current recommendations for managing persistent postsurgical pain”); Mark D. Neuman et al., *Inappropriate Opioid Prescription After Surgery*, 393 LANCET 1547, 1547 (2019) (tracing “the evolution of prescription opioid use for pain treatment after surgery in the USA, Canada, and other countries” and its impact on opioid over-prescribing and misuse).

<sup>18</sup> *See, e.g.,* Karina M. Berg et al., *Providers' Experiences Treating Chronic Pain Among Opioid-Dependent Drug Users*, 24 J. GEN. INTERNAL MED. 482, 483 (2009) (noting in a study of the experiences of physicians that “[a] central focus for many providers was the inherent ambiguity of pain treatment. Providers felt more comfortable treating chronic pain that was supported by concrete evidence”).

<sup>19</sup> *See, e.g.,* David G. Blanchflower & Andrew Oswald, *Unhappiness and Pain in Modern America: A Review Essay, and Further Evidence, on Carol Graham's Happiness for All?* 1 (Nat'l Bureau of Econ. Research, Working Paper No. 24087, 2017) (confirming that “Americans appear to be in greater pain than citizens of other countries, and most sub-groups of citizens have downwardly trended happiness levels.”); CAROL GRAHAM, HAPPINESS FOR ALL? UNEQUAL HOPES AND LIVES IN PURSUIT OF THE AMERICAN DREAM 80 (Princeton Univ. Press ed. 2017) (noting an epidemic of pain among all but the most affluent Americans).

<sup>20</sup> As a 2013 study suggests,

The widespread availability of opioid analgesics outside sanctioned channels and, paradoxically, medical and regulatory attempts to curb this through monitoring and

remained and, in many cases, worsened.<sup>21</sup> It is now well-recognized that, collateral to the overdose crisis response, the pendulum has swung too far away from access to pain pharmacotherapy.<sup>22</sup>

The overlap of pain and high-risk opioid use is especially pronounced among people who inject drugs without stable housing.<sup>23</sup> People who use drugs have never received adequate health care, including pain care—a situation aggravated by the current efforts to constrain access to opioid pain pharmacotherapy. Individuals in this highly-marginalized group are forced to inject in settings that put them at high risk for otherwise avoidable infections, which can produce a cascade of excruciating conditions.<sup>24</sup> Self-medication

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limiting prescribing, appear to be drawing a new generation into higher risk heroin injecting . . . [users are] ultimately persuaded by market forces when their pill of choice becomes unavailable or unaffordable.

Sarah G. Mars et al., “Every ‘Never’ I Ever Said Came True”: *Transitions from Opioid Pills to Heroin Injecting*, 25 INT’L J. DRUG POL’Y 257, 264 (2013).

<sup>21</sup> See Jianren Mao, *Opioid-Induced Abnormal Pain Sensitivity*, 10 CURRENT PAIN & HEADACHE REP. 67, 68 (2006) (finding that, as opioid therapy progresses for an individual, the continued use of opioids as treatment activates a pronociceptive mechanism that increases pain sensitivity).

<sup>22</sup> See George Comerici Jr. et al., *Controlling the Swing of the Opioid Pendulum*, 378 NEW ENG. J. MED. 691, 691-93 (2018) (describing how hard line blanket refusals to prescribe opioids can increase patient suffering); Meredith Lawrence, *How the CDC Guidelines Killed My Husband*, 8 NARRATIVE INQUIRY IN BIOETHICS 219, 219 (2018) (describing the author’s husband’s decision to commit suicide after his pain care was drastically reduced after the guidelines were announced); Joseph V. Pergolizzi Jr. et al., *Three Years Down the Road: The Aftermath of the CDC Guideline for Prescribing Opioids for Chronic Pain*, 36 ADVANCES IN THERAPY 1235, 1235-38 (2019) (suggesting that efforts to reduce overdose have stimulated a silent epidemic of unmanaged chronic pain); Stefan G. Kertesz & Kate M. Nicholson, *No More ‘Shortcuts’ in Prescribing Opioids for Chronic Pain. Millions of Americans Need Nuanced Care*, STAT NEWS, (Apr. 26, 2019), <https://www.statnews.com/2019/04/26/no-shortcuts-prescribing-opioids-chronic-pain/> [<https://perma.cc/YX62-M58L>] (“The health care system’s failure to allow for nuance has put at risk the more than 10 million Americans who take opioids to manage pain.”).

<sup>23</sup> Cf. Pauline Voon et al., *Self-Management of Pain Among People Who Inject Drugs in Vancouver*, PAIN MGMT. 27, 31 (Mar. 2014) (finding that “a large majority (97.5%) of the recruited active [study participants who inject drugs] who reported moderate-to-extreme pain had self-managed their pain within their lifetime” and that homelessness was positively associated with self-managed pain).

<sup>24</sup> See, e.g., Carl Latkin et al., *My Place, Your Place, and No Place: Behavior Settings as a Risk Factor for HIV-Related Injection Practices of Drug Users in Baltimore, Maryland*, 22 AM. J. CMTY. PSYCHOL. 415, 426-27 (1994) (finding that reports of injecting at shooting galleries and semi-public areas were significantly associated with risky injection practices partly explained by the lack of availability of sanitation resources); Will Small et al., *Public Injection Settings in Vancouver: Physical Environment, Social Context and Risk*, 18 INT’L J. DRUG POL’Y 27, 28 (2007) (noting that those who inject in public display increased risk for adverse health outcomes like abscesses, injection related vein damage, HCV infection, and

for these harms and barriers to care are also mediated by emotional pain and other vulnerabilities like mental illness or serious physical disability.<sup>25</sup> Injection in public settings is associated with an especially high risk of violence and other injuries.<sup>26</sup> Many of these individuals would benefit from medication therapy, but a number of barriers prevent them from doing so.<sup>27</sup> For some, the primary barrier is a chaotic daily existence, which does not align with regimented and often overbearing requirements of treatment; inadequate insurance and other logistical barriers limit access, too.<sup>28</sup> Pervasive stigma, criminalization, and racism undermine patient care and facilitate patient abandonment.<sup>29</sup>

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overdose); David Vlahov et al., *Reductions in High-Risk Drug Use Behaviors Among Participants in the Baltimore Needle Exchange Program*, 16 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & HUMAN RETROVIROLOGY 400, 401 (1997) (noting the importance of considering physical settings of where injections occur, as injections performed in public are less likely to be hygienic than those performed in residences).

<sup>25</sup> See *infra* Section II.B and note 57.61.

<sup>26</sup> See, e.g., Paula Braitstein et al., *Sexual Violence among a Cohort of Injection Drug Users*, 57 SOC. SCI. & MED. 561, 566 (2003) (finding a high prevalence of lifetime sexual violence among the studied cohort of injection drug users); Mary Clare Kennedy et al., *Residential Eviction and Exposure to Violence among People Who Inject Drugs in Vancouver, Canada*, 41 INT'L J. DRUG POL'Y 59, 59 (2017) (noting that people who inject drugs experience significantly elevated rates of both physical and sexual violence); Lindsey A. Richardson et al., *Socioeconomic Marginalisation in the Structural Production of Vulnerability to Violence Among People Who Use Illicit Drugs*, 69 J. EPIDEMIOLOGY & COMMUNITY HEALTH 686, 687-91 (2015) (noting that violence is common among people who use drugs, and that lack of secure income-generating opportunities produces much of the risk for experiencing violence).

<sup>27</sup> Some impediments are logistical, administrative, or legal. See, e.g., Gary Enos, *Advocate: Philadelphia Smoking Ban Shuts Some Patients out of Treatment*, 31 ALCOHOLISM & DRUG ABUSE WKLY., no. 23, 2019, at 1, 5 (noting one social worker's position that the same city smoking ban induces patients to leave treatment or results in their administrative discharge); Brooke Feldman, *Why Philly's Smoking Ban at Addiction Treatment Centers Will Be Harmful*, FILTER (Feb. 12, 2019), <https://filtermag.org/philadelphia-smoking-ban-addiction-treatment-harm-reduction/> (describing a city ban on smoking outside residential substance abuse treatment centers as a further barrier people who use drugs must consider when deciding to enter treatment); Paul M. Roman et al., *Using Medication-Assisted Treatment for Substance Use Disorders: Evidence of Barriers and Facilitators of Implementation*, 36 ADDICTIVE BEHAVS. 584, 587 (2011) (describing multiple barriers to successful adoption of substance use disorder medications, such as rigid treatment ideology and lack of access to prescribing physicians).

<sup>28</sup> Unmanaged pain can be extremely destabilizing. See *infra* Part II.B.

<sup>29</sup> See, e.g., DL Biancarelli et al., *Strategies Used by People Who Inject Drugs to Avoid Stigma in Healthcare Settings*, 198 DRUG & ALCOHOL DEPENDENCE 80, 81-83 (2019) (presenting the stigmatizing experiences of people who inject drugs and how those experiences influence poor health care decisions to avoid anticipated stigma); C.E. Paquette, *Stigma at Every Turn: Health Services Experiences Among People Who Inject Drugs*, 57 INT'L J. DRUG POL'Y 104, 106-08 (2018) (describing the pervasiveness of stigma people who inject drugs



Increasing concerns about relinquishing control over opioid analgesic supplies, along with institutional and law enforcement pressure to improve medication stewardship have contributed to reluctance to provide adequate pain treatment. As a result, some people experience numerous touchpoints with healthcare and criminal justice systems, but opportunities for supportive services go unrealized.<sup>30</sup> When care is provided, it happens far downstream in expensive and inherently untherapeutic acute care settings or jails, despite the broadly acknowledged benefits of supporting such “frequent flyers” with resources upstream.<sup>31</sup>

Experience in other countries suggests that one important tool for reducing drug-related harms among such marginalized individuals is access to a stable and safe supply of opioids.<sup>32</sup> But in view of wide-spread concerns about over-utilization and diversion of opioid analgesics, we propose providing this health service within a well-recognized healthcare model: Directly-Observed Therapy (DOT). A framework for Directly-Observed Therapy for

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face and how stigmatization surrounding participants’ access to resources like syringes and methadone treatment discourages them from seeking to purchase syringes and accessing treatment in the future).

<sup>30</sup> See Marc R. Laroche et al., *Touchpoints—Opportunities to Predict and Prevent Opioid Overdose: A Cohort Study*, 204 DRUG & ALCOHOL DEPENDENCE 1, 4 (2019) (noting that, in a Massachusetts study, effective interventions at critical healthcare and criminal justice system touchpoints could have eliminated up to 50% of opioid overdose deaths, but that the systems lacked effective interventions to recognize areas for improvement).

<sup>31</sup> See, e.g., Burris et al., *supra* note 10, at 1096-98 (discussing the use of supervised injection facilities as a legally feasible and less socially costly alternative to current prevailing regimes for addressing illegal drug use in the United States, where studies suggest many people who use illegal drugs are subject to criminal prosecution and sent to jail rather than treatment, confounding therapeutic intent); Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 185 (2018) (concluding that “[w]e have lost the commonsense imperative to engage those who use opioids in comprehensive care, especially during periods when access to opioids may be fluctuating”); Uchenna Emeche, *Is a Strategy Focused on Super-Utilizers Equal to the Task of Health Care System Transformation? Yes*, 13 ANNALS FAM. MED. 6, 6 (2015) (finding that so-called “super-utilizers” of health care, not limited to people who inject drugs, represent 50% of health care expenditures, which can be reduced by intervening before emergency visits are required); Brendan Saloner et al., *A Public Health Strategy for the Opioid Crisis*, 133 PUB. HEALTH REP. 24S, 31S (2018) (finding that investing in programs which help people to safely use drugs, among other things, will better ensure patient survival and public safety than abstinence-only drug policies); Grant G. Simpson et al., *A Patient-Centered Emergency Department Management Strategy for Sickle-Cell Disease Super-Utilizers*, 18 WESTERN J. EMERGENCY MED. 335, 335 (2017) (suggesting that coordinated care plans are feasible and potentially effective in reducing emergency department visits among super-utilizers with sickle-cell disease); Bara Vaida, *For Super-Utilizers, Integrated Care Offers A New Path*, 36 HEALTH AFF. 394 (2017) (describing several nascent models for reducing super-utilizers’ cost burden by connecting them with resources and intervening to ensure care before it is emergent).

<sup>32</sup> See *infra* Section II.D.

Pain (DOT-P) would resemble a specialty intensive pain care clinic, where healthcare professionals would provide pharmaceutical-grade opioids like hydromorphone in a monitored setting, along with key wraparound services. DOT-P would address concerns with polypharmacy<sup>33</sup> and overdose,<sup>34</sup> while also operationalizing a “closed system.” Operating similarly to iOAT clinics that exist in other international settings, a DOT-P model would be reserved for highly vulnerable people who inject drugs, have diagnosable acute or serious chronic pain, and have not benefited from other pharmacotherapy. This approach would provide essential care to a marginalized population while minimizing risk of diversion—a principal concern in the context of the current crisis.<sup>35</sup>

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<sup>33</sup> See, e.g., Aubrey Whelan, *Pennsylvania’s Overdose Crisis Is Shifting*, *New DEA Report Finds*, PHILA. INQUIRER (Oct. 2, 2019), <https://www.inquirer.com/health/dea-philadelphia-statewide-overdose-numbers-shifting-20191002.html> [https://perma.cc/37FH-R5DT] (“Most—87%—overdose victims had two or more drugs in their system, 46% had four or more drugs, and 16% had six or more drugs.”).

<sup>34</sup> See *infra* notes 91–92.

<sup>35</sup> Although diversion does not fully explain the opioid crisis, see *supra* note 9 and accompanying text, it is an important and concerning phenomenon. Diversion takes many forms. Sometimes unused opioids, which are prescribed for one individual’s post-surgical analgesia, end up being used nonmedically by another individual. See, e.g., Sean Esteban McCabe, Christian J. Teter, & Carol J. Boyd, *Illicit Use of Prescription Pain Medication Among College Students*, 77 *DRUG & ALCOHOL DEPENDENCE* 37, 41 (2005) (describing diversion and illicit use of prescription pain medication among undergraduate students at a large Midwestern university). In many other instances, opioids were diverted into illicit channels by unscrupulous pill mills or at other points in the supply chain. James A. Inciardi et al., *The Diversion of Prescription Opioid Analgesics*, 7 *LAW ENFORCEMENT EXEC. FORUM* 127, 133 (2007). There are longstanding concerns about the diversion of methadone. See, e.g., Alison Ritter & Richard Di Natale, *The Relationship Between Take-Away Methadone Policies and Methadone Diversion*, 24 *DRUG & ALCOHOL REV.* 347, 348 (2005) (finding, on a high level, less diversion in Australian states with stricter methadone take-away policies). Today, there is even evidence of wide-scale diversion of buprenorphine, although the nature of that diversion is complex and may say more about inadequate access to medication treatment, rather than recreational use. See Jennifer J. Carroll, Josiah D. Rich & Traci C. Green, *The More Things Change: Buprenorphine/Naloxone Diversion Continues While Treatment Remains Inaccessible*, 12 *J. ADDICTION MED.* 459, 459 (2018) (finding that rates of diverted buprenorphine use among Rhode Island-based survey respondents remained similar between 2009 and 2016); Theodore J. Cicero, Matthew S. Ellis & Howard D. Chilcoat, *Understanding the Use of Diverted Buprenorphine*, 193 *DRUG & ALCOHOL DEPENDENCE* 117, 117 (2018) (finding that 58% of surveyed adults meeting DSM-IV criteria for substance use disorder and primary opioid use reported a history of using diverted buprenorphine, which partly reflects inadequate access to buprenorphine through health care channels); Chris-Ellyn Johanson et al., *Diversion and Abuse of Buprenorphine: Findings from National Surveys of Treatment Patients and Physicians*, 120 *DRUG & ALCOHOL DEPENDENCE* 190, 190 (2012) (finding increasing diversion to be a threat to the continued approval of buprenorphine for treatment of OUD).

Though distinguishable from maintenance, iOAT, and SCFs,<sup>36</sup> DOT-P shares some of their strengths including overdose prevention, providing linkages to services, reducing drug use in public settings, and reducing community disorder.<sup>37</sup>

Unfortunately, DOT-P is not currently implemented in the United States in a robust or systematic way. We argue that to reduce overdose risks and other health harms from drug injection, far more must be done to address the patients' underlying pain. This Article begins in Part II by explaining the co-occurrence of pain, opioid use disorder (OUD), and housing instability through a vignette and through a review of relevant epidemiological research. We then describe the benefits of DOT-P for this population in terms of underlying theory and related evaluation research. In Part III, we provide a reasonable legal roadmap for operationalizing such an approach. We conclude in Part IV with some normative observations and predictions.

## II. THE IMPORTANCE OF PAIN-CENTERED CARE

### A. *John's Life of Self-Medicating Pain*

John is 42 years old and has lived in Kensington, a Philadelphia neighborhood, for his entire life. For the past eight years, he has injected heroin. Sometimes John lives with his sister and at other times he bounces between shelters and street homelessness. John's day-to-day life is physically challenging. For years he has lived with depression, chronic obstructive pulmonary disorder (COPD), and persistent lower back and extremity pain.

John is practiced at finding a vein and minimizing risk of infection while injecting. He always uses sterile syringes obtained from the local syringe exchange. But still he has had a number of infections in recent years, which he attributes to a handful of instances when impending withdrawal forced him to inject quickly in a poorly lit area with heroin not purchased from his usual dealer. When an abscess appeared on his leg recently, he delayed treatment because of past negative experiences in the local hospital. However, a vicious fever and disabling thigh pain forced him into the emergency department where he learned that the infection had infiltrated his blood and colonized in his femur. After a two-day inpatient stay in the local hospital, John left against medical advice because he felt that the people caring for him viewed him suspiciously and (perhaps relatedly) because his pain was undertreated.

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<sup>36</sup> See *infra* note 234 and accompanying text describing the statutory and regulatory definitions of maintenance and detoxification. There is no single definition of "Supervised Consumption Facility," but the model proposed so far in the United States would require people who use drugs to bring illicit substances into the facility for self-administration. See *United States v. Safehouse*, No. 19-0519, 2019 WL 4858266, at \*2, \*27 (E.D. Pa. Oct. 2, 2019).

<sup>37</sup> See *infra* notes 59–61.

The physical challenges in John's life add to considerable social challenges. John has some wonderful personality traits. He considers himself an elder statesperson among some of the people who inject drugs in the neighborhood. He is quick to share a cigarette or knowledge about how to inject more safely. He is often witty and self-aware. But his life is frequently hectic and always stressful. Finding ways to pay for heroin consumes his thoughts and energy, and to stave off impending withdrawal he sometimes steals, which adds to the sense of shame he experiences when living on the street or getting care at the emergency department for injection-related harms. He has a deep love for his sister and once had diverse interests and hopes. And he often wishes and sometimes plans to find and stick with treatment. But the daily hustle has sapped his strength, and the idea of confronting the terrible things he has experienced without the euphoric escape of heroin is daunting. Pain is persistent and overwhelming for most of his waking day.

John is not typical of all people who inject drugs.<sup>38</sup> But John's medical and social complexities are common among the small portion of people who inject drugs in public spaces. These people often have overlapping and synergizing vulnerabilities including unstable housing, mental illness, physical disability, and a history of trauma. They have the greatest unmet healthcare needs and would benefit the most from coordinated medical homes. But developing and sustaining trusting relationships with marginalized people is not a strength of institutional medicine. Stigma explains part of why people like John report negative healthcare experiences. So too does fear: John requires clinical management for considerable pain, but he looks like the type of patient for whom too much prescribing might elicit a call from the authorities. In the next section, we describe how often pain and OUD co-occur among people with unstable housing.

### *B. Co-Occurrence of OUD, Serious Pain, and Housing Instability*

Pain is the single greatest source of disability in developed countries.<sup>39</sup> An estimated 50 million American adults (more than 20% of the United States

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<sup>38</sup> John's story is based on an agglomeration of real individuals' experiences and meant to illuminate the conditions that this group endures.

<sup>39</sup> Musculoskeletal conditions are the leading contributor to disability worldwide, with low back pain being the single leading cause of disability globally. James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016*, 67 *MORBIDITY & MORTALITY WKLY REP.* 1001-06 (2018); Jan Hartvigsen et al., *What Low Back Pain Is and Why We Need to Pay Attention*, 391 *LANCET* 2356-67 (2018); Andrew S. C. Rice et al., *Pain and the Global Burden of Disease*, 157 *PAIN* 791, 792 (2015) (describing how chronic low back pain, neck pain, migraine, and other musculoskeletal disorders consistently featured in the top ten reasons for years lived with disability worldwide,

population) suffer from chronic pain, meaning it affects more people in the United States than diabetes and cancer.<sup>40</sup> Chronic and acute pain<sup>41</sup> are especially common among people with OUD. Systematic reviews and meta-analyses suggest that somewhere between 48% and 64% of people who use opioids nonmedically have chronic pain,<sup>42</sup> with individual studies reporting prevalence as high as 81%.<sup>43</sup>

The relationship between OUD, pain, and housing instability is multidirectional. Over 60% of OUD patients experienced chronic pain before the onset of their OUD.<sup>44</sup> In many instances, people were over- or unnecessarily-

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and indicating that seven of the commonest chronic conditions globally were primary pain conditions); *Musculoskeletal Conditions*, WORLD HEALTH ORG. (Aug. 9, 2019), <https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions> [<https://perma.cc/VN9Y-BGKX>].

<sup>40</sup> James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016*, 67 MORBIDITY & MORTALITY WKLY REP. 1002, 1003 (2018). According to the most recent surveillance estimates of the population living in the United States, there are just over 30 million people with diabetes and less than 16 million people living with cancer. DIV. OF DIABETES TRANSLATION, CTR. DISEASES CONTROL & PREVENTION, NATIONAL DIABETES STATISTICS REPORT, 2017, at 2 (2017), <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf> [<https://perma.cc/8CUJ-P593>]; *Cancer Stat Facts: Cancer of Any Site*, NAT'L CANCER INST., <https://seer.cancer.gov/statfacts/html/all.html> [<https://perma.cc/D84L-BVPP>] (last visited Nov. 13, 2019).

<sup>41</sup> Acute pain is a useful and temporary activation of the sympathetic nervous system in response to a specific disease or injury. See Katherine P. Grichnik & Francis M. Ferrante, *The Difference Between Acute and Chronic Pain*, 58 MT. SINAI J. MED. 217-20 (1991). Chronic pain is a persistent condition serving no useful biological purpose. *Id.* Treatment of acute pain aims to address the underlying cause; treatment of chronic pain requires a multidisciplinary approach targeting physiological and psychological etiologies. *Id.*

<sup>42</sup> See Benedikt Fischer et al., *The Prevalence of Mental Health and Pain Symptoms in General Population Samples Reporting Nonmedical Use of Prescription Opioids: A Systematic Review and Meta-Analysis*, 13 J. PAIN 1029, 1029 (2012) (noting pain has been associated with non-medical prescription opioid use (NMPOU) in general populations, and finding the pooled prevalence of pain in general populations reporting NMPOU to be 48%); Yih-Ing Hser et al., *Chronic Pain Among Patients with Opioid Use Disorder: Results from Electronic Health Records Data*, 77 J. SUBSTANCE ABUSE TREATMENT 26, 29 (2017) (finding in a review of 5307 electronic health records over the course of a decade that most OUD patients (64.4%) had chronic pain conditions).

<sup>43</sup> See Kevin Vowles et al., *Rates Of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review And Data Synthesis*, 156 PAIN 569, 569, 573-74 (2015) (noting rates of opioid prescriptions have increased and are among the most frequently prescribed medications, and finding the range of rates of problematic use to be even broader than reported in previous work with rates ranging from 0.08% to 81%).

<sup>44</sup> See Yih-Ing Hser et al., *supra* note 42, at 29 (finding in a study of 5307 adult patients with OUD in a large healthcare system that most patients with opioid use disorder developed it after developing chronic pain); Roger G. Weiss et al., *Reasons for Opioid Use Among Patients with Dependence on Prescription Opioids: The Role of Chronic Pain*, 47 J. SUBSTANCE ABUSE TREATMENT 140, 140 (2014) (reporting from a survey of 653 participants

prescribed opioids for pain management;<sup>45</sup> in other instances, however, OUD resulted from undertreatment of pain by clinicians.<sup>46</sup>

OUD may also produce pain through a process called hyperalgesia.<sup>47</sup> Chronic use of high doses of opioids increases sensitivity to painful stimuli.<sup>48</sup> Hyperalgesia can stimulate new pain or exacerbate preexisting pain.<sup>49</sup> Combined with tolerance, it can contribute to a dangerous cycle in which patients with OUD need increasingly higher doses of opioids to avoid withdrawal, which lowers tolerance to painful stimuli. Hyperalgesia can

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that participants with chronic pain were significantly more likely than those without chronic pain to cite pain management the primary reason for initiation of opioid use).

<sup>45</sup> See Gillian Beauchamp et al., *Moving Beyond Misuse and Diversion: The Urgent Need to Consider the Role of Iatrogenic Addiction in the Current Opioid Epidemic*, 104 AM. J. PUB. HEALTH 2023, 2023 (2014) (“Some individuals transition to nonmedical use and addiction despite their intention to use medications only as directed and only for pain relief.”); Martin Makary, Heidi N Overton & Peiqi Wang, *Overprescribing Is Major Contributor to Opioid Crisis*, 359 BRIT. MED. J. 4792, 4792-93 (2017) (noting that a major contributor to the opioid epidemic is physician overprescribing, evidenced by 2016 Medicare data suggesting that about 80% of patients were prescribed more pain tablets than the best practice range after routine laparoscopic cholecystectomy); Barry Meisenberg et al., *Assessment of Opioid Prescribing Practices Before and After Implementation of a Health System Intervention to Reduce Opioid Overprescribing*, 1 [J]AMA NETWORK OPEN 1, 2 (2018) (noting that surging opioid overdose deaths were “preceded by a 300% expansion of retail opioid prescribing beginning in the early 1990s and peaking in 2012,” and that prescription opioids, “including diverted prescription opioids, were the initial source of opioids for most current heroin users”).

<sup>46</sup> Kelly K. Dineen, *Defining Misprescribing to Inform Prescription Opioid Policy*, 48 HASTINGS CTR. REP. 5-6 (2018) (noting that underprescribing, characterized by withholding appropriate opioids, rapid tapering, as well as refusals to refer patients for medication-assisted treatment, can lead to unnecessary suffering, suicide, and use of illicit drugs); Howard L. Fields, *The Doctor’s Dilemma: Opiate Analgesics and Chronic Pain*, 69 NEURON 591, 591-94 (2011) (addressing how much harm is done to patients with chronic pain by withholding opiate analgesics due to inadequate pain relief); Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 405, 405-16 (2008) (“Undertreatment of pain among addicted persons may lead to the adverse medical, social and personal consequences associated with continued drug-seeking behavior.”).

<sup>47</sup> See Marion Lee et al., *A Comprehensive Review of Opioid-Induced Hyperalgesia*, 14 PAIN PHYSICIAN 145, 145 (2011) (defining opioid-induced hyperalgesia (OIH) as a state of nociceptive sensitization caused by exposure to opioids, and explaining that OIH is characterized by a paradoxical response whereby a patient receiving opioids for the treatment of pain could actually become more sensitive to certain painful stimuli).

<sup>48</sup> See Larry Chu, Martin Angst & David Clark, *Opioid-Induced Hyperalgesia in Humans: Molecular Mechanisms and Clinical Considerations*, 24 CLINICAL J. PAIN 479, 485-86 (2008) (describing case reports and studies of OIH in patients receiving high dose opioids).

<sup>49</sup> See, e.g., Stephen P. Cohen et al., *The Effect of Opioid Dose and Treatment Duration on the Perception of a Painful Standardized Clinical Stimulus*, 33 REGIONAL ANESTHESIA & PAIN MED. 199, 199 (2008) (finding in a study of 355 patients that “[b]oth opioid dose and duration of treatment directly correlated with pain intensity and unpleasantness scores”).

result from chronic exposure to any opioid, including methadone,<sup>50</sup> threatening adherence to treatment when pain is poorly managed.<sup>51</sup>

Prevalence of pain is even higher for people with OUD who are not stably housed.<sup>52</sup> Unmanaged pain and OUD are often contributing factors in transitions away from stable employment and housing, which, in turn, produce more pain and greater challenges to managing OUD.<sup>53</sup> Without employment some people turn to theft or sex work, increasing risk of trauma and involvement with the criminal justice system.<sup>54</sup> Without adequate shelter, people experience

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<sup>50</sup> See, e.g., Mark Doverty et al., *Methadone Maintenance Patients Are Cross-Tolerant to the Antinociceptive Effects of Morphine*, 93 PAIN 155, 155 (2001) (“Our findings suggest that methadone patients are cross-tolerant to the antinociceptive effects of morphine, and conventional doses of morphine are likely to be ineffective in managing episodes of acute pain amongst this patient group.”).

<sup>51</sup> See Peggy Compton, V.C. Charuvastra & Walter Ling, *Pain Intolerance in Opioid-Maintained Former Opiate Addicts: Effect of Long-Acting Maintenance Agent*, 63 DRUG & ALCOHOL DEPENDENCE 139, 142 (2001) (describing a study of 36 methadone or buprenorphine-maintained patients where the authors found that control patients “remain[ed] in the ice bath more than twice as long as the former opioid abusers,” suggesting that methadone or buprenorphine mediated hyperalgesia as measured by a lower tolerance to pain caused by cold sensitivity); Mark Doverty et al., *Hyperalgesic Responses in Methadone Maintenance Patients*, 90 PAIN 91, 93-94 (2001) (finding that the ratio of pain tolerance to pain detection was lower for patients receiving methadone medication in cold pressor and electrical stimulation tests, suggesting that such patients could endure a painful stimulus for shorter periods of time than control patients after initial detection of the stimulus).

<sup>52</sup> See Rebecca Fisher et al., *The Nature And Prevalence of Chronic Pain in Homeless Persons: An Observational Study*, 2 F1000 RES., July 30, 2013, at 1, 1, 6 (noting that the prevalence of chronic pain in homeless participants is substantially higher than the prevalence in several large population studies); Marc Vogel et al., *Chronic Pain Among Homeless Persons with Mental Illness*, 18 AM. ACAD. PAIN MED. 2280, 2282, 2285 (2017) (noting that 43.4% of homeless participants had clinically significant chronic pain and “more than a third reported using street drugs to control pain”).

<sup>53</sup> See, e.g., CTR. ON BUDGET & POLICY PRIORITIES, MEETING THE HOUSING NEEDS OF PEOPLE WITH SUBSTANCE USE DISORDERS (2019), <https://www.cbpp.org/sites/default/files/atoms/files/5-1-19hous.pdf> [<https://perma.cc/8D4H-4CC9>]; SUSAN G. PFEFFERLE, SAMANTHA S. KARON & BRANDY WYANT, U.S. DEP’T OF HEALTH AND HUMAN SERVS., CHOICE MATTERS: HOUSING MODELS THAT MAY PROMOTE RECOVERY FOR INDIVIDUALS AND FAMILIES FACING OPIOID USE DISORDER 4-5 (2019), <https://aspe.hhs.gov/pdf-report/choice-matters-housing-models-may-promote-recovery-individuals-and-families-facing-opioid-use-disorder> [<https://perma.cc/NA3W-ABRG>].

<sup>54</sup> See generally Paula Braitstein et al., *Sexual Violence Among a Cohort Of Injection Drug Users*, 57 SOC. SCI. MED. 561 (2003); Clifford A. Butzin, Steven S. Martin & James A. Inciardi, *Treatment During Transition from Prison to Community and Subsequent Illicit Drug Use*, 28 J. SUBSTANCE ABUSE & TREATMENT 351 (2005); Mary Clare Kennedy et al., *Residential Eviction and Exposure to Violence Among People Who Inject Drugs in Vancouver, Canada*, 41 INT. J. DRUG POL’Y 59, 62 (2017); Daniel J. O’Connell, *Investigating Latent Trait and Life Course Theories as Predictors of Recidivism Among an Offender Sample*, 31 J. CRIM. JUST. 455 (2003); Jerome J. Platt, *Vocational Rehabilitation of Drug Abusers*, 117 PSYCHOL. BULL. 416 (1995).

more violence and other injuries.<sup>55</sup> The marginalization that comes with homelessness makes it more likely that untreated injuries and infections become chronic conditions, as indicated by high prevalence of serious tooth decay, cancer, cardiovascular disease, asthma, and other persistent sources of discomfort, disability, and death.<sup>56</sup> Homelessness, pain, and OUD are also linked through shared associations with third factors, chief among them being childhood adversity.<sup>57</sup> Traumatic early life experiences are associated with

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<sup>55</sup> Health problems are exacerbated by the conditions of homelessness, such as lack of a comfortable sleeping place, exposure to weather, prevalence of violence, inadequate health and hygiene practices, overcrowding at shelters, unreliable food sources, and extensive walking. Kennedy et al., *supra* note 54, at 62.

<sup>56</sup> See Lillian Gelberg & Lawrence S. Linn, *Assessing the Physical Health of Homeless Adults*, 262 [J]AMA 1973, 1975-76, 1978 (1989) (finding that “[p]ersons sampled in emergency shelters. . . had the fewest symptoms of physical illness; persons in centers were intermediate in their physical health; and persons sampled from outdoor areas had the most physical health problems” such as acute skin injury, abnormal gait, elevated liver enzyme levels, mean corpuscular hemoglobin concentrations, and globulin levels, high lactate dehydrogenase levels, and low serum urea nitrogen levels); Margot B. Kushel, Eric Vittinghoff & Jennifer S. Haas, *Factors Associated with the Health Care Utilization of Homeless Persons*, 285 [J]AMA 200, 200 (2001) (noting that “research has documented that homeless persons have high rates of physical illness, mental illness, substance abuse, and early mortality”); Christine L. Savage et al., *Health Care Needs of Homeless Adults at a Nurse-Managed Clinic*, 23 J. COMMUNITY HEALTH NURSING 225, 229-31 (2006) (noting homeless adults’ emergency department (ED) use during the six months prior to the survey was reported by 61% of participants; of these, 40% used the ED at least once per month with the most frequently reported medical diagnoses relating to behavioral health and the most frequently reported physical health diagnoses including hypertension, arthritis, asthma, and chronic back pain).

<sup>57</sup> Adverse childhood experiences (ACEs) have been implicated in almost every major harm. See, e.g., Robert Anda et al., *Adverse Childhood Experiences and Chronic Obstructive Pulmonary Disease in Adults*, 34 AM. J. PREV. MED. 396, 396 (2008) (finding that five or more ACEs increased risk of COPD by 2.6 times with only partial attenuation of the relationship when controlling for smoking, the primary risk factor for COPD); DP Chapman et al., *Adverse Childhood Experiences and the Risk of Depressive Disorders in Adulthood*, 82 J. AFFECTIVE DISORDERS 217, 217 (2004) (finding that experiencing childhood emotional abuse increased risk for lifetime depressive disorders over 2.5 times, with more childhood adversity associated with more depression in a dose-response relationship); SR Dube et al., *Childhood Abuse, Household Dysfunction and the Risk of Attempted Suicide Throughout the Life Span: Findings from the Adverse Childhood Experiences Study*, 286 [J]AMA 3089, 3089 (2001) (finding that having one or more adverse childhood experiences accounts for 67%, 64%, and 80% of the risk for lifetime, adult, and childhood/adolescent suicide attempts, respectively.); CL Whitfield et al., *Adverse Childhood Experiences and Hallucinations*, 29 CHILD ABUSE & NEGLECT 797, 797 (2005) (finding that people with seven or more ACEs had a five-fold increase in the risk of reporting hallucinations compared to someone with no reported ACEs). It is hardly surprising, then, that OUD often co-occurs with other physical and mental illness. See, e.g., Tea Rosic et al., *The Impact of Comorbid Psychiatric Disorders on Methadone Maintenance Treatment in Opioid Use Disorder: A Prospective Cohort Study*,



both more painful conditions<sup>58</sup> and greater sensitivity to painful stimuli.<sup>59</sup> When these painful conditions exist in populations experiencing other vulnerabilities, adequate care is less likely, increasing the risk for self-medication.<sup>60</sup> This complex set of factors explains why some epidemiologists have suggested that nearly two thirds of injection drug use can be attributed to adverse childhood experiences.<sup>61</sup>

### *C. Practice and Underlying Theory*

Non-adherence to treatment is common across patient populations and clinical indications, with as many as half of all patients failing to take

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13 NEUROPSYCHIATRIC DISEASE & TREATMENT 1399, 1399 (2017) (finding that 80% of patients receiving methadone treatment had a co-occurring psychiatric disorder and 42% had another co-occurring substance use disorder). Furthermore, early childhood adversity is heavily associated with opioid use disorder and its harms and may predict relapse. See Genevieve Chandler, Karen Kalmakis & Teri Murtha, *Screening Adults with Substance Use Disorder for Adverse Childhood Experiences*, 29 J. ADDICTIONS NURSING 172, 172 (2018) (finding that more than 80% of individuals in an OUD recovery program had six or more ACEs); Karen J. Derefinko et al., *Adverse Childhood Experiences Predict Opioid Relapse During Treatment Among Rural Adults*, 96 ADDICTIVE BEHAV. 171, 171 (2019) (observing that higher ACEs were associated with a higher probability of relapse at medication-assisted treatment centers, but also finding that relapse rates went down as individuals continued treatment); Michael D. Stein et al., *Adverse Childhood Experience Effects on Opioid Use Initiation, Injection Drug Use, and Overdose Among Persons with Opioid Use Disorder*, 179 DRUG & ALCOHOL DEPENDENCE 325, 325 (2017) (reporting associations between high levels of ACEs in patients seeking detoxification and age of initiation of drug use, injection drug use, and overdose).

<sup>58</sup> See Natalie J. Sachs-Ericsson et al., *When Emotional Pain Becomes Physical: Adverse Childhood Experiences, Pain, and the Role of Mood and Anxiety Disorders*, 73 J. CLINICAL PSYCHOL. 1403, 1404-05 (listing the many ways that ACEs have been found to be linked to painful medical conditions).

<sup>59</sup> See Julia I. Herzog & Christian Schmahl, *Adverse Childhood Experiences and the Consequences on Neurobiological, Psychosocial, and Somatic Conditions Across the Lifespan*, 9 FRONTIERS PSYCHIATRY, Sept. 4, 2018, at 1, 4 (2018) (detailing a variety of circumstances in which ACEs predict unusual and heightened sensitivity to pain stimuli).

<sup>60</sup> See Pauline Voon et al., *Pain As a Risk Factor for Substance Use: A Qualitative Study of People Who Use Drugs in British Columbia, Canada*, 15 HARM REDUCTION J. 35, 35 (2018) (finding that “experiences with inadequately managed pain in various policy, economic, physical, and social environments reinforced marginalization, such as restrictive policies, economic vulnerability, lack of access to socio-physical support systems, stigma from health professionals, and denial of pain medication leading to risky self-medication.”); Pauline Voon et al., *Denial of Prescription Analgesia Among People Who Inject Drugs in a Canadian Setting*, 34 DRUG AND ALCOHOL REV. 221, 225 (2015) (finding that around two thirds of people who inject drugs have been denied prescription analgesia, leading a majority of those denied to turn to street drugs as a high-risk means of self-managing their pain).

<sup>61</sup> Robert F. Anda et al., *Childhood Abuse, Neglect, and Household Dysfunction and the Risk of Illicit Drug Use: The Adverse Childhood Experiences Study*, 111 PEDIATRICS 564, 568 (2003).

medications as directed.<sup>62</sup> Non-adherence presents particularly important challenges in opioid therapy because of the risks of overdose, hyperalgesia, polypharmacy, and diversion.<sup>63</sup> Directly-Observed Therapy (DOT) is recognized by the Centers for Disease Control and Prevention (CDC) as the most effective strategy for ensuring treatment adherence.<sup>64</sup> DOT has proven especially important in the response to diseases like tuberculosis, in which failing to complete a course of treatment can result in the development of drug resistance.<sup>65</sup> DOT is a simple model: the patient takes the medicine under the supervision of a clinician who can also advise about associated or other unrelated health issues. Given that supervision is inherently intrusive and that logistical barriers to participation are potentially considerable, it is important to provide DOT in settings that are welcoming and accessible.<sup>66</sup>

A clinic providing DOT-P would provide an appropriate opioid dose to people with pain, co-occurring OUD, and housing instability. After the administration of the opioid, clinic staff would provide care and linkages to other services. Such administration of opioids has existed in one form or another for over a hundred years, with some of the earliest incarnations in the United States.<sup>67</sup> Although the United States abandoned the practice in the

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<sup>62</sup> Marie T. Brown & Jennifer K. Bussell, *Medication Adherence: WHO Cares?*, 84 MAYO CLINIC PROC. 304, 304 (2011).

<sup>63</sup> See *supra* notes 28-29.

<sup>64</sup> TB 101 FOR HEALTHCARE WORKERS, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/tb/webcourses/tb101/page3832.html> [<https://perma.cc/6Z92JVEF>] (last visited Oct. 8, 2019).

<sup>65</sup> See generally Richard S. Garfein, *Feasibility of Tuberculosis Treatment Monitoring by Video Directly Observed Therapy: A Binational Pilot Study*, 19 INT'L J. TUBERCULOSIS & LUNG DISEASE 1057, 1062-63 (2015) (describing the successes of a low-cost variation of DOT in Tijuana and San Diego in reducing the tuberculosis rates in each respective population); Gebremedhin Gebrezgabihier et al., *Treatment Outcome of Tuberculosis Patients Under Directly Observed Treatment Short Course and Factors Affecting Outcome in Southern Ethiopia: A Five-Year Retrospective Study*, 11 PLOS ONE, Feb. 2016, at 1, 2, 8 (finding that DOT was effective for treating tuberculosis in an Ethiopia hospital over the course of five years and for meeting the WHO's treatment goals).

<sup>66</sup> See Thomas R. Frieden & John A. Sbarbaro, *Promoting Adherence to Treatment for Tuberculosis: The Importance of Direct Observation*, 85 BULL. WORLD HEALTH ORG. 407, 409 (2007) ("The key challenge of direct observation of treatment is to implement it well, maximizing convenience of and respectful interaction with patients.").

<sup>67</sup> See DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 76-82 (3d ed. 1999) (detailing the rise and abrupt decline of heroin and morphine maintenance in the treatment of addiction); see also Alyson J. Bond & John Witton, *Perspectives on the Pharmacological Treatment of Heroin Addiction*, 8 CLINICAL MED. INSIGHTS: PSYCHIATRY 1, 2 (2017) (explaining the development of methadone maintenance programs in the United States in the 1960s); Edward Lewis, *A Heroin Maintenance Program in the United States?*, 223 [J]AMA 539, 539 (1973) ("[H]eroin appeared in the United States Pharmacopeia from

1920s, a number of countries have since operated similar programs under various names.<sup>68</sup> In some programs, pharmaceutical grade heroin is administered,<sup>69</sup> which might seem strange, but heroin is widely used for analgesia in the United Kingdom.<sup>70</sup> A program in the United States, however, would probably follow Canada's recent preference for hydromorphone, which is a cheap<sup>71</sup> and frequently prescribed opioid<sup>72</sup> with a great safety profile when administered under medical supervision.<sup>73</sup>

Centering on pain in the care of people with refractory OUD makes sense because pain complicates OUD treatment in multiple ways. One is technical: it is difficult to dose agonists or analgesics for people with heightened opioid tolerance, which is common among people with OUD.<sup>74</sup> Another is social and contextual: providers are uneasy treating this population because of clinical

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1910 to 1920 . . . by 1920, recognizing the problems of heroin addiction . . . the American Medical Association resolved that use of the drug in the United States should be discontinued.”); Nicola Metrebian et al., *Patients Receiving a Prescription for Diamorphine (Heroin) in the United Kingdom*, 25 DRUG & ALCOHOL REV. 115, 115 (2006) (noting that the United Kingdom started to offer heroin maintenance in the 1920's).

<sup>68</sup> Common names include Heroin-Assisted Treatment (HAT) and Injectable Opioid Agonist Treatment (iOAT). BEAU KILMER ET AL., CONSIDERING HEROIN-ASSISTED TREATMENT AND SUPERVISED DRUG CONSUMPTION SITES IN THE UNITED STATES xv, 24 (2018) (ebook).

<sup>69</sup> *Id.* at vi.

<sup>70</sup> See Michael Gossop & Francis Keaney, *Research Note—Prescribing Diamorphine for Medical Conditions: A Very British Practice*, 34 J. DRUG ISSUES 441, 443-44 (2004) (noting that heroin is prescribed and administered in the U.K. for acute pain, chronic pain, intractable pain, and pediatric postoperative pain).

<sup>71</sup> In the United States, the wholesale cost is about \$0.07 per 2 mg dose. *National Drug Acquisition Cost as of 2019-02-27*, DATA.MEDICAID.GOV, <https://data.medicare.gov/Drug-Pricing-and-Payment/NADAC-as-of-2019-02-27/s7c9-pfa6> [<https://perma.cc/55Q4-ML4X>] (enter “hydromorphone” in search field; view “NADAC\_Per\_Unit” column) (last visited Mar. 3, 2019); see also *Hydromorphone*, DRUG ENFORCEMENT ADMIN. (July 2013), [https://www.deadiversion.usdoj.gov/drug\\_chem\\_info/hydromorphone.pdf](https://www.deadiversion.usdoj.gov/drug_chem_info/hydromorphone.pdf) [<https://perma.cc/V7ES-VS5P>] (“The street price of a 4 mg tablet of Dilaudid® ranges from \$5 to \$100 per tablet depending on the region.”).

<sup>72</sup> In 2016, Dilaudid was the 212th most prescribed medication in the United States, with more than 2.5 million prescriptions. See *The Top 300 of 2019*, CLINICALC, <https://clincalc.com/Drug-Stats/Top300Drugs.aspx> [<https://perma.cc/4DFA-6BU6>] (last visited Dec. 22, 2018).

<sup>73</sup> See generally E. Oviedo-Joekes et al., *Safety Profile Of Injectable Hydromorphone and Diacetylmorphine for Long-Term Severe Opioid Use Disorder*, 176 DRUG ALCOHOL DEPENDENCE 55 (2017) (finding that the safety profile of injectable hydromorphone involved fewer adverse and serious adverse events than for diacetylmorphine, although both were recommended for treating OUD in a supervised injection model).

<sup>74</sup> See generally Amy Wachholtz, Simmie Foster & Martin Cheatle, *Psychophysiology of Pain and Opioid Use: Implications for Managing Pain in Patients with an Opioid Use Disorder*, 146 DRUG & ALCOHOL DEPENDENCE 1 (2015) (describing hyperalgesia in people with OUD and addressing the difficulties inherent in treating their pain by attempting to explain the psychophysiology of pain for those with OUD).

ambiguity and the potential to cause harm or experience regulatory sanctions.<sup>75</sup> This uneasiness produces poor treatment and amplifies providers' mistrust of patients.<sup>76</sup> The most important, however, is practical: an enormous body of research confirms that patients must be ready to engage in treatment for OUD or to make other change in health behavior to have a reasonable chance of long-term benefits, but people in serious pain are not ready to do anything until that pain is treated.<sup>77</sup>

Few individualized interventions produce durable changes in decision-making absent a readiness to change.<sup>78</sup> This is at the same time a heretical and an obvious statement. It is heretical because we want to believe that counseling alone can change behavior. But even simple changes—like exercising more or eating better—are not hard because we lack information about their value or encouragement, or even the means (especially for those reading seventy-page articles like this); they are hard because we are unprepared to make them.<sup>79</sup>

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<sup>75</sup> See, e.g., Fiona Webster et al., *An Ethnography of Chronic Pain Management in Primary Care: The Social Organization of Physicians' Work in the Midst of the Opioid Crisis*, 14 PLOS ONE, May 2019, at 1, 1 (reporting that while treating patients with chronic pain, "many providers describe being most challenged by the work involved in helping patients who also struggled with poverty, mental health, and addiction," especially because of "concerns that they could lose their license for inappropriate prescribing, thus shifting their work from providing treatment and care to policing their patients for malingering and opioid abuse").

<sup>76</sup> See Berg et al., *supra* note 18, at 484-86 (noting that providers treating people with OUD and pain follow one of two very different treatment frameworks with one focused on treating the pain and the other focused on treating the OUD, with those in the latter systematically undertreating the pain).

<sup>77</sup> See, e.g., Bobbi Jo H. Yarborough et al., *Methadone, Buprenorphine and Preferences for Opioid Agonist Treatment: A Qualitative Analysis*, 160 DRUG & ALCOHOL DEPENDENCE 112, 116 (2016) (noting pain as a barrier to entering MAT and noting that some participants were more willing to accept maintenance if they believed their pain would be managed adequately).

<sup>78</sup> See generally Gerdien H. de Weert-van Oene et al., *Motivation for Treatment and Motivation for Change in Substance-Dependent Patients with Co-Occurring Psychiatric Disorders*, 47 J. PSYCHOACTIVE DRUGS 393 (2015) (noting that "[m]otivation for change has been related to treatment seeking, treatment attendance, treatment retention, and treatment participation" and concluding that lower readiness for both change and treatment predicts, to an extent, a stronger likelihood of premature attrition from treatment); Vincent Wagner et al., *Initiation of Addiction Treatment and Access to Services: Young Adults' Accounts of Their Help-Seeking Experiences*, 27 QUALITATIVE HEALTH RES. 1614 (2017) (describing different experiences of the decision to seek treatment).

<sup>79</sup> See, e.g., James O. Prochaska et al., *The Transtheoretical Model and Stages of Change*, in HEALTH BEHAVIOR: THEORY, RESEARCH, AND PRACTICE 125, 127-28 (Karen Glanz et al. eds., 5th ed. 2015) (describing the length of time people spend in the precontemplation and contemplation stages before entering the preparation stage of the Transtheoretical Model's (TTM's) Stages of Change framework, positing that it isn't necessarily the difficulty of the task, but rather the individual's internal motivation to match their needs).

Health behavior researchers have various ways of describing this concept. One of the most common is the Stages of Change model, which posits that changing behavior requires people to transition from precontemplation to contemplation to preparation before sustainable action takes hold.<sup>80</sup> Progression through these stages is often nonlinear and frequently iterative.<sup>81</sup> People with OUD remain in the precontemplation phase for many reasons.<sup>82</sup> Contemplation requires thoughtful reflection, and moving from contemplation to preparation requires self-efficacy.<sup>83</sup> Both are difficult if not impossible for someone

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<sup>80</sup> See, e.g., Carlo C. DiClemente et al., *Readiness and Stages of Change in Addiction Treatment*, 13 AM. J. ON ADDICTIONS 103, 114 (2004) (“A stage of change represents the current state of the individual with respect to changing a single behavior or constellation of behaviors.”); John C. Norcross et al., *Stages of Change*, 67 J. CLINICAL PSYCHOL. 143, 143-48 (2011) (defining the stages of change and reviewing meta-analyses of studies exploring the ability of stages of change measures to predict treatment outcomes).

<sup>81</sup> See, e.g., John R. Gallagher et al., *A Perspective from the Field: Five Interventions to Combat the Opioid Epidemic and Ending the Dichotomy of Harm-Reduction Versus Abstinence-Based Programs*, 37 ALCOHOLISM TREATMENT Q. 404, 410-12 (2019) (describing a program in which the goal was not abstinence but motivation for change, which resulted in increased retention in treatment, referrals to detoxification and inpatient treatment programs, and, most importantly, promoted recovery and wellbeing); David H. Morris et al., *Substance Use Consequences, Mental Health Problems, and Readiness to Change Among Veterans Seeking Substance Use Treatment*, 94 J. SUBSTANCE ABUSE TREATMENT 113, 114 (2018) (noting in the context of research on alcohol and drug dependence that Readiness to Change (RTC) is conceptualized as a combination of one’s perceived importance to make a change and confidence in ability to achieve it (self-efficacy), with greater self-efficacy associated with increased treatment engagement, more attempts to quit, better treatment retention, sustained abstinence, and reduction of substance use among individuals with problematic drug and alcohol use); Muhammad Washdev & Iqbal Afridi, *A Survey to Determine Motivating Factors to Quit Opioids in Treatment Seekers at a Tertiary Care Hospital*, 67 J. PAK. MED. ASS’N 1050, 1050-53 (2017) (proposing that motivation should be a main focus in addition to pharmacological treatment for those with OUD and suggesting that low motivation is the key predictor of poor treatment outcomes).

<sup>82</sup> See, e.g., Emine M. Akdağ et al., *The Relationship between Internalized Stigma and Treatment Motivation, Perceived Social Support, Depression and Anxiety Levels in Opioid Use Disorder*, 28 PSYCHIATRY & CLINICAL PSYCHOPHARMACOLOGY 394, 400 (2018) (noting that many people with OUD struggled to advance through the early Stages of Change because of internalized stigma); Ramin Mojtabei et al., *Comparing Barriers to Mental Health Treatment and Substance Use Disorder Treatment Among Individuals with Comorbid Major Depression and Substance Use Disorders*, 46 J. SUBSTANCE ABUSE TREATMENT 268, 270 (2014) (noting cost as a barrier to treatment); Li-Tzy Wu et al., *Treatment Use and Barriers Among Adolescents with Prescription Opioid Use Disorders*, 36 ADDICTIVE BEHAVS. 1233, 1233 (2011) (“Only 4.2% of adolescents with opioid dependence, 0.5% of those with abuse, and 0.6% of subthreshold users reported a perceived need for treatment of nonmedical opioid use.”).

<sup>83</sup> See, e.g., Theodore J. Cicero & Matthew S. Ellis, *The Prescription Opioid Epidemic: A Review of Qualitative Studies on the Progression from Initial Use to Abuse*, 19 DIALOGUES CLINICAL NEUROSCIENCE 259, 264 (2017) (“The most cited reasons [for continued opioid

experiencing pain.<sup>84</sup> To the extent that contemplation is contingent on reasonable comfort, addressing pain is a key step in supporting people who are stuck in the earlier stages of change. This accounts for why people with moderate to severe pain are less likely to access drug-related health services.<sup>85</sup> It also explains how some heavy-handed or insensitive strategies can undermine readiness to change by increasing stress and decreasing self-efficacy.<sup>86</sup>

DOT-P would be community-based for three reasons. First, it would be deployed in the community at a clinic rather than in a hospital. Hospitals are not designed to provide an environment that is welcoming to DOT-P

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use] included use as a response to life stressors . . . or as a means of self-medicating psychological issues, effects of trauma, or emotional pain.”); de Weert-van Oene et al., *supra* note 78, at 394 (finding in a study evaluating the association between readiness for change and treatment adherence that readiness was more important than sociodemographics, drug use, and other background variables in the prediction of retention in treatment.); Rebekka S. Palmer et al., *Substance User Treatment Drop-Out from Client and Clinician Perspectives: A Pilot Study*, 44 J. SUBSTANCE USE & MISUSE 1021, 1029 (2009) (finding that the most commonly reported reasons for dropping out of treatment were individual or personal factors rather than program-related factors).

<sup>84</sup> See Mojtabai et al., *supra* note 82, at 270 (2014) (finding in a study of 393 adults with twelve-month major depressive episodes and substance use disorders that 38.9% of subjects reported no interest in stopping drug use).

<sup>85</sup> As Garland et al. observe:

Chronic pain, which affects 55%–61% of people receiving MMT, contributes to continued opioid use, relapse, and MMT dropout. Further, traditional MAT does not directly address the emotion regulation and reward processing deficits characteristic of OUD—critical mechanisms of addiction and chronic pain. Through opponent processes in the brain, emotion dysregulation and reward deficits may amplify stress sensitization and opioid craving, serving as critical risk factors for OUD that may be neglected by traditional MAT.

Eric L. Garland et al., *Mindfulness-Oriented Recovery Enhancement Reduces Opioid Craving Among Individuals with Opioid Use Disorder and Chronic Pain in Medication Assisted Treatment: Ecological Momentary Assessments from a Stage 1 Randomized Controlled Trial*, 203 DRUG & ALCOHOL DEPENDENCE 61, 61 (2019); see Taeho G. Rhee & Robert A. Rosenheck, *Use of Drug Treatment Services Among Adults With Opioid Use Disorder: Rates, Patterns, and Correlates*, PSYCHIATRIC SERVS. IN ADVANCE 1, 5-6 (2019) (finding that that moderate to extreme self-reported pain was associated with a lower likelihood of using drug-related health services in adjusted multivariable analyses).

<sup>86</sup> See Rachel Ayres et al., *Enhancing Motivation Within a Rapid Opioid Substitution Treatment Feasibility RCT: A Nested Qualitative Study*, 9 SUBSTANCE ABUSE TREATMENT, PREVENTION, & POL’Y 1, 5-7 (2014) (noting that internalized motivation is more effective on long-term change than external motivation and that pressure to be in treatment from family, law enforcement, and healthcare professionals can provoke resistance or undermine self-efficacy); DiClemente et al., *supra* note 80, at 112 (“Methadone maintenance programs often require abstinence from all ‘unauthorized’ drugs. However, individuals who apply to and participate in these programs often are ready to change only one or two of the drug abuse behaviors that they are engaging in and not all unauthorized drugs.”).

patients. Many of these patients have significant and well-founded mistrust of healthcare providers and go to great lengths to avoid emergency departments even in the face of extremely dangerous and painful conditions.<sup>87</sup> Second, DOT-P would provide the intense social support—that is, the community—required for managing pain and OUD.<sup>88</sup> Finally, given that patients are otherwise likely to be injecting in public settings, a DOT-P approach also would be community care in that it reduces harms that communities experience related to OUD including public intoxication, injection-related litter, and illicit drug dealing.<sup>89</sup>

It is important that DOT-P incorporate a patient-centered model, which accounts for each patient's unique experiences, challenges, and aspirations. Such holistic care is essential for reaching a population with a history of trauma and other overlapping vulnerabilities. Implementation of DOT-P would need to occur in an accessible, welcoming, and well-resourced setting. The services provided must be oriented to the unique needs of the person, which, given the target population, are often extensive and interrelated. In addition to being a high threshold intervention, DOT-P is also a high intensity and—necessarily and appropriately—low-scale intervention. Most people with OUD do not want or would not benefit from DOT-P.<sup>90</sup>

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<sup>87</sup> See Robert Harris et al., *Experiences with Skin and Soft Tissue Infections Among People Who Inject Drugs in Philadelphia: A Qualitative Study*, 187 *DRUG & ALCOHOL DEPENDENCE* 8, 11, 12 (2018) (describing how many people who inject drugs in Philadelphia delayed seeking medical care for skin and soft tissue infections, or engaged in self-care, to avoid repeating negative healthcare experiences).

<sup>88</sup> See Jazmin Warren et al., *Role of Social Support and Self-Efficacy in Treatment Outcomes Among Clients with Co-occurring Disorders*, 89 *DRUG & ALCOHOL DEPENDENCE* 267, 272 (2007) (describing how higher levels of social support among clients in treatment were predictive of better psychological health and less use of heroin and cocaine at follow-up); cf. Markus Heilig et al., *Time to Connect: Bringing Social Context into Addiction Neuroscience*, 17 *NATURE REVIEWS. NEUROSCIENCE* 592, 592 (2016) (describing how the use of drugs impairs social connections, which in turn leads to more drug use).

<sup>89</sup> See Alison Sutter et al., *Public Drug Use in Eight U.S. Cities: Health Risks and Other Factors Associated with Place of Drug Use*, 64 *INT'L J. DRUG POL'Y* 62, 63-64 (2019) (finding that nearly half of individuals using syringe exchange programs reported that one of their top two most frequent places of drug use is a public place, and describing the harms related to public drug use, such as increased risk of overdose and improper disposal of used needles).

<sup>90</sup> See, e.g., Thomas V. Perneger et al., *Randomised Trial of Heroin Maintenance Programme for Addicts Who Fail in Conventional Drug Treatments*, 317 *BRIT. MED. J.* 13, 17 (1998) (finding that, in one randomized controlled trial in Switzerland testing the outcomes between a group receiving heroin administration versus conventional methadone maintenance, there were clear benefits for the first group, yet less than half of the latter chose to receive heroin administration at the end of the study, with most preferring to continue medication methadone); Ambros Uchtenhagen, *The Role and Function of Heroin Assisted Treatment at the Treatment System Level*, 19 *HEROIN ADDICTION & RELATED CLINICAL PROBS.* 5, 7 (2017)

#### D. Evidence from Other Countries

An enormous body of research suggests that DOT-P would provide considerable benefits in the United States without any substantial counter-vailing harms. Understanding the benefits of DOT-P requires drawing from experience and evaluations related to different interventions focusing on different problems. DOT-P integrates some of the most beneficial features of SCFs, OAT, iOAT, and DOT in the care of people with diseases like tuberculosis and HIV/AIDS. In this section, we review research documenting these benefits with less emphasis on SCFs, OAT and DOT, only because they have been the focus of so many research reviews recently or previously.

A clinic providing DOT-P would provide medical supervision for people while they experience opioid-related intoxication, which is one of the key benefits of SCFs. Research has established that SCF personnel can effectively reverse overdoses when they occur, saving thousands of lives across the over 160 SCFs that currently operate around the world.<sup>91</sup> It is estimated that opening a SCF in Philadelphia, for example, would result in immediate reduction up to 76 fatal overdoses each year.<sup>92</sup> These facilities also provide a secure and hygienic space, which minimizes the risk of infections or other injuries.<sup>93</sup> Almost all SCFs offer health and social services, including

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(finding that less than 10% of people receiving treatment for OUD in Switzerland are enrolled in DOT-P). Moreover, research on Supervised Consumption Facilities suggests that people who are stably housed are likely to continue injecting at home whenever possible if a facility opened. See Robert Harris et al., *Perceptions About Supervised Injection Facilities Among People Who Inject Drugs in Philadelphia*, 52 INT'L J. DRUG POL'Y 56, 57-58 (2018) (noting from interviews with people who inject drugs a clear preference for injection at home for those stably housed and only likely use of a facility among those lacking stable housing).

<sup>91</sup> See Chloé Potier et al., *Supervised Injection Services: What Has Been Demonstrated? A Systematic Literature Review*, 145 DRUG & ALCOHOL DEPENDENCE 48, 62-64 (2014) (finding that the presence of healthcare workers in SCFs improved the outcome of overdose cases).

<sup>92</sup> See SHARON LARSON ET AL., MAIN LINE HEALTH CTR. FOR POPULATION HEALTH RES., SUPERVISED CONSUMPTION FACILITIES—REVIEW OF THE EVIDENCE 6-7 (2017), [https://dbhids.org/wp-content/uploads/2018/01/OTF\\_LarsonS\\_PHLReportOnSCF\\_Dec2017.pdf](https://dbhids.org/wp-content/uploads/2018/01/OTF_LarsonS_PHLReportOnSCF_Dec2017.pdf) [<https://perma.cc/G4NQ-PUCH>] (finding that overdose deaths in Philadelphia could be reduced by 24 to 76 annually by creating SCFs).

<sup>93</sup> See EA Enns et al., *Potential Cost-Effectiveness of Supervised Injection Facilities in Toronto and Ottawa, Canada*, 111 ADDICTION 475, 485 (2015) (describing reductions in infections associated with SCFs in Toronto and Ottawa).



access to drug treatment.<sup>94</sup> Perhaps most importantly, research documents that the most vulnerable people who inject drugs, including those at high risk for serious health conditions and unstable housing, are willing to use SCFs to improve their health and the health of the community.<sup>95</sup> It is also important to note that SCFs have been associated with improved community health and that no negative community effects have been observed.<sup>96</sup>

It is clear that OUD is partly a physiological phenomenon.<sup>97</sup> It is hardly surprising then that treatment with medications that target related neurochemical pathways is more effective than abstinence or behavioral interventions at reducing the harm of unmanaged OUD and at bridging the gap to long-term detoxification. Patients receiving methadone are over four times more likely to remain engaged in treatment compared to patients

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<sup>94</sup> See, e.g., Larson et al., *supra* note 92, at 26 (“Generally, SCFs offer an array of other comprehensive health and social services, including detoxification and other substance use treatment services, medical care, counseling, and legal assistance.”); Thomas Kerr et al., *A Micro-Environmental Intervention to Reduce the Harms Associated with Drug-Related Overdose: Evidence from the Evaluation of Vancouver's Safer Injection Facility*, 18 INT’L J. DRUG POL’Y 37, 38 (2007) (finding that SCFs in Vancouver typically refer drug users to health and social services, in addition to providing safe spaces for drug use).

<sup>95</sup> See, e.g., BA Bouvier et al., *Willingness to Use a Supervised Injection Facility among Young Adults Who Use Prescription Opioids Non-Medically: A Cross-Sectional Study*, 14 HARM REDUCTION J., 2017, at 1, 7 (“If a SIF were opened, more than six in ten of our study participants reported they would use the service, and more than eight in ten of participants who have injected drugs reported they would use the service.”); Alex Kral et al., *Acceptability of a Safer Injection Facility Among Injection Drug Users in San Francisco*, 110 DRUG & ALCOHOL DEPENDENCE 160, 161 (2010) (“Eighty-five percent [of injection drug users] said that they would use a [safer injection facility] should it be convenient for them.”); Harris et al., *supra* note 87, at 57-58 (noting that in interviews of people who inject drugs those who inject in public settings would use a SCF in part to avoid exposing people in the community to their public drug use and intoxication).

<sup>96</sup> Potier et al., *supra* note 91, at 63 (noting that there have been no additional observed harms and fewer injection materials discarded in public in neighborhoods with established SCFs).

<sup>97</sup> That opioids target pain receptors and reward endorphins explains much of their attraction. This neurochemical process is easily observable in functional brain scans. See e.g., Henry W. Chase, *The Neural Basis of Drug Stimulus Processing and Craving: An Activation Likelihood Estimation Meta-Analysis*, 70 BIOLOGICAL PSYCHIATRY 785, 787 (2011) (explaining meta-analysis studies of brain imaging, showing cue responses effects for people with substance use disorders). Though this neurochemical effect is often more proximal and psychological issues are often more distal, they are fully and inextricably linked. See, e.g., Igor Elman & David Borsook, *The Failing Cascade: Comorbid Post Traumatic Stress and Opioid Use Disorders*, 103 NEUROSCIENCE & BIOBEHAVIORAL REVS. 374, 379 (2019) (finding a common neurological foundation between PTSD and opioid use disorder).

receiving a placebo.<sup>98</sup> Opioid Agonist Therapy (OAT) with methadone and buprenorphine are the “gold standard” treatments for OUD.<sup>99</sup>

Despite the benefits of OAT, some patients on these medications do continue or return to active, unmanaged consumption of illicit drugs,<sup>100</sup> others avoid these medications because of a variety of logistical, resource, and stigma factors.<sup>101</sup> Another strategy for reducing harms among people who struggle to start or adhere to OAT or other supportive services is iOAT, which involves providing pharmaceutical-grade heroin or hydromorphone to people for self-administration.<sup>102</sup> To date, nine randomized controlled trials<sup>103</sup> have evaluated interventions that are programmatically similar to iOAT and DOT-P. The trials provided opioids other than methadone or buprenorphine to people who would otherwise consume street drugs.<sup>104</sup> The first was conducted

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<sup>98</sup> *Fentanyl: The Next Wave of the Opioid Crisis: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 82 (2017) (statement of Wilson M. Compton, Deputy Director, National Institute on Drug Abuse).

<sup>99</sup> Hilary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARV. REV. PSYCHIATRY 63, 64 (2015) (“The evidence for efficacy both in reducing opioid use and retaining patients in care is strongest for agonist treatment; methadone maintenance remains the gold standard of care for OUD.”).

<sup>100</sup> Brittany Burns Dennis et al., *The Effectiveness of Opioid Substitution Treatments for Patients with Opioid Dependence: A Systematic Review and Multiple Treatment Comparison Protocol*, 3 SYSTEMATIC REVIEWS, Sept. 19, 2014, at 1, 1-2; see also Ada Lo et al., *Factors Associated with Methadone Maintenance Therapy Discontinuation Among People Who Inject Drugs*, 94 J. SUBSTANCE ABUSE TREATMENT 43 (2018) (noting that only 35-54% of patients continue with methadone treatment through the first year, meaning that over half of patients who initiate methadone treatment will cease treatment and resume using non-prescription opioids within twelve months).

<sup>101</sup> See Yarborough et al., *supra* note 7777, at 114-15 (2016) (delineating the many barriers individuals face and perceive when making decisions about OAT treatment).

<sup>102</sup> Guidelines for the delivery of iOAT in Canada were released earlier this fall. See generally Nadia Fairbairn et al., *Injectable Opioid Agonist Treatment for Opioid Use Disorder: A National Clinical Guideline*, 191 CAN. MED. ASSOC. J. E1049 (2019) (identifying best practices and laying out recommendations for iOAT with injectable heroin and hydromorphone for individuals with severe OUD).

<sup>103</sup> Randomized Controlled Trials (RCT) are the gold standard for assessing the causal effects of an intervention. The FDA generally requires one large RCT demonstrating the efficacy of a drug compared to a similar product or therapy before it can be approved to enter the commercial market. See 21 C.F.R. § 314.126(b) (2018) (emphasizing that when approving new drug applications, an “adequate and well-controlled study” includes randomization and control groups, while not explicitly describing these studies as RCTs).

<sup>104</sup> See generally Isabelle Demaret et al., *Efficacy of Heroin-Assisted Treatment in Belgium: A Randomised Controlled Trial*, 21 EUR. ADDICTION RES. 179 (2015); Christian Haasen et al., *Heroin-Assisted Treatment for Opioid Dependence: Randomised Controlled Trial*, 191 BRIT. J. PSYCHIATRY 55 (2007); Richard L. Hartnoll et al., *Evaluation of Heroin Maintenance in Controlled Trial*, 37 ARCHIVES GEN. PSYCHIATRY 877 (1980); Joan Carles March

in 1980, when ninety-six high-functioning heroin users in London were randomly assigned to receive a prescription for home-use heroin or methadone.<sup>105</sup> After twelve months, patients receiving the heroin prescription had fewer arrests and higher treatment adherence compared to patients receiving methadone.<sup>106</sup> Social and health outcomes were otherwise stable and similar.<sup>107</sup> The second trial began in 1995, in Switzerland, with fifty-one participants.<sup>108</sup> Unlike their counterparts in the United Kingdom, the Swiss participants had significantly greater physical and social challenges including more unemployment, mental illness, and participation in high-risk practices.<sup>109</sup> Patients receiving heroin, which was administered by healthcare providers three times daily, experienced significantly better physical, social, emotional, and mental functioning at the end of the trial compared to the control group.<sup>110</sup>

Researchers in the Netherlands completed a much larger and more complex trial a few years later when they randomly assigned 549 treatment-resistant heroin users to either standard methadone medication treatment or methadone medication treatment with the option of being administered

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et al., *Controlled Trial of Prescribed Heroin in the Treatment of Opioid Addiction*, 31 J. SUBSTANCE ABUSE TREATMENT 203 (2006); Eugenia Oviedo-Joekes et al., *Diacetylmorphine Versus Methadone for the Treatment of Opioid Addiction*, 361 NEW ENG. J. MED. 777 (2009) [hereinafter Oviedo-Joekes et al., *Diacetylmorphine Versus Methadone*]; Eugenia Oviedo-Joekes et al., *Hydromorphone Compared with Diacetylmorphine for Long-Term Opioid Dependence: A Randomized Clinical Trial*, 73 [J]AMA PSYCHIATRY 447 (2016) [hereinafter Oviedo-Joekes et al., *Hydromorphone Compared with Diacetylmorphine*]; Perneger et al., *supra* note 90; John Strang et al. *Supervised Injectable Heroin or Injectable Methadone Versus Optimised Oral Methadone as Treatment for Chronic Heroin Addicts in England After Persistent Failure in Orthodox Treatment (RIOTT): A Randomised Trial*, 375 LANCET 1885 (2010); Wim van den Brink et al., *Medical Prescription of Heroin to Treatment Resistant Heroin Addicts: Two Randomised Controlled Trials*, 327 BRIT. MED. J. 310 (2003). The evidence base is nicely summarized in a recent RAND report. See KILMER ET AL., *supra* note 68, at iii (“This mixed-methods report assesses evidence on and arguments made about HAT and SCSs and examines some of the issues associated with implementing them in the United States.”).

<sup>105</sup> These patients were considered high functioning because many were able to remain employed either full- or part-time and they experienced relatively good health. See Hartnoll et al., *supra* note 104, at 881 (noting that 32% of participants were employed full time at intake and only 10% of both groups experienced bad health).

<sup>106</sup> See *id.* at 880-81 (noting that 48% of HAT patients had no arrests, whereas only 28% of MMT patients had no arrests; that 32% of MMT patients spent time in prison compared to 19% of HAT patients; and that over 12 months, 74% of HAT patients continued to receive their prescriptions compared to only 29% of MMT patients). This study was essentially an RCT of drug control because denial of HAT was otherwise available.

<sup>107</sup> *Id.*

<sup>108</sup> See Perneger et al., *supra* note 90, at 14-17.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

heroin.<sup>111</sup> Once again, the group with access to heroin administration experienced better outcomes, measured by a composite functioning index, compared to the group that only received normal treatment with methadone.<sup>112</sup> The benefits for those in the treatment group notably dissipated in the two months after their heroin treatment stopped.<sup>113</sup>

A small fourth trial was completed in Spain in 2006, with a focus on people engaging in injection drug use with other serious co-occurring conditions.<sup>114</sup> In the control group, oral methadone was dispensed to patients once a day.<sup>115</sup> The patients in the treatment group received heroin in the morning and at night along with one dose of oral methadone around 8 p.m.<sup>116</sup> Yet again, compared with the control group, the treatment group experienced improved general health status, decreased drug-related problems, and reduced HIV-related risk behavior.<sup>117</sup> The findings from a large trial in Germany emerged in 2007.<sup>118</sup> Across multiple cities, researchers randomly assigned over 1,000 participants with opioid dependence to receive heroin for self-administration under supervision in outpatient clinics or standard methadone treatment.<sup>119</sup> Consistent with previous trials, retention was substantially higher in the group receiving heroin, as were improvements in self-reported health.<sup>120</sup> There was, once again, a much larger reduction in illicit use of street drugs in the group receiving heroin.<sup>121</sup>

The first trial in North America reported findings in 2009 from the random assignment of 251 long-term users of injectable heroin with a history

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<sup>111</sup> See van den Brink et al., *supra* note 104, at 310-12; see also Isabelle Demaret et al., *Loss of Treatment Benefit When Heroin-Assisted Treatment is Stopped after 12 Months*, 69 J. SUBSTANCE ABUSE TREATMENT 72, 74 (2016) (noting that the benefits of treatment in a Belgian study totally dissipated and that those receiving heroin returned to active use of street drugs at the same rate of those in the control group).

<sup>112</sup> van den Brink et al., *supra* note 104, at 310-12.

<sup>113</sup> *Id.* at 311-12.

<sup>114</sup> See March et al., *supra* note 104, at 204 (conducting the study specifically to address injection drug use in individuals with at least two of the following: “infectious disease related to intravenous drug use, mental health problems, and social maladjustment”).

<sup>115</sup> *Id.* at 205.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 208-09 (finding that patients receiving HAT had approximately three times fewer days engaging in criminal activity compared to MMT control patients and higher score of general health—2.5 times higher than the control group—including avoiding behaviors correlated with contracting HIV and that “[t]he rate of improvement was higher within the DAM group, as compared with the control group, in terms of general health status[,] . . . drug related problems, and reduced HIV-risk behavior”).

<sup>118</sup> See Haasen et al., *supra* note 104, at 55, 57, 59-60.

<sup>119</sup> *Id.* at 55.

<sup>120</sup> *Id.* at 57, 59.

<sup>121</sup> *Id.* at 58-59.

of relapse after one or more treatments with methadone who were living in Vancouver.<sup>122</sup> Retention was significantly higher in the treatment group, as was the reduction in illicit-drug use and other illegal activity.<sup>123</sup> Some overdoses were observed and reversed, leading the researchers to conclude that such treatment should be medically supervised.<sup>124</sup> The following year, researchers reported on a trial in London evaluating the effects of the assignment of 301 patients to supervised injectable methadone, supervised injectable heroin, and optimized oral methadone.<sup>125</sup> Treatment with supervised injectable heroin led to immediate and significant reductions in the use of illicit heroin compared with supervised injectable methadone or oral methadone.<sup>126</sup> An eighth trial was conducted in Belgium where seventy-four participants were randomly assigned to supervised self-administration of heroin or methadone prescriptions for home use. After twelve months, participants in the treatment group reported significantly less illicit drug use and significantly better physical and mental health.<sup>127</sup>

In the most recent trial, completed in 2011, researchers explored whether the benefits of heroin-administration could be replicated with hydromorphone.<sup>128</sup> In this non-inferiority trial, 202 long-term street opioid injectors were randomly assigned to receive either injectable heroin or hydromorphone (up to three times daily) for six months under supervision.<sup>129</sup> The researchers observed equivalent benefits—that is, with no statistically significant differences—in the form of reduced street heroin use and reduced use of any street opioids.<sup>130</sup> There were fewer adverse events such as seizures and overdoses in the group receiving hydromorphone.<sup>131</sup>

The delivery of iOAT has occurred with and without clinical supervision. Although some people do not require supervision, for others supervision is likely to offer a number of important benefits. These benefits are evident from the broader experience of Directly-Observed Therapy in other contexts. DOT

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<sup>122</sup> Oviedo-Joekes et al., *Diacetylmorphine Versus Methadone*, *supra* note 104, at 779.

<sup>123</sup> *See id.* at 782 (observing a 43.5% reduction in illicit drug usage and illegal activities in the HAT group relative to 28.8% in the MMT group and an 87.8% retention rate in the HAT group compared to a 54.1% rate in the MMT group).

<sup>124</sup> *Id.* at 784.

<sup>125</sup> Strang et al., *supra* note 104.

<sup>126</sup> *Id.* at 1891-92.

<sup>127</sup> Demaret et al., *supra* note 104, at 183-85.

<sup>128</sup> Oviedo-Joekes et al. *Hydromorphone Compared with Diacetylmorphine*, *supra* note 104, at 448-49.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 452-53.

<sup>131</sup> *See id.* at 447 (reporting from a study conducted with 202 patients and the efficacy of hydromorphone as a substitute for diacetylmorphine was evaluated through measuring the days of street heroin use in each group, with the assumption that street heroin use is inversely correlated to efficacy).

is the standard of care for ensuring compliance with treatment protocols when noncompliance can produce serious individual or communal harm, as with the development of drug resistant tuberculosis when medication is discontinued.<sup>132</sup> There is a long history of culturally sensitive DOT, which addresses potential nonadherence not through after-the-fact punishment, which does not work, but through extensive social supports.<sup>133</sup>

These studies collectively suggest that DOT-P would improve the quality of life for individuals with OUD, provide benefits to the community, and would not result in other harms. Two systematic reviews<sup>134</sup> emphasize that the relative advantage of iOAT compared with methadone treatment is greater for individuals with severe OUD,<sup>135</sup> who are more likely to experience homelessness<sup>136</sup> and have co-occurring mental health disorders.<sup>137</sup> DOT-P

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<sup>132</sup> See C. Patrick Chaulk et al., *Eleven Years of Community-Based Directly Observed Therapy for Tuberculosis*, 274 [J]AMA 945, 949-50 (1995) (reporting on a substantial decline in TB following implementation of community-based DOT in Baltimore despite prevalent risk factors); Stephen E. Weis et al., *The Effect of Directly Observed Therapy on the Rates of Drug Resistance and Relapse in Tuberculosis*, 330 NEW ENG. J. MED. 1179, 1182 (1994) (reporting from observation of over 400 patients receiving traditional treatment for tuberculosis and over 580 patients receiving DOT that DOT was associated with less drug resistance and fewer relapses).

<sup>133</sup> See, e.g., Jimmy Volmink, Patrice Matchaba & Paul Garner, *Directly Observed Therapy and Treatment Adherence*, 355 LANCET 1345, 1346-49 (2000) (reviewing other strategies to improve and augment DOT with a focus on patients' needs, convenience, and relationships).

<sup>134</sup> Marica Ferri, Marina Davoli & Carla A. Perucci, *Heroin Maintenance for Chronic Heroin-Dependent Individuals*, 12 COCHRANE DATABASE SYSTEMATIC REVIEWS, no. 12, 2011, at 1; John Strang et al., *Heroin on Trial: Systematic Review and Meta-Analysis of Randomised Trials of Diamorphine-Prescribing as Treatment for Refractory Heroin Addiction*, 207 BRIT. J. PSYCHIATRY 5 (2015).

<sup>135</sup> See Marcel G.W. Dijkgraaf et al., *Cost Utility Analysis of Co-Prescribed Heroin Compared with Methadone Maintenance Treatment in Heroin Addicts in Two Randomised Trials*, 330 BRIT. MED. J. 1297, 1299 (2005) (reporting that the program of prescribing heroin with methadone in the Netherlands resulted in an average savings of \$16,122 per patient per year when compared to methadone treatment alone).

<sup>136</sup> See Lo et al., *supra* note 100, at 41, 73 (noting that patients experiencing homelessness during treatment are 2.5 times more likely to stop MMT).

<sup>137</sup> See William C. Becker et al., *Non-Medical Use, Abuse and Dependence On Prescription Opioids Among U.S. Adults: Psychiatric, Medical and Substance Use Correlates*, 94 DRUG & ALCOHOL DEPENDENCE 38, 38 (2008) ("Among those with past-year non-medical prescription opioid use, those with abuse/dependence were [70%] more likely to have panic and social phobic/agoraphobic symptoms."). Antidepressants increased the efficacy of patients receiving agonist therapy of opioid dependence in a meta-analysis of eight RCTs, leading to a 2.3 times reduction in depressive symptoms when compared to control patients. Ahmed N. Hassan et al., *Management of Mood and Anxiety Disorders in Patients Receiving Opioid Agonist Therapy: Review and Meta-analysis*, 26 AM.J. ADDICTION 551, 551 (2017). These data suggest that the prevalence of clinical depression among patients receiving agonist therapy for opioid addiction is high.

and iOAT have the built-in advantages of preventing criminal activity<sup>138</sup> associated with obtaining illicit drugs and preventing harms that occur with the injection of drugs of unknown purity.<sup>139</sup>

### III. THE REGULATORY FRAMEWORK

#### A. *Clinical Care, Instead of Self-Medication, for John*

One day an outreach worker invites John to visit a local specialized clinic. At the clinic, John's various conditions are diagnosed. The clinic physician documents that John is in considerable pain, which is exacerbating and complicated by a secondary diagnosis of opioid dependence. John is on his feet most of the day or resting on a hard sidewalk. When he has to scramble to stave off withdrawal, it is excruciating limping from one place to another. The clinic physician describes the following course of treatment: John can come into the clinic and be administered hydromorphone as many times as needed to treat his pain between 6 AM and 10 PM, as long as he spends time in the clinic after so that staff can be sure he is not at risk of overdose. Dosing is determined by clinic staff in close collaboration with John to treat his pain without producing or intensifying hyperalgesia. If he wants to start maintenance or detoxification therapy, he can access methadone or buprenorphine at an affiliated clinic next door. John is encouraged to stay off his feet as much as possible to give his leg adequate time to heal. The facility has respite housing to enable such rest.

Given the benefits to John and to the community, it is likely that the locality and state would support such care for John.<sup>140</sup> But federal law

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<sup>138</sup> In Spain, patients receiving heroin had more days free of crime than the control group receiving methadone, from eleven days per month to less than one day a month. March et al., *supra* note 104, at 208. Swiss patients receiving in the control arm acquired 3123 Swiss francs in illicit income before treatment and 4931 after treatment, whereas treated patients reduced their illicit income from 3372 to 311. Perneger et al., *supra* note 90, at 16. In Canada, patients receiving diacetylmorphine were 40% more likely to demonstrate a reduction in illegal activities and illegal drug use relative to patients receiving methadone. Oviedo-Joekes et al., *Diacetylmorphine Versus Methadone*, *supra* note 104, at 782.

<sup>139</sup> Only 1.5% of patients receiving heroin in Switzerland experienced an overdose event during six months of treatment whereas 48% experienced an overdose event in the six months preceding treatment. Perneger et al., *supra* note 90, at 15. Overdoses that occur at Swiss facilities are routinely reversed. KILMER ET AL., *supra* note 68, at x (noting that thousands of overdoses have occurred over thirty years with no or only a few fatal overdoses).

<sup>140</sup> They may also very well not. State legislatures and state boards of medicine could prevent such a facility from opening, as could local officials. Analysis of the legal and political mechanisms related to states and localities is beyond the scope of this analysis. Broadly speaking, though, we think it reasonable that a locality like Philadelphia

enforcement is fickle, ideological, and politically distanced from individual people and communities. Local Drug Enforcement Administration (DEA) officials might condemn or even bring charges against a clinic caring for John in this way. In the next three Sections we provide context that would guide courts in assessing such a case.

### *B. Federal Regulation of Medicine Generally: Hands-Off*

Since the founding of the country, medicine has been regulated predominantly at the local and state levels.<sup>141</sup> This is operationalized primarily through licensing: states delegate authority to physicians to define educational standards, specify the limits of practice through informal and formal rulemaking, and enforce rules through professional self-regulation.<sup>142</sup>

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would support a pain-centered approach and that state officials would not interfere. See Kate Kilpatrick, *Philadelphia's Plan for Opioid Safe Injection Site Splits Opinion*, GUARDIAN (July 18, 2018, 6:00 PM), <https://www.theguardian.com/us-news/2018/jul/18/philadelphia-opioid-safe-injection-site-plan> [<https://perma.cc/89LC-6NUP>] (discussing the push and pull between stakeholders in Kensington, the Philadelphia neighborhood most likely to see the implementation of an SCF if its legality is ultimately decided).

<sup>141</sup> The practice of medicine emerged from public health practice. And public health practice is the paradigmatic example of police power. See, e.g., *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (noting regulation of health and safety is “primarily, and historically, a matter of local concern”); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) (“It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state’s police power. The state’s discretion in that field extends naturally to the regulation of all professions concerned with health.”); *State v. Gee*, 236 P.2d 1029, 1033 (Ariz. 1951) (noting in concluding that it is unquestioned that state legislatures have the power and duty to control and regulate the health professions and practices affecting the public health and welfare including the definition of terms like “healing”).

<sup>142</sup> See, e.g., ROBERT I. FIELD, *HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE* 19 (2007) (noting that the “cornerstone” of medical practice regulation is states’ licensing schemes). In some cases, state boards also might take actions to prevent unlicensed individuals from practicing medicine. Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look at Medical Licensure Boards*, 3 HEALTH MATRIX 309, 326-30 (1993).



Congress has respected this arrangement for historical,<sup>143</sup> political,<sup>144</sup> and instrumental reasons.<sup>145</sup>

There are notable exceptions. The Food and Drug Administration (FDA) regulates the approval and marketing of pharmaceuticals, and other various agencies of the Department of Health and Human Services (HHS) and the DEA restrict availability of controlled substances to approved uses<sup>146</sup>

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<sup>143</sup> “Early in United States history, most acts considered crimes were subject only to state criminal law. Federal criminal laws were limited to areas in which the Constitution gave Congress specifically enumerated powers. Over time, Congress began to criminalize much ordinary criminal activity under the guise of regulating interstate commerce. With the Controlled Substances Act of 1970, however, Congress established virtually unlimited federal jurisdiction for all drug offenses as a way to protect public morals—without even the pretense of regulating interstate commerce.” Sandra Guerra, *The Myth of Dual Sovereignty: Multijurisdictional Drug Law Enforcement and Double Jeopardy*, 73 N.C. L. REV. 1159, 1165-66 (1995) (internal citations omitted).

<sup>144</sup> See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 2* (2d ed. 2017) (describing the ability of the American Medical Association from the 1940s until the 1970s to prevent regulatory encroachments, including calls for universal insurance or other restraints on practice through concentrated lobbying).

<sup>145</sup> The decentralization of lawmaking authority has enabled a vigorous policy learning process in the United States in which states and localities implement policy innovations, which are evaluated, providing data for ongoing reform and dissemination in other jurisdictions. See, e.g., Scott Burris & Evan Anderson, *Legal Regulation of Health-Related Behavior: A Half Century of Public Health Law Research*, 9 ANN. REV. L. SOC. SCI. 95, 106-07 (2013) (finding that research on legal interventions regarding individual health behavior determines how and why certain laws may fail or succeed); see also *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“Denial of the right to experiment may be fraught with serious consequences to the Nation. It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”).

<sup>146</sup> The Fifth Circuit stated:

Congress fashioned the Comprehensive Drug Control Act to provide a closed system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

*United States v. Collier*, 478 F.2d 268, 273 (5th Cir. 1973) (internal quotation marks omitted). The primary role of the DEA is to prevent the diversion of substances into illicit channels. Under the CSA, the DEA is responsible for preventing, detecting, and investigating the diversion of controlled substances while ensuring the availability of these drugs for legitimate use. *U.S. Organization, Mission and Functions Manual: Drug Enforcement Administration*, U.S. DEP’T OF JUSTICE, <http://www.justice.gov/jmd/mps/manual/dea.htm> [https://perma.cc/A9WC-PHGD] (last visited Nov. 3, 2019) (discussing the DEA’s mission). The primary role of HHS, operating through the FDA, under the CSA is to perform technocratic medical assessments of controlled substances and provide recommendations to the DEA in

based on their classification on five drug schedules.<sup>147</sup> The DEA also determines who can interact with scheduled substances, which, importantly for our purposes, includes the registration of clinicians.<sup>148</sup>

These regulatory schemes position the federal government as a gatekeeper of pharmaceutical therapy. Schedule I substances are kept outside the gate, a substantial barrier to effective medical practice and research.<sup>149</sup> But physicians retain broad authority to administer, dispense, and prescribe for any legitimate medical purpose all other substances once the FDA approves them for medical use. The definition of what constitutes legitimate medical practice is left to self-governing boards and extends well beyond federally approved uses of drugs.<sup>150</sup> The statutes that define the gatekeeping role of

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regard to scheduling and other CSA-related decisions. *Controlled Substance Staff Functional Roles*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/controlled-substance-staff-functional-roles> [<https://perma.cc/345A-924S>] (last updated July 9, 2018).

<sup>147</sup> See 21 U.S.C. § 812(b) (2018) (listing the schedules under which narcotic drugs are classified). The CSA and associated laws regulate access to controlled substances throughout the supply chain from production to dispensing. See generally, e.g., Evan Anderson & Corey Davis, *Breaking the Cycle of Preventable Suffering: Fulfilling the Principle of Balance*, 24 TEMPLE INT'L & COMP. L.J. 329 (2010) (discussing how international agreements and conventions govern the international drug control system).

<sup>148</sup> See *U.S. Organization, Mission and Functions Manual: Drug Enforcement Administration*, *supra* note 146. The registration requirement for individuals interacting with scheduled narcotics, including clinicians, is found at 21 U.S.C. § 823.

<sup>149</sup> Schedule I substances are classified as having no currently accepted medical use and high potential for abuse yet include heroin, which is widely used as a medication for opioid dependence and for analgesia in other places, and marijuana (cannabis), which is now permitted in medical and recreation use. See *supra* text accompanying notes 103-31 (describing the medical benefits of using heroin, a schedule I narcotic, to treat OUD); *infra* text accompanying note 292 (observing that the federal government's oblique recognition of marijuana's medical value by refraining from prosecuting individuals for its prescribed uses despite its being a schedule I narcotic). While an important practical limitation, placement of substances into Schedule I is in some sense not an example of federal regulation of medicine because the substances are deemed to have no medical applications. See David B. Brushwood, *Defining "Legitimate Medical Purpose"*, 62 AM. J. HEALTH-SYS. PHARMACY 306, 307 (2005) ("A practice that is medical is legitimate and is legal under the DEA regulation. DEA does not regulate within medical practice but simply discerns whether a practice is medical or nonmedical.").

<sup>150</sup> Indeed, so-called off-label prescribing is a common and widely accepted practice. The Supreme Court has supported and even encouraged the off-label use of FDA regulated drugs. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (holding that off-label use is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

the FDA, DEA and HHS explicitly claim not to otherwise interfere with legitimate medical practice.<sup>151</sup>

Since medicine became a mature profession,<sup>152</sup> very few cases have explored putative transgressions of federal gatekeeping rules by clinicians providing care in good faith. One commonly cited guidepost is the Supreme Court's *Moore* decision from 1975.<sup>153</sup> But it offers little practical guidance: Moore wantonly prescribed methadone for home-use to hundreds of people a day without any meaningful medical evaluation while billing based on the amount prescribed and not medical services provided.<sup>154</sup> The Supreme Court allowed the DEA to treat Moore like a "large-scale pusher"<sup>155</sup> rather than a bona fide physician. Lower federal courts have issued analogous rulings related to similarly venal activity.<sup>156</sup> Even in these instances, however, courts

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<sup>151</sup> The Food Drug and Cosmetics Act's (FDCA) authorizing language is explicit that it should not "be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device . . . within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396; *id.* § 801a(3) ("[N]othing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health and Human Services on the basis of a consensus of the views of the American medical and scientific community."). Similar language in other federal laws also preserves the practice of medicine's special status, leaving it generally unregulated at the federal level. The Social Security Amendments of 1954, for example, provided that "[n]othing in this title shall be construed as authorizing the Commissioner of Social Security or any other officer or employee of the United States to interfere in any way with the practice of medicine . . ." 42 U.S.C. § 416 (1954); *see also* 21 U.S.C. § 823(g)(2)(H)(i) (2018) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

<sup>152</sup> *See infra* text accompanying notes 178-84 (discussing cases in the 1910s and 1920s, when addiction-treatment exceptionalism emerged, and before medicine had established consistent therapeutic benefits).

<sup>153</sup> *United States v. Moore*, 423 U.S. 122 (1975).

<sup>154</sup> Moore issued over 11,000 prescriptions for methadone in a five-month period, which translated into over 800,000 methadone tablets and over 100 prescriptions a day. *Id.* at 126. He billed based on the quantity prescribed not the performance of a medical service. *Id.* Unlike typical medical care, and certainly medical care culminating in opioid therapy, he provided "only the most perfunctory examination" and typically provided a prescription for the amount of methadone requested. *Id.* On return visits, Moore issued refills without another medical examination. *Id.* These practices yielded in excess of \$200,000 over this time period. *Id.*

<sup>155</sup> *Id.* at 143 (internal quotation marks omitted).

<sup>156</sup> *See, e.g., United States v. Hurwitz*, 459 F.3d 463, 474 (4th Cir. 2006) (holding that there was probable cause to admit evidence from defendant's practice because it was "permeated with the illegal distribution of drugs," from high initiation and maintenance fees paid in cash to prescribing heavy narcotics doses); *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004) (upholding a lower court's finding that the defendant acted without a legitimate medical purpose in distributing hydrocodone prescriptions over the internet and hiding proceeds of sales); *United States v. Steele*, 147 F.3d 1316 (11th Cir. 1998) (reiterating that defendant's knowledge that he dispensed drugs based on forged prescriptions was sufficient evidence to

have noted that while the FDA “was obviously intended to control the *availability of drugs* for prescribing by physicians,” it “did not purport to regulate the practice of medicine.”<sup>157</sup> There are no cases in the appellate record on our reading that examine good faith divergences.<sup>158</sup>

Given that healthcare delivery has been regulated by the states historically, DOT-P would also implicate principles of preemption. These principles provide few if any hard limits on federal power. Despite the longstanding norm of federal noninterference in medicine, it is clear that the federal government can regulate medical practice if it makes its intention to do so clear and unambiguous. Supreme Court jurisprudence related to marijuana underscores the special breadth and dominance of federal power over drug control.<sup>159</sup>

Though the Court’s preemption jurisprudence does not insulate states from federal intrusions, there is a longstanding presumption against preemption, particularly in areas of traditional state regulation.<sup>160</sup> This presumption colored the resolution of another controversy over whether states or the federal

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show that that activity was outside of the course of professional practice); *United States v. Rosenberg*, 515 F.2d 190, 200 (9th Cir. 1975) (upholding the conviction of a physician who prescribed opioids to undercover agents without any physical examination).

<sup>157</sup> *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981); *see also* *United States v. Regenerative Sci., LLC*, 878 F. Supp. 2d 248, 255 (D.D.C. 2012) (“Defendants state[d] that Congress has left the practice of medicine to the States to regulate. FDA does not disagree with these principles.”); RICHARD A. EPSTEIN, *MANHATTAN INST., THE FDA’S MISGUIDED REGULATION OF STEM-CELL PROCEDURES: HOW ADMINISTRATIVE OVERREACH BLOCKS MEDICAL INNOVATION* 12 (2013) (describing the regulation of medical practice as distinct from the FDA’s regulation of drugs and biologics).

<sup>158</sup> This is not surprising. The prevailing model for understanding physician overprescribing does not recognize good faith innovations or reasonable extensions of the traditional practice. *See, e.g.*, Kelly K. Dineen & James M. DuBois, *Between a Rock and Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 *AM. J.L. MED.* 7, 15-18 (describing and criticizing the AMA’s heuristic for categorizing overprescribing oriented around the “four Ds,” which refer to physicians who are dated, duped, disabled, and dishonest).

<sup>159</sup> After California authorized home production and home use of marijuana for medical purposes in the late 1990s, federal officials continued to enforce federal prohibitions on all marijuana-related activity. In dispensing with any pretense of a limiting principle for federal drug control pursuant to the Interstate Commerce Clause, the Court’s decision in *Raich* threw out an injunction aiming to stop federal law enforcement from interfering with activity that California had authorized. *Gonzales v. Raich*, 545 U.S. 1, 33 (2005); *see also id.* at 49 (O’Connor, J., dissenting) (“[T]he Court’s definition of economic activity for purposes of Commerce Clause jurisprudence threatens to sweep all of productive human activity into federal regulatory reach.”).

<sup>160</sup> *See* Mary J. Davis, *The “New” Presumption Against Preemption*, 61 *HASTINGS L.J.* 1217, 1223 (evaluating the most recent decades in Supreme Court jurisprudence and affirming that the presumption against preemption continues to “operate as a meaningful default rule in express preemption cases” where there is no clarity from Congress).

government define medical practice with controlled substances. In 1999, Congress failed to pass an act prohibiting use of controlled substances for physician-assisted suicide<sup>161</sup> because of widespread concern among lawmakers that it impermissibly federalized regulation of medicine.<sup>162</sup> The Attorney General sought the same result by issuing an interpretive rule stating that physician-assisted suicide is not legitimate medical practice.<sup>163</sup> The rule would have exposed clinicians in Oregon to criminal prosecution under the federal law, even if they complied with all the requirements of the state's Death with Dignity statute.<sup>164</sup>

According to the Supreme Court, the Attorney General lacked such authority. The Court reached this result through a narrow interpretation of the power of the Attorney General to promulgate rules.<sup>165</sup> It was “evident” that “Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the [Controlled Substances Act (CSA)]. Rather, he can promulgate rules relating only to ‘registration’ and ‘control,’ and ‘for the

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<sup>161</sup> The Pain Relief Promotion Act of 1999, H.R. 2260, 106th Cong. (2000).

<sup>162</sup> See, e.g., *Pain Relief Promotion Act: Hearing Before the Comm. on the Judiciary*, 106th Cong. 22 (2000) (statement of Sen. Ron Wyden) (“[The bill] would allow the Federal Government to intrude into the doctor-patient relationship at one of the most difficult and personal times of an individual's life.”); S. REP. NO. 106-299, at 61 (2000) (“[T]his poorly written, poorly thought-out statute would wreak havoc on States’ traditional police authority to regulate their own doctors—an authority they have enjoyed for more than 200 years . . . . In our view, the DEA is not qualified to handle investigations into allegation [sic] of the misuse of pain management drugs.”).

<sup>163</sup> According to the interpretive rule,

assisting suicide is not a “legitimate medical purpose” within the meaning of 21 CFR 1306.04 (2001), and . . . prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act. Such conduct by a physician registered to dispense controlled substances may “render his registration . . . inconsistent with the public interest” and therefore subject [it] to possible suspension or revocation under 21 U.S.C. 824(a)(4). The Attorney General’s conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

66 Fed. Reg. 56,608, 56,608 (Nov. 9, 2001).

<sup>164</sup> *Id.*

<sup>165</sup> See 21 U.S.C. § 821 (2018) (providing that the Attorney General may “promulgate rules . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.”); *id.* § 871(b) (authorizing the Attorney General to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter”); *Gonzales v. Oregon*, 546 U.S. 243, 259 (2006) (“The CSA gives the Attorney General limited powers, to be exercised in specific ways.”).

efficient execution of his functions’ under the statute.”<sup>166</sup> These provisions, according to the Court, do not empower the Attorney General “to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.”<sup>167</sup> This reading of the statute relied on an understanding that Attorney General “control” under the CSA is limited to the prevention of diversion.<sup>168</sup>

It is important not to read too much into the *Oregon* decision. The outcome might have differed if the Attorney General had used notice and comment rulemaking or if the rulemaking had come from the Secretary of HHS.<sup>169</sup> Nevertheless, in striking down the interpretive rule, the Court explained that “Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking,” but the CSA “manifests no intent to regulate the practice of medicine generally.”<sup>170</sup> The Court did, however, note that “[e]ven though regulation of health and safety is primarily, and historically, a matter of local concern, there is no question that the Federal Government can set uniform national standards in these areas.”<sup>171</sup> The Court ended that sentence by listing a section of the Public Health Services Act,<sup>172</sup> to which we now turn.

### C. Federal Regulation of OUD Treatment: Hands-On (The Exception)

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<sup>166</sup> *Gonzales*, 546 U.S. at 259. The limits on the Attorney General’s authority under § 821 are discussed further below. As to § 871, the Court wrote:

This section allows the Attorney General to best determine how to execute “his functions.” It is quite a different matter, however, to say that the Attorney General can define the substantive standards of medical practice as part of his authority. To find a delegation of this extent in § 871 would put that part of the statute in considerable tension with the narrowly defined delegation concerning control and registration. It would go, moreover, against the plain language of the text to treat a delegation for the “execution” of his functions as a further delegation to define other functions well beyond the statute’s specific grants of authority.

*Id.* at 264-65.

<sup>167</sup> *Id.* at 258.

<sup>168</sup> *See id.* at 260 (“The statutory references to ‘control’ outside the scheduling context make clear that the Attorney General can establish controls ‘against diversion,’ e.g., §823(a)(1), but do not give him authority to define diversion based on his view of legitimate medical practice.”).

<sup>169</sup> *See id.* at 265 (“The CSA allocates decision making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary [of HHS].”).

<sup>170</sup> *Id.* at 270.

<sup>171</sup> *Id.* at 271.

<sup>172</sup> *Id.*; 42 U.S.C. § 290bb-2a (2018).

The Supreme Court has found one exception in which the federal government does appear to regulate medical practice: maintenance and detoxification treatment.<sup>173</sup> It is a longstanding and curious exception. Prior to the Harrison Narcotics Tax Act in 1914, controlled substances were mostly unregulated.<sup>174</sup> Pursuant to the Harrison Narcotics Tax Act, all distribution of heroin, morphine, and cocaine was banned except for prescriptions “by a physician . . . in the course of his professional practice.”<sup>175</sup>

Physicians, who were still transforming from a trade to a profession,<sup>176</sup> tested the limits of this exception. The results of many of these cases were described then and are still sometimes described today as convictions for prescribing heroin and other drugs for “maintenance” therapy.<sup>177</sup> The *Webb* decision in 1919 in particular is billed as a firm statement by the Supreme Court that heroin maintenance therapy is not a legitimate form of treatment.<sup>178</sup>

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<sup>173</sup> See *Gonzales*, 546 U.S. at 271 (“In connection to the CSA, however, we find only one area in which Congress set general, uniform standards of medical practice.”).

<sup>174</sup> Erik Grant Luna, *Our Vietnam: The Prohibition Apocalypse*, 46 DEPAUL L. REV. 483, 486, 503-04 (1997).

<sup>175</sup> Pub. L. No. 63-223, § 2(a), 38 Stat. 785, 786 (1914) (repealed 1939).

<sup>176</sup> The practice of medicine transformed in the first quarter of the twentieth century. Until that time, it was largely unregulated, and had little scientific basis. This little therapeutic reach perpetuated limited social and political power. For example, as Victor Vaughan, dean of the University of Michigan Medical School tellingly stated,

I served in the war with Spain in 1898, and I went time and again to a division officer and made certain requests or offered advice. As a rule, I was snubbed and told by action, if not by words, that I was only a medical officer, and that I had no right to make any suggestions, and it was imprudent of me to do so. The commanding general at Chickamauga [an army camp], when we had an increasing number of cases of typhoid fever, would every day ostentatiously ride up to a well which had been condemned and drink of this water to show his contempt. But in the late war I had a different experience. I never went to a line officer with a recommendation but that he said, “Doctor, it will be done” . . . .

STARR, *supra* note 144, at 141; see also MUSTO, *supra* note 67, at 185 (“The social and economic position of the registered physician was so sensitive [in the 1920-30s], trials so time consuming, and appeals so long and costly, that hostile agents could make cases against physicians with impunity and nearly ruin them whether charges were warranted or not.”).

<sup>177</sup> See Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 231, 260 (2008) (“These Supreme Court cases clearly established that registered physicians were permitted to prescribe and dispense narcotic drugs strictly within the bounds of their professional practice and that maintenance therapy for addicts was not within such bounds. They set the stage for practitioner investigations and prosecutions for years to come.” (internal quotation marks omitted)).

<sup>178</sup> *Webb v. United States*, 249 U.S. 96 (1919); see Richard C. Boldt, *Drug Policy in Context: Rhetoric and Practice in the United States and the United Kingdom*, 62 S.C. L. REV. 261, 280 (2010) (“In [*Webb*], the Court held that the legitimate practice of medicine did not include the provision of maintenance doses of narcotics to addicts.”).

But this is a strained reading. The issues in *Webb* and other cases like it were clear examples of profiteering either incidental or totally unrelated to maintenance therapy.<sup>179</sup> The Court recognized the conflation in *Webb* a few years later in its *Linder* decision. Linder had been prosecuted for prescribing a reasonable amount of cocaine and morphine to a woman with stomach pain following a normal medical examination, which was absent from other high-profile prosecutions.<sup>180</sup> The Court unanimously overturned the conviction, noting that “[o]bviously, direct control of medical practice in the states is beyond the power of the federal government.”<sup>181</sup>

Notwithstanding the Court’s full-throated defense of medical autonomy, the arrests and prosecution of hundreds of physicians in the time period between *Webb* and *Linder*<sup>182</sup> emboldened law enforcement and their

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<sup>179</sup> See, e.g., *United States v. Behrman*, 258 U.S. 280, 286-89 (1922) (holding that the indictment of a physician who prescribed to one person 150 grains of heroin, 360 grains of morphine, and 210 grains of cocaine to one person for home use as the “patient” saw fit was proper under the Narcotic Drug Act); *United States v. Jin Fuey Moy*, 241 U.S. 394, 400, 402 (1916) (upholding the lower court’s decision to quash an indictment for flagrant and indiscriminate morphine prescribing and charging per gram prescribed by narrowly reading the controlling statute solely as a revenue measure and confining its narcotic regulating powers).

<sup>180</sup> Compare *Linder v. United States*, 268 U.S. 5, 16-17, 22-23 (1925) (finding that the petitioner had not violated the Harrison Narcotics Tax Act by treating his opiate-addicted patient with a small amount of narcotics for her use alone), with *United States v. Doremus*, 249 U.S. 86, 94-95 (1919) (upholding § 2 of the Harrison Narcotics Tax Act as constitutional under the taxing authority of Congress, because a large volume of drugs dispensed to one individual likely would be sold to third parties in violation of the Act), and *Behrman*, 258 U.S. at 289 (upholding the indictment of a physician because, based on the enormous quantity of pills—more than 3000 ordinary doses—allegedly prescribed to a known addict, the defendant physician would not have been acting in the course of his professional practice).

<sup>181</sup> As the *Linder* Court explained,

The enactment under consideration levies a tax . . . upon every person who imports, manufactures, produces, compounds, sells, deals in, dispenses or gives away opium or coca leaves or derivatives therefrom, and may regulate medical practice in the States only so far as reasonably appropriate for or merely incidental to its enforcement. It says nothing of “addicts” and does not undertake to prescribe methods for their medical treatment. They are diseased and proper subjects for such treatment, and we cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purpose solely because he has dispensed to one of them, in the ordinary course and in good faith, four small tablets of morphine or cocaine for relief of conditions incident to addiction.

*Linder*, 268 U.S. at 18.

<sup>182</sup> More than 5000 physicians were fined or jailed for these offenses between 1915 and 1938. ARNOLD TREBACH, *THE HEROIN SOLUTION* 125 (1982).



legislative allies,<sup>183</sup> who quickly turned to limiting *Linder* through what can only be described as regulatory exceptionalism.<sup>184</sup> The resulting statutes were consolidated in 1970 with the adoption of the CSA.<sup>185</sup>

For our purposes, the CSA does four important things: it (1) forbids all activity with controlled substances by clinicians outside of “the course of [their] professional practice,”<sup>186</sup> (2) defines detoxification and maintenance as terms of art,<sup>187</sup> (3) limits the dispensing of schedule II substances for use in maintenance and detoxification,<sup>188</sup> and (4) requires clinicians providing

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<sup>183</sup> Even in the 1960s, four decades after *Linder*, Narcotics Bureau regulations advising doctors and pharmacists of their rights in dealing with addicts continued to ignore what the Supreme Court had so plainly said, and still relied on the discredited language of *Webb*:

An order purporting to be a prescription issued to an addict or habitual user of narcotics, not in the course of professional treatment but for the purpose of providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and intent of section 4705(c)(2), and the person filling such a [*sic*] order, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to narcotic drugs.

26 C.F.R. § 151.392 (1971), *repealed by* 36 Fed. Reg. 7778 (Apr. 24, 1971).

<sup>184</sup> One explanation for this exceptionalism is the meek and counter-productive actions of the fledgling American Medical Association (AMA). Indeed, a 1924 special committee of the AMA suggested that ambulatory treatment of narcotics addicts “begets deception, extends the abuse of habit-forming narcotic drugs, and causes an increase in crime.” Rufus G. King, *The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick*, 62 *YALE L.J.* 736, 745 (1953); *see also* MUSTO, *supra* note 67, at 185 (“The social and economic position of the registered physician was so sensitive, trials so time consuming, and appeals so long and costly, that hostile agents could make cases against physicians with impunity and nearly ruin them whether charges were warranted or not.”).

<sup>185</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2018)).

<sup>186</sup> 21 U.S.C. §§ 828(e); *accord id.* § 829.

<sup>187</sup> As defined by the CSA,

The term “maintenance treatment” means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs . . . . The term “detoxification treatment” means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

*Id.* § 802 (29)–(30).

<sup>188</sup> The CSA provides that:

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney

maintenance and detoxification to complete a special registration process.<sup>189</sup> In sum, under the CSA, no clinician can provide maintenance or detoxification treatment with unapproved substances without a special registration (with limited exceptions<sup>190</sup>) and no clinician can do anything with controlled substances outside of their professional practice.<sup>191</sup>

The Controlled Substances Act and the Public Health Services Act authorize the Attorney General and the Secretary of HHS to implement the CSA through rulemaking.<sup>192</sup> According to the Supreme Court, the rule-making authority of the Attorney General is limited to registration and

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General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)  
(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;  
(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and  
(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

*Id.* § 823.

<sup>189</sup> *Id.*

<sup>190</sup> Under the “three-day rule,” in emergency situations where the immediate relief of a person’s acute withdrawal symptoms is necessary, while arrangements for referral to an OTP for treatment are being made, a physician may administer narcotic drugs to that person, but only for a maximum of three days. 21 C.F.R. § 1306.07(b) (2018); *see also Emergency Narcotic Addiction Treatment*, U.S. DEP’T JUST. DRUG ENFORCEMENT ADMIN.: DIVERSION CONTROL DIVISION, [https://www.deadiversion.usdoj.gov/pubs/advisories/emerg\\_treat.htm](https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm) [<https://perma.cc/7UGX-XCSX>] (last visited Nov. 3, 2019) (confirming that the three-day rule can only be invoked by unregistered practitioners to alleviate a patient’s acute withdrawal symptoms when the treatment is given in single-day doses, for no longer than 72 hours, and while arranging for the patient to enter treatment). In addition to the “three-day rule,” the DEA permits wider latitude regarding treatment of intractable pain. *See* 21 C.F.R. § 1306.07(c).

<sup>191</sup> 21 U.S.C. § 829 (a)–(b).

<sup>192</sup> Aside from authority over scheduling, which is not relevant for our purposes, the CSA has two provisions authorizing the Attorney General to promulgate rules. Section 821 provides that she may “promulgate rules . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.” *Id.* §821. Section 871(b) authorizes the Attorney General to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.” *Id.* § 871(b).

controlling diversion.<sup>193</sup> This provides the basis for DEA regulations limiting prescriptions (i.e., authorizations to obtain substances for unsupervised home use),<sup>194</sup> which obviously present greater risk of diversion compared to direct administration.<sup>195</sup> DEA regulations include a general requirement limiting prescriptions to “legitimate medical practice”<sup>196</sup> and a specific prohibition of prescribing Schedule II substances for maintenance or detoxification treatment.<sup>197</sup>

The HHS Secretary’s rulemaking authority is considerably broader. The Public Health Services Act directs HHS to “determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts,” after consultation with the Attorney General.<sup>198</sup> HHS has utilized this authority to promulgate regulations restricting this practice in Opioid Treatment Programs (OTPs).<sup>199</sup> An OTP is a “program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under” the section of the CSA

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<sup>193</sup> See *Gonzales v. Oregon*, 546 U.S. 243, 259-60 (2006) (holding that the Attorney General “can promulgate rules relating only to registration and control, and for the efficient execution of his functions under the statute” but cannot “define diversion based on his view of legitimate medical practice.” (internal quotation marks and citations omitted)).

<sup>194</sup> 21 C.F.R. § 1300.01(b). “[P]rescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).” *Id.* (emphasis removed).

<sup>195</sup> The important distinction between administration and prescription has been obscured in drug policy discourse. As Rufus King explains,

There is a much-neglected distinction between prescription of narcotics *to an addict for self-administration*, and direct administration by the physician. The former is the subject of valid criticism, i.e., it *does* remove all restraints on consumption by the addict, and the drugs prescribed may be resold in the illicit traffic. There is merit in the suggestion, made from time to time, that all self-administration of narcotics should be made illegal. The ‘official line’ has always ignored this distinction, equating prescription for self-administration with direct or supervised administration, and attacking both as ‘ambulatory treatment.

King, *supra* note 184, at 740 n.23.

<sup>196</sup> 21 C.F.R. § 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”).

<sup>197</sup> *Id.* § 1306.04(c) (“A prescription may not be issued for ‘detoxification treatment’ or ‘maintenance treatment,’ unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.”). Nevertheless, dispensing is permitted. See *id.* § 1306.07(a) (“A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets [qualifying] conditions . . .”).

<sup>198</sup> 42 U.S.C. § 290bb-2a (2018).

<sup>199</sup> See 42 C.F.R. §§ 8.1-8.2.

defining maintenance and detoxification treatment.<sup>200</sup> Those operating under this catchall “shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration . . . in the treatment of opioid use disorder,” which under associated regulations only includes methadone, levomethadyl acetate (LAAM), or buprenorphine.<sup>201</sup>

The DEA’s regulations provide some exceptions to the requirement that physicians specifically register to provide FDA-approved narcotics to treat OUD. In emergency situations where the immediate relief of a person’s acute withdrawal symptoms is necessary while arrangements for referral to an OTP for treatment are being made, a physician may administer narcotic drugs to that person, but only for a maximum of three days.<sup>202</sup> In addition to the “three-day rule,” the DEA also does not

impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.<sup>203</sup>

The DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) have unequivocally stated that restrictions related to maintenance and detoxification therapy do not apply to opioid therapy for pain.<sup>204</sup> Despite considerable discussion of opioid overprescribing, the closest

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<sup>200</sup> *Id.* § 8.2.

<sup>201</sup> *Id.* § 8.12(h)(2).

<sup>202</sup> 21 C.F.R. § 1306.07(b). For a description of the limited circumstances in which a practitioner who is unregistered as a narcotic treatment program may treat OUD in those experiencing acute withdrawal symptoms for up to 72 hours while arranging to refer the patient to an OTP, see *Emergency Narcotic Addiction Treatment*, *supra* note 190. What is not described is what happens if referral cannot be arranged within this time period and the patient continues to experience acute withdrawal symptoms. *Id.*

<sup>203</sup> 21 C.F.R. § 1306.07(c).

<sup>204</sup> See *id.* (stating that there are no “limitations on a physician or authorized hospital staff to . . . administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts”); OFFICE OF DIVERSION CONTROL, U.S. DEP’T OF JUSTICE, PHARMACIST’S MANUAL 54 (2004) (“A practitioner may prescribe methadone or any other narcotic to a narcotic addict for analgesic purposes.”). This allows treatment of patients with opioids indefinitely, if indicated. See *Questions & Answers: Prescriptions*, U.S. DEP’T JUST. DRUG ENFORCEMENT ADMIN.: DIVERSION CONTROL DIVISION, <https://www.deadiversion.usdoj.gov/faq/prescriptions.htm> [[https:// perma.cc/H3ZF-TAJC](https://perma.cc/H3ZF-TAJC)] (last visited Nov. 3, 2019) (“Federal law and regulations do not restrict the prescribing, dispensing, or administering of any schedule II, III, IV, or V narcotic medication, including methadone, for the treatment of pain, if such treatment is deemed medically necessary by a registered practitioner acting in the usual course of professional practice.”).

the federal government has come to regulating pain care “on the books”<sup>205</sup> is the release of guidelines by the CDC in 2016.<sup>206</sup> In response to condemnation from the American Medical Association’s House of Delegates in 2018,<sup>207</sup> the CDC underscored that the guidelines are recommendations, and not a mandate, and more recent efforts have focused on remedying policies and practices that have resulted from its misapplication.<sup>208</sup> There have also been some adjustments to Medicare,<sup>209</sup> and Congress previously granted the FDA authority to regulate post-marketing activity by drug manufacturers.<sup>210</sup> But even as the opioid crisis

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<sup>205</sup> As we note below in Part IV, investigations and prosecutions are also ways to regulate prescriptions. Those tools have been used with increasing breadth and intensity, with detrimental results. DOT-P is sensitive to such enforcement underscoring the importance of resisting knee-jerk supply-side responses, especially given their potential to perpetuate or increase opioid-related harms.

<sup>206</sup> The guidelines urge practitioners to avoid opioid dosing above 50 morphine milligram equivalents (MME) per day and to complete risk and benefit reviews. Deborah Dowell et al., *CDC Guidelines for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY & MORTALITY WKLY REP. 1, 22 (2016). For patients maintained on doses above 90 MME, doctors were told to conduct and document risk and benefit reviews. *Id.*

<sup>207</sup> The resolution read in part:

[N]o entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.

AM. MED. ASS’N HOUSE OF DELEGATES (I-18), REPORT OF REFERENCE COMMITTEE B 1-40 (2018), <https://www.ama-assn.org/system/files/2018-11/i18-refcomm-b-annotated.pdf> [<https://perma.cc/L8R2-FVVZ>].

<sup>208</sup> See *Opioid Overdose, Frequently Asked Questions*, CTRS. DISEASE CONTROL, <https://www.cdc.gov/drugoverdose/prescribing/faq.html> [<https://perma.cc/3PRH-TRNC>] (last visited Oct. 9, 2019) (“The Guideline is not a regulation, but rather a set of recommendations. The recommendations in the Guideline are voluntary, rather than prescriptive standards.”).

<sup>209</sup> These adjustments include a mandated system of electronic prescribing for controlled substances, electronic prior authorization requirements for Part D drugs, a new drug management program or “lock-in program,” for Part D patients, hard safety edits for opioids, and seven-day limits on initial opioid prescriptions for acute pain under Part D. See generally CTRS. FOR MEDICARE & MEDICAID SERVS., A PRESCRIBER’S GUIDE TO THE NEW MEDICARE PART D OPIOID OVERUTILIZATION POLICIES FOR 2019 (2018), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE18016.pdf> [<https://perma.cc/76H7-3G7X>]. There will also be a real-time safety edit at 90 morphine milligram equivalents (MME) per day, which could be triggered when a beneficiary reaches a cumulative level of 90 MME per day across all their opioid prescriptions. *Id.* at 2-3. Patients in hospice care, long-term care facilities, or who are receiving palliative or end-of-life care, or are being treated for cancer-related pain, will be exempt from these rules. *Id.* at 4-5.

<sup>210</sup> See, e.g., Marta J. Brooks, *Mitigating the Safety Risks of Drugs with a Focus on Opioids: Are Risk Evaluation and Mitigation Strategies the Answer?*, 89 MAYO CLINIC PROC. 1673,

intensified, federal agencies have endeavored not to deter pain care at least in formal written policy.<sup>211</sup>

#### D. *A Straight Path with the Law on the Books*

Large cities in the United States are grappling with dramatic increases in public injection drug use. The people engaged in this public injection drug use represent a very small portion of the overall population of people with OUD. In Philadelphia, for example, there are an estimated 50,000 people misusing prescription opioids and an estimated 70,000 people using heroin,<sup>212</sup> but fewer than 2,000 people with a substance use disorder are “street homeless” at any given time.<sup>213</sup> Frontline social and health service providers report that the needs of this population are extensive, but many are not ready to engage in maintenance or detoxification treatment. Although medication treatment is scarce in many parts of the country, in some cities, such as Philadelphia, as many as a quarter of all inpatient beds are empty.<sup>214</sup> To the extent that pain is

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1678 (2014) (describing the history of Risk Evaluation and Mitigation Strategies (REMS) and noting that the FDA approved a REMS program for extended-release and long-action opioids in 2012 that included new product labeling and required manufacturers to offer opioid training programs for prescribers on a voluntary basis).

<sup>211</sup> In light of concerns that the CSA overly burdens access to opiates and other controlled substances needed in the treatment of pain, federal agencies have reaffirmed their role in ensuring that anti-diversion efforts do not compromise the provision of medical care. *See, e.g.*, Dispensing Controlled Substances for the Treatment of Pain Notice, 71 Fed. Reg. 52,719, 52,719–20 (Sept. 6, 2006) (“DEA takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians.”). *But see infra* note 305 and accompanying text noting that in practice the DEA and other law enforcement agencies have increased investigations and prosecutions of clinicians.

<sup>212</sup> MAYOR’S TASK FORCE TO COMBAT THE OPIOID EPIDEMIC IN PHILA., FINAL REPORT & RECOMMENDATIONS 6, 7 (2017), [http://dbhids.org/wp-content/uploads/2017/05/OTF\\_Report.pdf](http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf) [<https://perma.cc/2D58-CG5K>].

<sup>213</sup> PHILA. OFFICE OF HOMELESS SERVS., ADDITIONAL HOMELESS POPULATIONS SUMMARY FOR PA-500 - PHILADELPHIA CoC (2019), <http://philadelphiaofficeofhomelesservices.org/wp-content/uploads/2019/05/Subpopulations.pdf> [<https://perma.cc/BKF2-WZ9P>] (reporting, from a one night census conducted on January 23, 2019, that 767 people with SUD stayed in emergency shelters, 159 in transitional shelters, 133 in safe havens, and 608 people with SUD remained unsheltered).

<sup>214</sup> Aubrey Whelan, *As Philly Pushes for More Medication-Assisted Drug Treatment, Thousands of Treatment Slots Are Still Empty*, PHILA. INQUIRER (Jan. 18, 2019), <https://www.inquirer.com/health/philadelphia-opioids-medication-assisted-treatment-capacity-overdose-crisis-20190118.html> [<https://perma.cc/D2SC-DDFE>]. This is because of administrative and logistical barriers, including issues like tobacco smoking bans and bans on cannabis. Brooke Feldman, *Why Philly’s Smoking Ban at Addiction Treatment Centers Will Be Harmful*,

an impediment to stabilizing the lives of people to enable the contemplation required for behavior change, a locality might implement DOT-P, as we have described it above.

The federal government might argue that DOT-P is engaged in addiction maintenance treatment that does not comply with the multiple statutory and regulatory requirements. Operating outside of these boundaries would expose DOT-P clinicians to deregistration and criminal prosecution. A clinic offering DOT-P would be on strong footing arguing that DOT-P is not maintenance, but simply analgesia.<sup>215</sup> If the clinic prevailed on this first level of the analysis, as we expect it would, the federal government might then offer a more nebulous declaration that DOT-P does not constitute professional practice.<sup>216</sup>

At its core, then, this would present an interpretive case. The threshold question for the analysis is whether there is ambiguity in the relevant statutes and regulations:<sup>217</sup> specifically, whether DOT-P fits within the definition of maintenance.<sup>218</sup> We actually think, in contrast, that it is reasonable to read the plain language of the CSA and its associated regulations as unambiguously carving DOT-P out of the definition of maintenance. However, on the chance that a court differed from our plain language analysis, we also construe potential ambiguities in the legal text in terms of legislative intent and in light of principles of statutory interpretation.

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FILTER MAG. (Feb. 12, 2019), <https://filtermag.org/philadelphia-smoking-ban-addiction-treatment-harm-reduction/> [<https://perma.cc/W75X-EATM>]; Enos, *supra* note 27, at 5; Nina Feldman, *Philly Health Officials, Advocates Split on Impact of Smoking Ban at Inpatient Rehabs*, WHYY (June 25, 2019), <https://whyy.org/articles/philly-health-officials-advocates-split-on-impact-of-smoking-ban-at-inpatient-rehabs/> [<https://perma.cc/S6ZM-2Z5E>].

<sup>215</sup> This is not to say that medical necessity arguments do not make sense conceptually or that other constitutional arguments are not worth arguing. Some cases hint at a constitutional right to adequate pain relief. *See, e.g.*, *Washington v. Glucksberg*, 521 U.S. 702, 736-37 (1997) (O'Connor, J., concurring) (“The parties and amici agree that in these States a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death.”). However, we find it hard to believe that the Roberts Court would rely on constitutional principles in addressing a DOT-P challenge, when interpretive arguments provide a less disruptive way of resolving the dispute.

<sup>216</sup> DOT-P does not involve prescribing opioids, so the “legitimate medical practice” standard does not apply. *See infra* note 196 and accompanying text.

<sup>217</sup> Textual ambiguity is a required predicate for engaging in statutory construction using legislative intent. *See Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992) (“[W]hen the words of a statute are unambiguous, then, this first canon is also the last: ‘judicial inquiry is complete.’”); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 452-53 (1987) (Scalia, J., concurring) (“Judges interpret laws rather than reconstruct legislator’s intentions. Where the language of those laws is clear, we are not free to replace it with an unenacted legislative intent.”).

<sup>218</sup> Of the two definitions, maintenance provides a more challenging hurdle for DOT-P proponents, so we focus on it rather than detoxification.

The plain language argument in support of DOT-P is simple: the CSA regulations at 21 C.F.R. § 1306.07(c) affirmatively recognize a distinction between maintenance and primary pain care in the presence of secondary OUD. Specifically, they include an exception from OTP regulations, which reads:

a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.<sup>219</sup>

A grammatically correct construction of the sentence reduces to a carve-out from the definitions and therefore the requirements of OTP for “a physician . . . to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.”<sup>220</sup> A physician providing DOT-P to John could reasonably fit this definition, if the primary indication for John was documented as pain.<sup>221</sup> A factual analysis would show that local healthcare entities spent hundreds of thousands of dollars treating John through other clinical channels, yet his pain remained the same. There is no legislative or regulatory discussion of what constitutes “intractable pain” or “reasonable efforts.”<sup>222</sup> But a recent administrative decision makes clear that these determinations are medical ones and must be based on the standards of medical practice as evaluated by a physician.<sup>223</sup>

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<sup>219</sup> 21 C.F.R. § 1306.07(c) (2018).

<sup>220</sup> *Id.*

<sup>221</sup> This is so even in a case where a practitioner treats acute pain in a patient with a chemical dependency on controlled substances and lowers the dosage over time, in what would appear to be treatment similar to detoxification. *See* William F. Skinner, M.D.; Continuation of Registration, 60 Fed. Reg. 62,891, 62,891 (Dec. 7, 1995) (finding that, although the patient was dependent on the drugs and the respondent was not specially registered as an NTP, the patient did not fall under the statutory definition of an “addict” and the respondent was “acting in the usual course of his professional practice” by tapering prescriptions following an acute pain episode, not performing maintenance or detoxification treatment).

<sup>222</sup> *See* 21 C.F.R. § 1306.07(c).

<sup>223</sup> *See* Morris W. Cochran, M.D.; Revocation of Registration, 77 Fed. Reg. 17,505, 17,505 (Feb. 1, 2012). In this decision, the administrator disputed an ALJ determination that the respondent violated 21 C.F.R. § 1306.07(c) because “his charts failed to show the use of any treatment options besides the prescribing of controlled substances,” and so he had not employed “reasonable efforts” to find relief. *Id.* at 17,520. Instead, the administrator read the regulation as requiring “a clinical judgment which must be assessed by reference to the standards of medical practice as set by the state medical boards and the profession itself.” *Id.* A failure to recommend alternative treatments was only “some evidence” of failure to comply with the regulation when dispensing narcotic drugs without a license to a patient suffering from pain. *Id.* While the respondent ultimately had his registration revoked for other violations, this



The government surely would minimize the regulatory language in the CFR and rely on the more seemingly encompassing language in the CSA itself. It would probably begin by noting that maintenance treatment is defined broadly as “the dispensing . . . of a narcotic drug in the treatment of an individual *for* dependence upon heroin or other morphine-like drugs”<sup>224</sup> and that registrations and other requirements attach to any practitioner who “dispense[s] narcotic drugs to individuals *for* maintenance treatment.”<sup>225</sup> However, DOT-P provides treatment *with* a narcotic drug to people *with* opioid dependence; it does not provide that treatment *for* opioid dependence.<sup>226</sup> Given that the DEA and SAMHSA note that the treatment with opioids for pain and for OUD are distinguishable clinically and legally,<sup>227</sup> the choice of *for* rather than *with* should be read as deliberate and understood as limiting.<sup>228</sup>

The DEA might also argue that the other exception in § 1306.07(b) contemplates and therefore restricts treatment for people with co-occurring pain and OUD. The “three-day rule” allows immediate relief of acute withdrawal symptoms to bridge the gap to an OTP treatment for someone in a hospital.<sup>229</sup> But treatment of withdrawal is not the primary or even necessarily a secondary aim of DOT-P; few DOT-P participants need help preventing withdrawal given the ubiquity of street opioids, which contrasts with someone experiencing withdrawal inside of a hospital.

The legislative history and appellate record related to section 1306.07(b) are sparse. There are only oblique references to the “three-day

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portion of the order underscores how the legitimate practice of medicine prevails when treating pain with narcotic drugs. *Id.* at 17522.

<sup>224</sup> 21 U.S.C. § 802(29) (2018) (emphasis added).

<sup>225</sup> *Id.* § 823(g) (emphasis added).

<sup>226</sup> Dependence is not defined in any statute or regulation. Dependence is defined as “a state in which an organism functions normally only in the presence of a drug.” *Definition of Dependence*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/teaching-packets/neurobiology-drug-addiction/section-iii-action-heroin-morphine/8-definition-dependence> [<https://perma.cc/7X5W-TLA5>] (last visited Nov. 3, 2019). It “manifest[s] as physical disturbances when the drug is removed.” *Id.*

<sup>227</sup> See *supra* note 204 and accompanying text 194.

<sup>228</sup> See, e.g., *United States v. Hayes*, 794 F.2d 1348, 1353 (9th Cir. 1986) (supporting the lower court’s contention that, if the defendant “prescribed the drugs in good faith for legitimate medical purpose in the usual course of professional practice and did not prescribe them for drug maintenance or addiction he is not guilty,” and obliquely supporting a finding of ‘not guilty’ in an instance where “a patient was an addict and the doctor treated his addiction with Sched[ule] II drugs, and the patient experienced chronic pain, and the doctor treated the chronic pain in a good faith effort”).

<sup>229</sup> See 21 C.F.R. § 1306.07(b) (allowing physicians to administer “narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment . . . Such emergency treatment may be carried out for not more than three days and may not be renewed or extended”); see also *Emergency Narcotic Addiction Treatment*, *supra* note 190.

rule” in judicial examinations of other subparts.<sup>230</sup> There is no discussion of the rule in the preambles of the Notice of Proposed Rulemaking (NPRM) or the Final Rule.<sup>231</sup> The DEA has forcefully stated that “[t]he 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent the separate registration requirement.”<sup>232</sup> But this simply reflects the interest of the DEA in preserving registration requirements for maintenance therapy.<sup>233</sup> If DOT-P is not maintenance therapy, the three-day rule is inapposite.

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<sup>230</sup> See, e.g., *United States v. Ilayayev*, 800 F. Supp. 2d 417, 446 (E.D.N.Y. 2011) (citing 21 C.F.R. § 1306.07(c) as an example of an exception to the limitations on prescribing opioids as part of a long discussion of the opioid crisis in the United States while ultimately upholding the defendant’s revoked supervised release and new sentence); *United States v. Witt*, 1982 U.S. Dist. LEXIS 14387, at \*3 (S.D.N.Y. 1982) (citing an older version of the regulation to uphold a pharmacist’s indictment for “willfully and knowingly” prescribing and dispensing scheduled drugs “without legitimate medical purpose and outside the usual course of professional practice” (internal quotation marks omitted)); *United States v. Cap Quality Care, Inc.*, 486 F. Supp. 2d 47, 50 n.3 (Me. 2007) (dispensing with 21 C.F.R. § 1306.07 as only indirectly supporting the fact that “prescriptions for methadone are illegal” in maintenance or detoxification treatment, instead finding that 21 C.F.R. § 1306.04(c) better supports that proposition).

<sup>231</sup> See 39 Fed. Reg. 37,983, 37,983 (Oct. 25, 1974); 39 Fed. Reg. 26,424, 26,424 (July 19, 1974). The legislative history and congressional records, too, were silent on subpart (b), which makes sense, since the DEA promulgated the rule four years after the CSA was passed giving relatively broad authority to the DEA to do what it pleased, and nothing in the authorizing statute makes any mention of any of these rules’ substance. See 21 U.S.C. § 821 (2018) (giving the Attorney General the authority to “promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.”).

<sup>232</sup> *Emergency Narcotic Addiction Treatment*, *supra* note 190.

<sup>233</sup> See Randall L. Wolff, M.D.; Decision and Order, 77 Fed. Reg. 5106, 5106 (Feb. 1, 2012) (finding that the “three-day rule” exception for non-registered physicians did not permit the prescribing of opioids, even to allay acute withdrawal symptoms, for an undefined period of time and concluding that the physician had not prescribed the controlled substances with a legitimate medical purpose and that the revocation of his registration to dispense controlled substances was in the public interest). There exists some case law in the states indicating that violating the DEA’s registration requirement for OTPs does not show negligence per se, and so good faith treatment beyond the “three-day rule” might end up going to a jury to decide whether a practitioner was negligent. See, e.g., *Friedel v. Osunkoya*, 994 A.2d 746, 756 (Del. Super. Ct. 2010) (finding that violating the DEA’s registration requirement for OTPs is not a basis to find negligence per se). Nevertheless, a jury trial and revocation of registration is a risk few practitioners would be willing to assume. See generally Beth Jung & Marcus M. Reidenberg, *The Risk of Action by the Drug Enforcement Administration Against Physicians Prescribing Opioids for Pain*, 7 PAIN MED. 353 (2006) (describing the fear physicians feel about losing their registrations for prescribing opioids for pain, although finding that, generally,

If a court disagreed with our plain language analysis of § 1306.07(c), it would approach the question about the definition of maintenance therapy as one of statutory ambiguity. That analysis would begin with an examination of legislative intent. The place to start would be the House and Senate discussion of the Narcotic Addict Treatment Act (NATA) of 1974, which defined maintenance and detoxification treatment and added HHS oversight to narcotics treatment.<sup>234</sup> As both reports indicate, the CSA additions in NATA primarily aimed to prevent diversion of controlled substances into illicit channels, which is impossible with DOT-P because opioids are directly administered in the clinic.

The Senate report began by declaring that the bill aimed to help “law enforcement agencies . . . investigate and to curb the diversion and abuse of narcotic drugs used in the treatment of narcotic addicts.”<sup>235</sup> Specifically, and notably, the amendment targeted the “increased opportunity for *diversion of methadone into the illicit market*” caused by the expansion of methadone programs after the CSA’s passage three years prior.<sup>236</sup> In drafting the bill, the Senate weighed the traditional powers the states had to regulate “the general practice of medicine” against “the specialized circumstances within the purview of the bill [specifically opioid treatment], which entail inordinate *risks of diversion and unethical profiteering*.”<sup>237</sup> The Senate report concludes by stating that the CSA amendments “will reaffirm the commitment Congress

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the risk of an action by the DEA is low for physicians with adequate documentation in the medical record).

<sup>234</sup> See Narcotic Addict Treatment Act, Pub. L. No. 93-281 §§ 2-3, 88 Stat. 124, 124-125 (1974).

<sup>235</sup> S. REP NO. 93-192, at 2 (1973).

<sup>236</sup> *Id.* at 4 (emphasis added).

<sup>237</sup> *Id.* at 13 (emphasis added). In the end, the Senate placed power in what is now the HHS to “approv[e] . . . treatment standards” based on its authority “to determine standards of treatment in this area.” *Id.* at 3, 12. This statement speaks to the fact that maintenance was, at that point, delivered exclusively through research exemptions, which was unsustainable. Until the Narcotic Addict Treatment Act of 1974 was passed, maintenance treatment was considered a “research endeavor[.]” *Id.* at 11. Programs proliferated well beyond the scope that had been anticipated, leading to the necessity of classifying them as defined treatment programs. See *id.* at 11-12 (finding that “[m]ethadone maintenance programs were first initiated as research endeavors” and that these criteria were “never intended to apply to the massive treatment efforts now in progress nor the proposed expanded approval of methadone to the status of a new drug which permits the use of methadone for the maintenance treatment of narcotic addiction for all addicts for whom it is medically justified”). This is in contrast to detoxification programs, which were already established and well recognized, and therefore—prior to this amendment—could not be regulated in a manner outside of any other general medical practice. See H.R. REP NO. 93-884, at 9 (1974) (“[T]he Bureau of Narcotics and Dangerous Drugs has required a separate registration of all maintenance programs but has lacked authority to require this of detoxification programs.”).

made to the nation when it passed the [CSA] by . . . facilitating the prosecution of those who engage in the criminal *distribution* of legitimate narcotic drugs *for profit*.”<sup>238</sup>

The House report similarly describes the Act as necessary to address diversion related to the massive expansion of methadone treatment programs.<sup>239</sup> It declares that the “bill is designed to permit flexibility in treatment, while requiring adequate accountability for narcotic drugs administered in that treatment,” and it places emphasis on “the increased regulation of methadone and other narcotic drugs used in the treatment of narcotic addicts.”<sup>240</sup> The way that representatives sought to accomplish both goals is illustrated in the report’s pronouncement that “[t]he intent of the bill is twofold: (1) to increase the DEA’s ability to deal with law enforcement aspects of diversion; and (2) to maintain jurisdiction within FDA over the medical, scientific, and public health aspects of narcotic addiction treatment.”<sup>241</sup> This second stated intention—to maintain FDA’s jurisdiction over medical practice in opioid treatment—specifically reflects the drafters’ reaction to FDA’s inability to regulate detoxification treatment, despite its similarities to maintenance treatment and the attendant potential for diversion.<sup>242</sup>

Given the textual and legislative intent arguments available, we think that DOT-P would be on solid legal footing facing a challenge from federal law enforcement: neither the plain language nor the legislative history suggests that treatment of pain with secondary OUD must conform with maintenance or any other requirements beyond the generally prevailing obligation of professional practice. But it is also important to note that even if federal lawyers could introduce more ambiguity into the analysis, the legal principles for addressing that ambiguity militate in favor of DOT-P. In particular, three constitutional issues inflect the construction of the statutes and regulations in ways that support DOT-P proponents: the presumption against preemption, the rule of lenity, and the plausible right to pain care.

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<sup>238</sup> S. REP NO. 93-192, at 15 (emphasis added).

<sup>239</sup> See H.R. REP NO. 93-884, at 1 (claiming that as narcotics treatment programs have expanded, methadone diversion from these programs has increased).

<sup>240</sup> *Id.* at 4.

<sup>241</sup> *Id.*

<sup>242</sup> The House Report explained that the joint DEA-FDA regulatory efforts did bring about some improvement in the quality of methadone maintenance programs, did result in the closing of some of the worst programs, and did lay the groundwork for further legal developments, but regrettably left many problems unsolved, particularly with respect to diversion of methadone used for detoxification.

*Id.* at 3.

The Court's preference for avoiding far-reaching constitutional rulings suggests that any one or all three provide a basis for steering the interpretation of maintenance towards a more limited construction.<sup>243</sup>

The Court has established that in areas of traditional state concern—of which regulation of medical practice is a classic example<sup>244</sup>—there exists a presumption against preemption.<sup>245</sup> The Court requires that, “when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require

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<sup>243</sup> What had once been called a “cardinal principle” of judicial restraint, the avoidance doctrine is the principle that, if faced with a statute whose interpretation raises a constitutional issue, a court should determine “whether a construction of the statute is fairly possible by which the question may be avoided.” *See* *Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 348 (1936) (Brandeis, J., concurring) (quoting *Crowell v. Benson*, 285 U.S. 22, 62 (1932)). In recent years, the Supreme Court has weaponized the avoidance doctrine, relying on “active avoidance” to develop new constitutional law principles and to rewrite statutes beyond how they might “more naturally” be read. *See e.g.*, *Nat’l Fed’n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 574 (2012) (“[I]t is only because we have a duty to construe a statute to save it, if fairly possible, that § 5000A can be interpreted as a tax.”); *see also* Neal Kumar Katyal & Thomas P. Schmidt, *Active Avoidance: The Modern Supreme Court and Legal Change*, 128 *HARV. L. REV.* 2109, 2112 (2019) (discussing how the modern shift in the constitutional avoidance doctrine under the Roberts Court “leads to tortured constructions of statutes that bear little resemblance to laws actually passed by the elected branches” through “sloppy and cursory constitutional reasoning”). Nevertheless, courts continue to rely on the doctrine generally. Tangentially, in an interesting parallel, *NFIB* used a maneuver similar to that employed in the early Harrison Narcotic Drug Act cases discussed *supra* by construing the federal government’s taxing powers to extend beyond their rational limits. *Compare NFIB*, 567 U.S. at 574 (“[I]t is only because we have a duty to construe a statute to save it, if fairly possible, that §5000A [a provision of the ACA] can be interpreted as a tax.”), *with* *United States v. Doremus*, 249 U.S. 86, 95 (1919) (upholding the constitutionality of the Harrison Act as a revenue measure—before the DEA, narcotics enforcement was administered by the Commissioner of Internal Revenue—because the defendant’s patient was prescribed more narcotic doses than he would likely use and “[h]e might sell some to others without paying the [Harrison Act’s] tax,” thus frustrating the overall goal of the Act, “facilitating the collection of the revenue”).

<sup>244</sup> The Court has emphasized that

There can be no question of the authority of the State in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs . . . . The right to exercise this power is so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question.

*Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921).

<sup>245</sup> According to the Supremacy Clause, the U.S. Constitution, federal statutes, federal regulations, and ratified treaties trump the laws of the states when a direct conflict exists. U.S. CONST. art. VI. However, there is a presumption against federal preemption when it comes to the exercise of “historic police powers of the States.” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

that Congress should have spoken in language that is clear and definite.”<sup>246</sup> This presumption exists also in administrative and civil cases, as the Court “ha[s] never assumed lightly that Congress has derogated state regulation, but instead ha[s] addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law.”<sup>247</sup>

Constitutional principles also require criminal statutes to clearly define proscribed activity.<sup>248</sup> Without such clarity, criminal laws are considered impermissibly vague for failing to warn citizens of potential sanctions and for inviting arbitrary enforcement.<sup>249</sup> This suggests that a court facing two plausible interpretations should shy away from the one involving prosecution of a practitioner acting with a reasonable claim to legality.<sup>250</sup> It also means

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<sup>246</sup> *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221-22 (1952).

<sup>247</sup> *N.Y. State Conf. Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (quoting *Santa Fe Elevator Corp.*, 331 U.S. at 230); *see also* JAMES T. O’REILLY, AM. BAR ASS’N, *FEDERAL PREEMPTION OF STATE AND LOCAL LAW: LEGISLATION, REGULATION AND LITIGATION* 7 (2006) (“If the subject matter was ‘traditionally regarded as properly within the scope of state superintendence,’ or a matter of public health or safety, then the courts rely more heavily on the presumption that states will continue to have an important role.”).

<sup>248</sup> As the *Connally* Court explained:

The terms of a penal statute . . . must be sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties . . . [A]nd a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.

*Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926).

<sup>249</sup> This is sometimes referred to as the Rule of Lenity. *See, e.g.*, *Papachristou v. City of Jacksonville*, 405 U.S. 156, 162 (1972) (“If a statute or ordinance is so indefinite that ‘it encourages arbitrary and erratic arrests and convictions,’ it will be void for vagueness.”); *Rewis v. United States*, 401 U.S. 808, 812 (1971) (holding that, where the statute is silent and legislative history absent on a particular issue, “ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity”); *United States v. Harriss*, 347 U.S. 612, 617 (1954) (“It is settled that, as a matter of due process, a criminal statute that ‘fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute’ is void for vagueness.”).

<sup>250</sup> *See, e.g.*, *United States v. Kozminski*, 487 U.S. 931, 952 (1988) (“[W]e adhere to the time-honored interpretive guideline that uncertainty concerning the ambit of criminal statutes should be resolved in favor of lenity.”); *Bell v. United States*, 349 U.S. 81, 83 (1955) (“When Congress leaves to the Judiciary the task of imputing to Congress an undeclared will, the ambiguity should be resolved in favor of lenity.”). *But see* Intisar A. Rabb, Response, *The Appellate Rule of Lenity*, 131 HARV. L. REF. F. 179, 198-99 (2018) (finding that “the Roberts Court rejected lenity in favor of broad constructions in 31 of its 44 lenity-eligible cases . . . . In the vast majority of these cases (all but 6), the Court asserted that its readings were dictated by the texts’ ‘plain meaning[s]’ . . . despite

that the prosecution would have to prove that the clinician knowingly or intentionally administered a prohibited narcotic outside the usual course of professional practice. Establishing the requisite intent—or mens rea—has proven difficult in misprescribing prosecutions.<sup>251</sup> Courts have generally allowed evidence of good faith in such cases.<sup>252</sup> Because these cases exclusively involve prescribing—as opposed to administration—usually with minimal or no medical evaluation, such good faith arguments are substantially weaker than a clinician providing DOT-P could offer.

The difficulty and uncertainty in the diagnosis and treatment of pain complicates identifying the requisite mens rea. Determining whether pain or OUD is the primary indication or whether addressing one is contingent on addressing the other relies on individualized assessments that cannot be reduced to bright lines and biologic indicators. Courts have been reluctant to impose criminal sanctions when guilt hinges on physicians making impossible clinical judgments—such as identifying the moment viability occurs in abortion-related

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concurrences or dissents raising alternative plausible meanings and sometimes arguing for lenity.” (internal quotation marks omitted).

<sup>251</sup> As the Ninth Circuit explained,

a practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) only if he does so intentionally. . . . Simply put, to convict a practitioner under § 841(a), the government must prove . . . that the practitioner acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor’s intent to act as a pusher rather than a medical professional.

United States v. Feingold, 454 F.3d 1001, 1007-08 (9th Cir. 2006).

<sup>252</sup> See, e.g., United States v. Hurwitz, 459 F.3d 463, 476 (4th Cir. 2006) (noting that “a doctor’s good faith generally is relevant to a jury’s determination of whether the doctor acted outside the bounds of medical practice or with a legitimate medical purpose when prescribing narcotics,” although still sentencing the defendant to nearly five years in prison); see also Diane E. Hoffmann, *Physicians Who Break The Law*, 53 ST. LOUIS U. L.J. 1049, 1072 (2009) (noting that “the legal system has responded much more discriminately, even compassionately in a number of cases where physicians appear to be acting to help their patients . . . when the law is in flux or when there is considerable societal ambivalence about a law,” as is the case with OUD).

litigation<sup>253</sup>—which constitute little more than “a trap for those who act in good faith.”<sup>254</sup>

Interpretive arguments would also unfold in the shadow of a plausible right to pain care. Although a majority of the Court has never acknowledged such a right in a single joint opinion, multiple legal scholars have observed that reading across plurality decisions, and some of the Justices have signaled that treatment for severe pain is a fundamental right.<sup>255</sup> Justice O’Connor once remarked that “[t]here is no dispute that dying patients in Washington

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<sup>253</sup> In the context of abortion, the Court stated,

The perils of strict criminal liability are particularly acute here because of the uncertainty of the viability determination itself. As the record in this case indicates, a physician determines whether or not a fetus is viable after considering a number of variables: the gestational age of the fetus, derived from the reported menstrual history of the woman; fetal weight, based on an inexact estimate of the size and condition of the uterus; the woman’s general health and nutrition; the quality of the available medical facilities; and other factors. Because of the number and the imprecision of these variables, the probability of any particular fetus’ obtaining meaningful life outside the womb can be determined only with difficulty. Moreover, the record indicates that even if agreement may be reached on the probability of survival, different physicians equate viability with different probabilities of survival, and some physicians refuse to equate viability with any numerical probability at all. In the face of these uncertainties, it is not unlikely that experts will disagree over whether a particular fetus in the second trimester has advanced to the stage of viability. The prospect of such disagreement, in conjunction with a statute imposing strict civil and criminal liability for an erroneous determination of viability, could have a profound chilling effect on the willingness of physicians to perform abortions near the point of viability in the manner indicated by their best medical judgment.

*Colautti v. Franklin*, 439 U.S. 379, 395-96 (1979).

<sup>254</sup> *United States v. Ragen*, 314 U.S. 513, 524 (1942); *see also Colautti*, 439 U.S. at 395 (“This Court has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of *mens rea*.”).

<sup>255</sup> Burt explained,

the Supreme Court has unanimously ruled that there is no constitutional right to physician-assisted suicide. Unexpectedly, however, the Court did much more than simply uphold the New York and Washington statutes prohibiting assisted suicide. A Court majority effectively required all states to ensure that their laws do not obstruct the provision of adequate palliative care, especially for the alleviation of pain and other physical symptoms of people facing death.

Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care*, 337 NEW ENG. J. MED. 1234, 1234 (1997); *see* Beth Packman Weinman, *Freedom from Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEG. MED. 495, 525-29 (2003) (analyzing different Justices’ concurring opinions in physician-assisted suicide cases and concluding that many of the opinions indicate that up to five of the Justices on the bench in 2003 “recognize[d] the right to pain relief as fundamental”).



and New York can obtain palliative care, even when doing so would hasten their deaths.”<sup>256</sup> It would be strange, indeed, if the Supreme Court effectively upheld a program that hastened death with opioids, over federal claims about the legitimacy of the practice (e.g., *Gonzales v. Oregon*), but not a program preventing death with opioids, over similar federal objections. Just as the Court avoided weighty constitutional issues about federalism and the right to die by disposing of the *Oregon* case on interpretive grounds, it might similarly avoid an interpretation that forced a decision on the right to pain care.

If, as we suspect, the federal government challenged DOT-P and lost the argument that DOT-P is maintenance, it might follow up by suggesting that DOT-P falls beyond the bounds of professional practice.<sup>257</sup> This would be a difficult argument. Considerable evidence and experience support the primary treatment modality of DOT-P.<sup>258</sup> The definition of what constitutes professional practice encompasses all good faith activity between patients and providers.<sup>259</sup> In the words of a former DEA Legal Counsel, in a description of the agency’s efforts to prosecute clinicians for violations of the CSA,

[a]cts of prescribing or dispensing of controlled substances which are done within the course of the registrant’s professional practice are, for purposes of the Controlled Substances Act, lawful. It matters not that such acts might constitute terrible medicine or malpractice. They may reflect

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<sup>256</sup> *Washington v. Glucksberg*, 521 U.S. 702, 736-37 (1997) (O’Connor, J., concurring).

<sup>257</sup> A practitioner’s liability for possibly violating the CSA in the case of DOT-P hinges on three statutory requirements: 1) a practitioner must knowingly or intentionally 2) dispense (including administer) a controlled substance 3) in the course of professional practice. 21 U.S.C. § 841(a) (2018). Section 829(a) states that, for Schedule II substances, a practitioner (other than a pharmacist) directly dispensing the controlled substance to an ultimate user does not need a prescription. *Id.* § 829(a). The definition of a practitioner in the CSA specifies that this dispensing must be “in the course of professional practice or research.” *Id.* § 802(21). Only later, once the DEA promulgated its regulations following the CSA’s passage, was an additional requirement that the practitioner must prescribe with “a legitimate medical purpose . . . in the usual course of his professional practice” added. 21 C.F.R. § 1306.04(a) (2018). Statutorily and regulatory-wise, the legitimate medical purpose requirement, therefore, only applies to prescribing, and not to a practitioner dispensing directly to an ultimate user, as would be the case with DOT-P. The distinction here is important to note, as a physician administering hydromorphone would only be subject to the ‘in the course of professional practice’ requirement.

<sup>258</sup> Based both on the existence of similar practices internationally and the research studies discussed in *supra* note 90.

<sup>259</sup> See Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States’ Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia’s Alternative Regulatory Approach*, 47 COLUM. J. TRANSNAT’L L. 210, 230 (2008) (“The professional practice requirement of the good faith defense . . . helps to ensure that physicians only prescribe controlled substances in the course of medical treatment.”).

the grossest form of medical misconduct or negligence.

They are nevertheless legal.<sup>260</sup>

The DEA itself, in its most current Practitioner's Manual, acknowledges that "[f]ederal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice' in a way that will provide definitive guidelines to address all the varied situations physicians may encounter."<sup>261</sup> Clinicians act outside of their professional practice only when their activities aim not at addressing a diagnosed medical complaint but at some other purpose like profit.<sup>262</sup> Undercover agents pursuing overprescribing physicians, the DEA Counsel notes, "should present themselves as persons seeking drugs and should never give a legitimate medical complaint."<sup>263</sup>

Few cases have explored either the professional practice or legitimate medical practice standard.<sup>264</sup> Some courts do not draw a distinction between

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<sup>260</sup> Stephen E. Stone, *The Investigation and Prosecution of Professional Practice Cases Under the Controlled Substances Act*, 10 DRUG ENFORCEMENT 21, 23 (1983).

<sup>261</sup> OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMIN., PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 30 (2006), [https://www.dea diversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](https://www.dea diversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf) [<https://perma.cc/6ZYS-TUX6>].

<sup>262</sup> According to Stone,

While every practitioner case is different, most lend themselves to an undercover approach in which agent, posing as a typical client, attempts to obtain drugs or prescriptions under circumstances showing lack of a physician-patient relationship. In order for a practitioner to prescribe or dispense in the course of his professional practice, there must exist between the doctor and the 'patient' a valid physician-patient relationship. To establish this relationship, the patient must come to the physician seeking treatment for some kind of physical or psychological condition or symptomology. The physician must then obtain from the patient enough of a medical history . . . [and] conduct an examination or other medically recognized procedure sufficient to make a diagnosis. Finally, there must be a logical connection, or nexus, between the drug ultimately prescribed and the physical or psychological condition diagnosed. Patients of violative physicians typically do not present medical complaints.

Stone, *supra* note 260, at 24.

<sup>263</sup> *Id.*

<sup>264</sup> It is worth noting that all of the following cases involve prescribing, not administering, but their opinions refer to dispensing generally, and so might represent the applicable caselaw in instances of administering, as well.

the two;<sup>265</sup> others refer to both but do not evaluate them separately.<sup>266</sup> In *Moore*, the Supreme Court appears to define professional practice based simply on whether the defendant procedurally acted like a physician, focusing on the fact that “he gave inadequate physical examinations or none at all[,] . . . [h]e did not give methadone at the clinic[,] . . . [h]e did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded[,] . . . [and h]e did not charge for medical services rendered, but graduated his fee according to the number of tablets desired.”<sup>267</sup> No self-respecting federal official would suggest that DOT-P fails the *Moore* test.<sup>268</sup>

#### IV. PRECISION IN OPIOID POLICY—NOT PENDULUM SWINGS— IS KEY TO REDUCING OVERDOSE

As this Article goes to print, federal law enforcement officials are appealing a decision in the Eastern District of Pennsylvania ruling that a

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<sup>265</sup> See, e.g., *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975) (holding that “[t]he two phrases [from 21 U.S.C. § 802(20) and 21 C.F.R. § 1306.04(a)(1974)] in the indictment have essentially the same meaning” for purposes of the defendant’s indictment, and relying on a “good faith” standard to determine whether the defendant was acting in the course of professional practice).

<sup>266</sup> See, e.g., *United States v. Joseph*, 709 F.3d 1082, 1103-04 (11th Cir. 2013) (relying on testimony regarding medical standards to support a finding that there was enough evidence to support the lower court’s sentencing, but incompletely matching that evidence to legitimate medical purpose and the usual course of professional practice, instead ruling on a more general “applicable standard of practice” that appears to subsume both terms); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986) (recognizing that there is a difference between the two terms and their provenance, but still supplying no language to differentiate their legal applicability); *United States v. Guerrero*, 650 F.2d 728, 730-31 (5th Cir. 1981) (reversing defendant’s convictions in the lower court because of erroneously admitted evidence pertaining to defendant’s conduct and going back and forth between the two terms when evaluating the evidence and combining them in interesting ways, such as “normal medical purposes” and “normal course of a medical practice,” but never distinguishing between any of the terms’ incarnations).

<sup>267</sup> *United States v. Moore*, 423 U.S. 122, 142-43 (1975).

<sup>268</sup> In the *Safehouse* case, Judge McHugh observed that the government’s counsel derided [*Safehouse*’s description of the program] as ‘Bizarro World,’ urged the Court to ‘be real,’ and seemingly rejected any therapeutic purpose, stating, ‘They’re not inviting people onto their property just to get treatment or whatever other services they’re offering. The whole purpose here is for people to use drugs.’ My inclination is to discount these remarks as a moment of overly zealous advocacy. But in any case, *no plausible reading of the pleadings before me supports such a caricature of what Safehouse proposes.* *United States v. Safehouse*, No. 19-0519, 2019 WL 4858266, at \*24 n.46 (E.D. Pa. Oct. 2, 2019) (emphasis added) (internal citations omitted).

planned SCF in Philadelphia does not violate a section of the CSA.<sup>269</sup> Philadelphia has the highest rate of fatal overdoses in the country among large cities.<sup>270</sup> The proposed SCF would help bring that rate down while addressing other individual and community harms associated with widespread injection drug use in public in one particular neighborhood.

It is a momentous decision. But as the case moves through the courts and clears other procedural hurdles, people will continue to experience avoidable harm including death. When the stakes are so high, in terms of immediate and preventable harm, any delay is horrific. In this Article, we introduce a new intensive pain care model to engage an especially vulnerable subset of people who inject drugs, namely those experiencing serious and otherwise unmanaged pain. This model is essential for addressing substantial avoidable harm including death and it is plainly within the bounds of professional practice. But we cannot deny that a case involving DOT-P might encounter legal roadblocks given the grand tradition of drug policy (“drugs bad; prosecution good”<sup>271</sup>) and the DEA’s recent surge in investigations and prosecutions.

Law enforcement action against DOT-P would be especially ironic and misguided. There are valid reasons to be concerned about overprescribing, especially in the pill mill incarnation of the problem, which the DEA miserably failed to identify and disrupt.<sup>272</sup> Preventing diversion and overdose among people prescribed opioids also remain legitimate and challenging public health priorities. However, the DOT-P model we propose—a highly structured dispensing and consumption environment designed to maximize benefits, while minimizing the risks—responds to these concerns and challenges with

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<sup>269</sup> See *id.* at \*11-12 (holding that the “Crack House” statute in the CSA is capable of multiple interpretations and that because Congress did not contemplate SCFs when creating or revising the provision, it does not apply against at SCF); Jeremy Roebuck & Aubrey Whelan, *Judge: Philly Supervised Injection Site Proposal Does Not Violate Federal Law*, PHILA. INQUIRER (Oct. 2, 2019), <https://www.inquirer.com/health/opioid-addiction/safehouse-supervised-injection-site-ruling-philadelphia-mchugh-opioids-20191002.html> [<https://perma.cc/AN27-GGF8>] (“Justice Department officials, who had asked the judge to declare the supervised injection plan illegal, vowed an immediate appeal.”).

<sup>270</sup> See Alexis M. Roth et al., *Overdose Prevention Site Acceptability Among Residents and Businesses Surrounding a Proposed Site in Philadelphia, USA*, 96 J. URBAN HEALTH 341, 341-42 (2019) (stating that the more than 1074 overdose deaths involving opioids in 2017 constituted a rate of 69.5 per 100,000, higher than in other U.S. cities).

<sup>271</sup> Burris et al., *supra* note 10, at 1123.

<sup>272</sup> See, e.g., Leo Beletsky & Jeremiah Goulka, *The Federal Agency That Fuels the Opioid Crisis*, N.Y. TIMES (Sept. 17, 2018), <https://www.nytimes.com/2018/09/17/opinion/drugs-dea-defund-heroin.html> [<https://perma.cc/M5Q3-VHJW>] (describing the DEA’s poor design for not being informed by public health or addiction science, and thus focusing on eradicating illicit drugs and being “unable to balance legitimate access to and control of prescription drugs.”).

precision. For this and other reasons, we expect the DOT-P approach and others like SCFs to triumph in a saner drug policy in the not so distant future. Our optimism is grounded not just on the hint of daylight provided by the *Safehouse* decision but also in converging epidemiological, political, public health, and legal dynamics.

In 2016, as the opioid crisis in the United States worsened, Congress passed the Comprehensive Addiction and Recovery Act (CARA).<sup>273</sup> It was the first time in four decades that Congress adopted major drug policy legislation underscoring the gravity of increasing opioid-related harms. Nevertheless, CARA only chipped at the edges of the crisis.<sup>274</sup> At the tail end of 2018, when it became clear that CARA was inadequate to reverse the opioid epidemic's toll, Congress passed the SUPPORT for Patients and Communities Act.<sup>275</sup> But it, too, operated on the periphery of the crisis.<sup>276</sup>

The policy response at the federal and state level has followed a long-term pattern in search of pharmacological counter-measures. Federal officials have accurately acknowledged limitations in existing treatment modalities. Former FDA Commissioner Scott Gottlieb recognized that, although current OUD treatments do improve outcomes, “relapse rates are still high” and “not all patients respond positively to such medications.”<sup>277</sup> But the FDA

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<sup>273</sup> Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-98, 130 Stat. 695 (2016).

<sup>274</sup> It expanded the number of patients who could be treated. *Id.* § 303. It also sought to improve information and training campaigns. *Id.* §§ 102, 202. At the same time, it made millions of dollars in grants available to states and medical facilities to expand access to methadone and buprenorphine. *Id.* § 201.

<sup>275</sup> Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 (2018).

<sup>276</sup> Among other small improvements, it focused on encouraging drug manufacturers and distributors to report and stop suspicious orders and expanded treatment programs concentrating on opioid diversion and OUD in specific populations, such as mothers and infants. *Id.* §§ 3272, 7061.

<sup>277</sup> Press Release, Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Encourage More Widespread Innovation and Development of New Treatments for Opioid Use Disorder (April 20, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-encourage-more-widespread-innovation-and> [<https://perma.cc/EQ92-MGTM>]. Indeed, he continued to “welcome” the development of new treatments for OUD and indicated that “such therapies may qualify for the agency’s expedited review programs.” *Id.* The FDA and the National Institute on Drug Abuse (NIDA) have highlighted the barriers to new MAT drug development. Nora D. Volkow et al., *Medication Development in Opioid Addiction: Meaningful Clinical End Points*, 10 SCI. TRANSLATIONAL MED., no. 434, at 1, 1 (noting that “developing new medications to reduce the burden caused by opioid-use disorders is a high priority”). The FDA also released draft guidance with an expanded list of endpoints to demonstrate the effectiveness of a drug for use in MAT. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: OPIOID USE DISORDER: ENDPOINTS FOR DEMONSTRATING EFFECTIVENESS OF DRUGS FOR MEDICATION-ASSISTED TREATMENT (2018), <https://www.fda.gov/media/114948/download> [<https://perma.cc/6SN5-Q6GB>].

has not approved a new medication treatment for maintenance and detoxification since 2002,<sup>278</sup> in part because the drug approval process is tedious, costly, and time-consuming.<sup>279</sup>

Improvements in access to methadone and buprenorphine are lifesaving for many people, but not all, or at least not without adequate pain control. Herein lies a key impediment to sensible reform but also an important practical opportunity: opioid use, opioid dependence, and opioid use disorder are not monolithic. They differ in their causes and in their clinical presentation.<sup>280</sup>

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<sup>278</sup> Letter from Cynthia G. McCormick, Dir., Div. of Anesthetic, Critical Care, and Addiction Drug Products, Office of Drug Evaluation II, Ctr. for Drug Evaluation and Research, U.S. Food & Drug Admin., to Alan N. Young, Dir., Regulatory Affairs, Reckitt Benckiser (Oct. 8, 2002), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2002/20732\\_20733ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20732_20733ltr.pdf) [<https://perma.cc/ZR4J-4XS3>] (“These new drug applications provide for the use of Subutex and Suboxone for the treatment of opioid dependence in patients 16 years of age and older.”). All MAT drugs have been specifically approved for this purpose through the FDA’s prescribed new drug application (NDA) process. *See id.*; Determination That ORLAAM (Levomethadyl Acetate Hydrochloride) Oral Solution, 10 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 32,366, 32,366 (June 6, 2011) (discussing the discontinuation of ORLAAM, but recognizing that it was submitted for approval via NDA for the management of opioid dependence and was approved in 1993); Approved New Drugs Requiring Continuation of Long-Term Studies, Records, and Reports; listing of Methadone With Special Requirements for Use, 37 Fed. Reg. 26,790, 26,795 (Dec. 15, 1972) (revising prior regulations and listing methadone as a drug subject to NDA approval). While the FDA has in recent years approved new forms and delivery mechanisms for MAT drugs, those have also gone through the NDA process. *See, e.g.*, U.S. FOOD & DRUG ADMIN., APPROVAL PACKAGE FOR SUBLOCADE (2017), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2017/209819Orig1s000Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209819Orig1s000Approv.pdf) [<https://perma.cc/WP5G-WU97>] (approving a new extended release form of buprenorphine for use in OTP). In fact, the FDA’s most recent draft guidance document encouraging the development of buprenorphine depot products solicits applications through the expedited NDA process. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: OPIOID USE DISORDER: DEVELOPING DEPOT BUPRENORPHINE PRODUCTS FOR TREATMENT (2018), <https://www.fda.gov/media/112739/download> [<https://perma.cc/EHG2-SL4F>]. However, this draft guidance document also hedges, stating that using the expedited 505(b)(2) NDA submission pathway “may be appropriate” for this form of buprenorphine. *Id.* at 1.

<sup>279</sup> *See* Cassandra L. Santoro, *Overdosing on Authority: Negative Side Effects of the FDA’s Proposal for Generic Label Changes May Include Increased Costs and Liabilities*, 49 SUFFOLK U. L. REV. 183, 185-88 & n.41 (2016) (stating that “[t]he process for filing a new drug application is cumbersome and extensive” and noting that, over the course of a decade, “brand-name drug manufacturers invested over \$500 billion in research and development for [300 approved] new drugs.”). The FDA itself has indicated in multiple statements and papers that it is seeking more, and better, drugs for use in MAT. *See supra* note 277. Nevertheless, even in its solicitations for a specific MAT drug that it intends to approve, it requires that the developer go through the NDA process, albeit on an expedited timetable. *See id.*

<sup>280</sup> Opioid Use Disorder (OUD) is defined as opioid use leading to a clinically significant impairment or distress, as indicated by two or more of ten possible symptoms. AM.PSYCHIATRIC ASS’N,

The people likely to benefit from DOT-P represent a concentrated subset of people who experience OUD along with co-occurring pain and housing instability. Better access to OUD pharmacotherapy alone will not fully address their needs, especially considering the limited models for providing OAT in the United States. And to the extent that their needs are not met, communities will continue to experience the effects of public injection drug use, which are largely preventable.

Federal officials have celebrated—sometimes cautiously and sometimes not<sup>281</sup>—that the epidemic has crested in part through federal initiatives.<sup>282</sup> But the evidence on the ground is far more complex. Public drug use is widely prevalent in many urban areas, producing infections and community effects.<sup>283</sup> An outbreak of hepatitis A in Philadelphia<sup>284</sup> underscores the challenges in reducing the incidence and harms of public injection drug use. The only way to break the cycles that perpetuate public injection is through interventions like DOT-P, and, to a lesser extent, SCFs. Although some of the most affected neighborhoods have opposed SCFs in the United States, that opposition is grounded in mistaken beliefs that SCFs will promote

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DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-5) § 2.17.22 (5th ed. 2013) (ebook). Of the 256 possible combinations of opioid-related symptoms that meet the diagnostic criteria, some are exclusively physiological, and others are exclusively social. *Id.* OUD severity is mild when there are 2 or 3 of these symptoms, mild when there are 4 or 5 of these symptoms, and severe when there are 6 or more of these symptoms. *Id.*

<sup>281</sup> See, e.g., Press Release, U.S. Dep't. of Health and Human Servs., Secretary Azar Statement on 2018 Provisional Drug Overdose Death Data (July 17, 2019), <https://www.hhs.gov/about/news/2019/07/17.html> [<https://perma.cc/DQG6-TU56>] (“While the declining trend of overdose deaths is an encouraging sign, by no means have we declared victory against the epidemic or addiction in general. This crisis developed over two decades and it will not be solved overnight.”); Donald Trump, Remarks in a Meeting on Opioids (June 12, 2019), <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-meeting-opioids/> [<https://perma.cc/4BA6-JHRV>] (“And I think what we do—this is a meeting on opioid [sic] and the tremendous effect that’s taken place over the last little period of time. And I’m very proud of it and the people working so hard on it.”).

<sup>282</sup> See Abby Goodnough, Josh Katz & Margot Sanger-Katz, *Drug Overdose Deaths Drop in U.S. for First Time Since 1990*, N.Y. TIMES (July 17, 2019), <https://www.nytimes.com/interactive/2019/07/17/upshot/drug-overdose-deaths-fall.html> [<https://perma.cc/LL5V-PC7C>] (noting that, although overdose deaths have decreased, much of that decrease is due to limits on opioid painkiller prescribing; whereas overdoses related to other drugs, such as fentanyl, have continued to increase).

<sup>283</sup> See Sutter et al., *supra* note 89, at 63, 65 (describing community harms associated with public injection drug use, such as increased secondary infections and syringe litter).

<sup>284</sup> See, e.g., Health Alert, Phila. Dep't. of Pub. Health, Hepatitis A Increases in Philadelphia: Considerations for Diagnosis, Control, and Prevention (June 12, 2018), [https://hip.phila.gov/Portals/\\_default/HIP/HealthAlerts/2018/PDPH-HAN\\_Alert\\_7\\_HepAIncrease\\_06122018.pdf](https://hip.phila.gov/Portals/_default/HIP/HealthAlerts/2018/PDPH-HAN_Alert_7_HepAIncrease_06122018.pdf) [<https://perma.cc/GSX2-874Q>] (noting an increase to 26 cases of Hepatitis A in the recent twelve-month period compared to an average rate of 6 cases annually between 2012 and 2016).

public disorder,<sup>285</sup> rather than abate it.<sup>286</sup> Recent research suggests that public opinion in the most affected neighborhoods is shifting in favor of SCFs.<sup>287</sup>

Social and political momentum is necessary but not sufficient to reform. There must be policy alternatives once limitations with traditional first-line approaches emerge. Drug policy in the United States has seldom offered such policy options in the last century. But the dynamics of drug policy are changing. Political scientists have often described policy reform in terms of punctuated equilibrium, meaning that in most regulatory domains there are long periods of stability and that when change happens, it is violent and revolutionary.<sup>288</sup> Legal reform related to marijuana fits the pattern, as do realignments in drug policy more generally. As Philadelphians confront an entrenched opioid crisis, well-funded corporations in the suburbs are managing pot farms for medical dispensing,<sup>289</sup> and recreational use is likely not far

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<sup>285</sup> See, e.g., Nina Feldman, *Kensington Neighbors Angered by Potential Location of Supervised Injection Site*, WHYY (Mar. 27, 2019), <https://whyy.org/articles/kensington-neighbors-angered-by-potential-location-of-supervised-injection-site/> [<https://perma.cc/8C8Y-TREP>] (describing how community members “expressed fear that a supervised injection facility would increase crime and keep drug dealers and drug use stuck in” their neighborhood); Kilpatrick, *supra* note 140 (describing one resident’s worry that “a safe-injection site in the neighborhood will cause more violence as dealers fight for corners surrounding the site” although studies on safe injection sites in Canada and Australia found no increase in crime in the surrounding areas).

<sup>286</sup> See NEIL DONNELLY & NICOLE MAHONEY, N.S.W. BUREAU OF CRIME STATISTICS AND RESEARCH, *TRENDS IN PROPERTY AND ILLICIT DRUG CRIME AROUND THE MEDICALLY SUPERVISED INJECTING CENTRE IN KINGS CROSS: 2012 UPDATE 8 (2013)* (finding, in a study spanning over a decade, “no evidence that [an Australian SCP] had a negative impact on property crime and little evidence that it had an adverse impact on drug use and dealing” in the surrounding neighborhood).

<sup>287</sup> See, e.g., Alexis M. Roth et al., *Overdose Prevention Site Acceptability among Residents and Businesses Surrounding a Proposed Site in Philadelphia, USA*, 96 J. URB. HEALTH 341, 344 (2019) (finding that 90% of individuals in Kensington, PA, the neighborhood with the highest drug-overdose mortality in Philadelphia, favor opening an SCF in that area).

<sup>288</sup> Political scientists brought this theory over from biology. See, e.g., James L. True, Bryan D. Jones & Frank R. Baumgartner, *Punctuated Equilibrium Theory: Explaining Stability and Change in Public Policymaking*, in *THEORIES OF THE POLICY PROCESS* 155, 180 n.1 (Paul A. Sabatier ed., 2d ed. 2007) (noting that the punctuated equilibrium theory was imported from evolutionary biology). See generally Stephen J. Gould & Niles Eldredge, *Review Article, Punctuated Equilibrium Comes of Age*, 366 NATURE 223 (1993) (describing the emergence and ultimate validation of punctuated equilibrium in the evolutionary research).

<sup>289</sup> See John George, *The Region’s First Medical Marijuana Grower Expects Its First Harvest Soon—and Is Already Expanding*, PHILA. BUS. J. (Aug. 30, 2019, 7:37 AM), <https://www.bizjournals.com/philadelphia/news/2019/08/30/the-regions-first-medical-marijuana-grower-expects.html> [<https://perma.cc/4BGY-VK3J>] (describing four corporations that grow and process medical marijuana in Philadelphia and its surrounding suburbs).



off.<sup>290</sup> This is not to suggest that irony or hypocrisy will provide any discipline in political or judicial discourse; we are not so naive. Rather, it demonstrates that drug control reforms have moved into the laboratories of the states, which produce evidence to support and accelerate ongoing legislative changes.<sup>291</sup>

These legislative developments may encounter judicial roadblocks. The Roberts Court may ultimately weigh in on SCFs if the *Safehouse* decision reaches the Supreme Court, but courts are unlikely to provide the final or determinative word. While the *Raich* decision appeared to be a victory for federal regulation of marijuana, the effects of the ruling withered almost immediately.<sup>292</sup> Practically speaking, the *Raich* decision never reached adolescence; medical and recreational marijuana use was minimally affected in California, which now has the largest legal marijuana market in the world,<sup>293</sup> and recreational marijuana use came to Colorado, the first of many states, less than a decade later.<sup>294</sup> The history of the Oakland Cannabis Buyers' Cooperative (OCBC) provides a better example of how little judicial outcomes matter in the face of secular changes in perceptions about drugs and associated willingness of localities to engage in consistent policy experiments.<sup>295</sup> There is plenty of

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<sup>290</sup> See Associated Press, *Gov. Tom Wolf Now Supports Legalizing Marijuana in Pennsylvania*, PHILA. INQUIRER (Sept. 25, 2019), <https://www.inquirer.com/news/pennsylvania/pennsylvania-legalize-marijuana-governor-tom-wolf-20190925.html> [<https://perma.cc/8V38-FL9P>] (“Pennsylvania Gov. Tom Wolf is now in favor of legalizing marijuana for recreational use, saying . . . that most of the state’s residents support it and that the state has a wealth of knowledge from the experience in other states to guide it.”).

<sup>291</sup> See generally Burris & Anderson, *supra* note 145 (noting that in regulatory domains in which states use their authority to experiment, there typically follows a process of policy learning in which innovations beget research opportunities, which incrementally enrich the understanding of underlying problems and point to paths for future refinement or retirement of legal interventions).

<sup>292</sup> See Press Release, Dep’t of Justice, Attorney General Announces Formal Medical Marijuana Guidelines (Oct. 19, 2009), <https://www.justice.gov/opa/pr/attorney-general-announces-formal-medical-marijuana-guidelines> [<https://perma.cc/X27K-CZ6Q>] (“It will not be a priority to use federal resources to prosecute patients with serious illnesses or their caregivers who are complying with state laws on medical marijuana . . .”).

<sup>293</sup> See Patrick McGreevy, *California Now Has the Biggest Legal Marijuana Market in the World. Its Black Market Is Even Bigger*, L.A. TIMES (Aug. 15, 2019, 5:00 AM), <https://www.latimes.com/california/story/2019-08-14/californias-biggest-legal-marijuana-market> [<https://perma.cc/7X9Q-4J23>] (reporting that California is expected to post \$3.1 billion in licensed marijuana sales for 2019, nearly twice those projected in Colorado and considerably more than in other countries).

<sup>294</sup> See COLO. CONST. art. XVIII, §16.

<sup>295</sup> OCBC provided marijuana to patients who complied with California laws authorizing medical use. The federal government issued an injunction halting OCBC’s activity, which was upheld by the Supreme Court despite reasonable arguments that marijuana was medically necessary to prevent considerable harm. See CAL. HEALTH & SAFETY Code §11362.5

reason to doubt that experiences with marijuana generalize to injection drugs. Yet we think that the mechanics broadly transfer across state and federal policy, with more open-minded thinking on marijuana likely to support saner, evidence-based reform in other areas.<sup>296</sup>

Broader contemplation and implementation of legislative reforms should extend to federal regulation of treatment for substance use disorder. The registration and waiver laws and regulations are a product of earlier and different eras, and they have persisted because of receding dynamics. When the Supreme Court issued its opinion in *Webb* in 1919,<sup>297</sup> the medical profession was still weak therapeutically and politically. It was only four years after the dean of the Harvard Medical School had said: “For the first time in history, . . . [a patient] stands a better than 50/50 chance of benefiting from a [clinical] encounter.”<sup>298</sup> But for most of the following decades, the medical profession has been good at both treatment and influencing national policy.<sup>299</sup> Physicians have become so powerful, in fact, that they, like most powerful interests, have tended not to question problems in the status quo that they could avoid, even if they had strong opinions purely on the merits.<sup>300</sup> This is what Paul Starr

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(West 2019) (authorizing the medical use of marijuana in California); *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 486 (2001). It remains a disappointing result (in allowing law enforcement to define medical practice), but practically irrelevant; despite its defeat, OCBC has issued over 100,000 medical marijuana ID cards in California. *Cannabis Badges*, PATIENT ID CTR., <http://www.cannabisbadges.com/index.php/patient-id-card> [<https://perma.cc/B44H-LHLW>] (last visited Sept. 18, 2019). It is now known as the Patient ID Center, or PIDC. *Mission Statement*, PATIENT ID CTR., <https://www.patientidcenter.org/index.php/mission-statement> (last visited Sept. 18, 2019).

<sup>296</sup> See Sanders, *supra* note 12 (describing Bernie Sanders’s support for SCFs); Warren, *supra* note 12 (describing Elizabeth Warren’s support for SCFs).

<sup>297</sup> See *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (holding that issuing an order for maintenance of a habitual morphine user “would be so plain a perversion of meaning” of a physician’s prescription that it cannot be considered as such).

<sup>298</sup> JACOB S. HACKER & PAUL PIERSON, *AMERICAN AMNESIA: HOW THE WAR ON GOVERNMENT LED US TO FORGET WHAT MADE AMERICA PROSPER* 45 (2016) (quoting Harvard Medical School Professor Lawrence Henderson).

<sup>299</sup> See STARR, *supra* note 144, at 285 (detailing the AMA’s campaign against universal health-care, which linked it to failed socialist policies, scuttling its passage on more than one occasion).

<sup>300</sup> This is evident in the medical industry’s ongoing battle against surprise billing reform in California. See Sarah Kliff & Margot Sanger-Katz, *In California, a ‘Surprise’ Billing Law Is Protecting Patients and Angering Doctors*, N.Y. TIMES (Sept. 26, 2019), <https://www.nytimes.com/2019/09/26/upshot/california-surprise-medical-billing-law-effects.html> [<https://perma.cc/KMZ7-8PJ4>] (describing the battle between patient advocacy groups and physicians and physician staffing firms to control the narrative regarding California’s recent “surprise billing” law limiting out-of-network payments for care in in-network facilities).

calls a Policy Trap.<sup>301</sup> Groups or individuals with privilege seldom put their privilege on the line for principle, if they can avoid it, when the potential downside far outweighs any potential personal upside. For example, Medicare for All sounds great in principle, but if your insurance is employer-based, your support is likely more conceptual than actual. Evidence-based treatment for people with OUD—and especially for the most marginalized—sounds great in theory, but getting physicians to demand it in the face of law enforcement opposition was always a big ask when the benefits for physicians were small.

But the dynamics here have changed, too. Opioids are commonly dispensed, and while their dispensing sometimes does more harm than good, the best evidence suggests that they can be essential for addressing disabling pain in many people.<sup>302</sup> The threat of regulatory sanctions for overprescribing has been exaggerated historically, with law enforcement actions limited generally to brazen or incompetent conduct far beyond the scope of reasonable practice.<sup>303</sup> Today, however, the DEA is casting a much wider net. Diane Hoffmann provides a compelling account of a number of prosecutions of physicians whose prescribing was reasonable if not exemplary, based on assessments from other medical experts.<sup>304</sup> Providers would understandably feel uncomfortable treating pain with opioids in this climate, especially with patients for whom pain co-occurs with OUD.<sup>305</sup> Prescribers are still reluctant

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<sup>301</sup> PAUL STARR, REMEDY AND REACTION: THE PECULIAR AMERICAN STRUGGLE OVER HEALTH CARE REFORM 122-23 (2011) (using the example of healthcare financing to describe the concept of a policy trap in the sense that many older Americans like Medicare enough and many affluent Americans like their employer-based insurance plans enough to not want to support healthcare reform that would probably, but not definitely, improve the status quo).

<sup>302</sup> See Dowell et al., *supra* note 206 (encouraging the balancing of the risks of opioid prescribing with the benefits of their use for treatment of chronic and acute pain).

<sup>303</sup> See generally, e.g., Peggy Eastman, *Fear of Prosecution for Prescribing Opioids Exaggerated, Law Study Concludes: Growing Sophistication by the States Leading to Leniency*, 25 ONCOLOGY TIMES, no. 11, at 62 (2003) (“Physicians overestimate their level of regulatory scrutiny when they use opioids legitimately in aggressive pain management.”); Donald M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 PAIN MED. 737 (2008) (noting that criminal and administrative charges for overprescribing opioids are rare and that pain specialists are no more likely than other providers to face prosecution).

<sup>304</sup> Hoffmann, *supra* note 177, at 239-56.

<sup>305</sup> Many physicians have described practicing defensively and skeptically given the threat of prosecution. See, e.g., Karina M. Berg et al., *Providers’ Experiences Treating Chronic Pain Among Opioid-Dependent Drug Users*, J. GEN. INTERNAL MED. 482, 484 (2009); Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J. L., MED. & ETHICS 21, 21-40 (2003) (noting that some physicians inadequately prescribe opioids due to fear of regulatory scrutiny and potential disciplinary action, which leads to immense suffering for their patients with serious pain).

to prescribe buprenorphine as a maintenance agent, partly because it consistently gets diverted when prescribed.<sup>306</sup>

In the minds of providers faced with such patients, their hands are tied: they could be sued for abandonment if they refuse to treat patients as they believe (and as evidence indicates) is proper or they might be prosecuted for overprescribing or contributing to drug diversion. While this is a false dichotomy, even in this era of intensified law enforcement oversight, the real possibility of either prospect occurring is enough to intrude on the normal functioning of the physician-patient relationship. The DEA has always policed medicine from a law enforcement—rather than patient care—perspective,<sup>307</sup> but physicians have also provided a vacuum by failing to vigorously regulate themselves<sup>308</sup> or to strenuously defend evidence-based interventions. We expect providers to flex more of their political muscle, collateral benefits to drug

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<sup>306</sup> See generally Jennifer J. Carroll, Josiah D. Rich & Traci Green, *The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible*, 12 J. ADDICTION MED. 459 (2018) (finding that the use of diverted buprenorphine remains common among people who use opioids non-medically); Theodore J. Cicero, Matthew S. Ellis & Howard D. Chilcoat, *Understanding the Use of Diverted Buprenorphine*, 193 DRUG & ALCOHOL DEPENDENCE 117 (2018) (conducting a medical study to understand diversion of buprenorphine within an adult population).

<sup>307</sup> See generally Ruth C. Stern & J. Herbie DiFonzo, *The End of the Red Queen's Race: Medical Marijuana in the New Century*, 27 QUINNIPIAC L. REV. 673 (2009) (describing the DEA's intense scrutiny of marijuana, among other narcotics, and the intensity and lack of discerning beginning prior to its inception and continuing to today despite vast medical and scientific evidence to the contrary).

<sup>308</sup> See Corey S. Davis, *Commentary on Pardo (2017) and Moyo Et Al. (2017): Much Still Unknown About Prescription Drug Monitoring Programs*, 112 ADDICTION 1797, 1797-98 (2017); Corey S. Davis & Derek Carr, *Physician Continuing Education to Reduce Opioid Misuse, Abuse, and Overdose: Many Opportunities, Few Requirements*, 163 DRUG & ALCOHOL DEPENDENCE 100, 100-07 (2016) (finding that continuing medical education can help improve medical and provider knowledge to guard against overprescribing of opioids); Corey S. Davis & Derek Carr, *Physician Continuing Education to Reduce Opioid Misuse, Abuse, and Overdose: Many Opportunities, Few Requirements*, 163 DRUG & ALCOHOL DEPENDENCE 100, 100-07 (2016) (finding that continuing medical education can help improve medical and provider knowledge to guard against overprescribing of opioids); Corey S. Davis et al., *Laws Limiting the Prescribing or Dispensing Of Opioids for Acute Pain in the United States: A National Systematic Legal Review*, 194 DRUG & ALCOHOL DEPENDENCE 166, 166-72 (2019) (finding that just over half of all states have enacted laws that restrict the prescribing or dispensing of opioids for acute pain); Nathan Guevremont, Mark Barnes & Claudia E. Haupt, *Physician Autonomy and the Opioid Crisis*, 46 J. L., MED. & ETHICS 203, 203-19 (2018) (discussing the limitations on physician autonomy related to opioids and impacts of opioid-specific regulations the patient-physician relationships).

policy, as pressure on prescribers broadens and deepens.<sup>309</sup> Without this evidence-based precision, the pendulum will continue to swing broadly and harmfully.

## CONCLUSION

In the effort to reduce overdose morbidity and mortality, we must do more to address underlying pain among those most at risk. DOT-P is a reasonable, scientifically supported intervention that will improve the lives of the most marginalized people with OUD: those with co-occurring pain. Considerable evidence suggests that DOT-P will also benefit the communities in which injection drug use occurs in public. Federal law enforcement has challenged other similarly evidence-based interventions recently (e.g., SCFs) and in the past (e.g., syringe exchanges). However, DOT-P falls clearly within the bounds of professional practice. Clinicians in the United States retain broad authority to use opioids in the treatment of pain, including when that pain co-occurs with OUD. A plain reading of the CSA supports practitioners' leeway in this area, as do congressional intent and constitutional principles. While DOT-P is an incremental innovation in the United States, this country's history with narcotics use and states' willingness to push federal boundaries indicate that DOT-P's implementation is inevitable, and help may soon be on the way for thousands of people in need of evidence-based treatment.

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<sup>309</sup> But let us be plain: problems with opioids also reflect deeper problems in healthcare delivery. A healthcare system that privileges volume of services will always produce incidental harm (think: overprescribing) and fail to adequately support people with the greatest unmet needs, especially when those needs cannot be addressed exclusively by highly reimbursable technological solutions like precision medicine. While we expect physicians to respond to the current moment, health institutions are enormously cumbersome and slow to change. Institutional medicine seems incapable of focusing on the things that work (e.g., investments in the social determinants of health, etc.) rather than the moonshots that pay (e.g., proton therapy, immunotherapy, etc.).