

# A More Sensible Surge: Ending DOJ's Indiscriminate Raids of Healthcare Providers

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# A MORE SENSIBLE SURGE: ENDING DOJ’S INDISCRIMINATE RAIDS OF HEALTH CARE PROVIDERS

MICHAEL BARNES\*

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## INTRODUCTION

Overdose deaths in the United States continue to pose a significant threat, although provisional statistics suggest that overdose deaths may be declining.<sup>1</sup> Most opioid-related deaths involve illicit substances, such as heroin and fentanyl.<sup>2</sup> Conversely, opioid prescribing and overdose deaths related to prescription opioids have both declined significantly in recent years.<sup>3</sup> Nevertheless, the federal government has committed to further restricting the availability of prescription opioid medication.<sup>4</sup>

To that end, the Department of Justice (DOJ) has implemented an aggressive effort to shut down rogue prescribers and pharmacists.<sup>5</sup> As part of this effort, however, the DOJ has raided, searched, and investigated a past president of the American Academy of Pain Medicine (AAPM), the editor-in-chief of the *Practical Pain Management* medical journal, the immediate past president of the American Society of Addiction Medicine (ASAM), and a past president of ASAM's affiliate, the Tennessee Society of Addiction Medicine.<sup>6</sup> None of these influential physicians has been charged with a crime.

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<sup>1</sup> See Aaron Glickman and Janet Weiner, *Why Deaths Continue to Rise in the Opioid Epidemic*, PENN LDI (Jan. 22, 2019), <https://ldi.upenn.edu/healthpolicysense/why-deaths-continue-rise-opioid-epidemic>. *But see* Julia Jacobo, *Drug-overdose Deaths on the Precipice of Declining for First Time in Decades, CDC Says*, ABC NEWS (June 26, 2019), <https://abcnews.go.com/US/drug-overdose-deaths-precipice-declining-time-decades-cdc/story?id=63958453> (predicting that the number of drug-related deaths in 2018 was lower than in 2017, although the statistics have not been released).

<sup>2</sup> *See id.*

<sup>3</sup> CTR. FOR DISEASE CONTROL & PREVENTION, CHANGES IN OPIOID PRESCRIBING PATTERNS (2018), <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

<sup>4</sup> *See generally* SUPPORT Act, Pub. L. No. 115-271 (2018).

<sup>5</sup> *See infra*, Part IIB.

<sup>6</sup> *See infra*, Part IIB.

Indiscriminate raids, searches, and investigations of health care professionals put patients' lives at risk, destroy professionals' livelihoods and careers, and create confusion, fear, and reluctance to prescribe among other health care professionals. This chilling effect undermines congressional efforts to expand the number of professionals who prescribe medications to treat opioid use disorder (OUD).<sup>7</sup>

To ensure that professionals feel confident prescribing or dispensing medication to treat opioid use disorder and other conditions that may require treatment with controlled medications, complaints against licensed health care professionals, including pharmacists, should be investigated first by professional licensing boards, which are governed and staffed by professionals with health-specific expertise, rather than by law enforcement.

Congress and state legislators should, therefore, amend federal and state laws to require law enforcement to obtain a referral from the appropriate state health-profession licensing board before instituting, aiding in, or defending an investigation or criminal or civil action against a prescriber or dispenser of FDA-approved medications in which medical need or patient care, including the prescribing or dispensing of medications, is at issue.

## I. BACKGROUND

### A. THE U.S. OVERDOSE CRISIS PRIMARILY INVOLVES SUBSTANCES OTHER THAN OPIOID PAIN RELIEVERS

Substance abuse is among the most difficult of health and social problems to address.<sup>8</sup> The nearly two-decade upward trend in drug overdose deaths, at 70,237 in 2017,<sup>9</sup> illustrates the need for preventive and responsive measures. Opioid analgesics were involved in most opioid-related overdose deaths from 2002 until 2011.<sup>10</sup> Opioid analgesic prescribing peaked in 2012 but decreased 28 percent by 2017.<sup>11</sup> This decline reflects the fact that some health care providers

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<sup>7</sup> See *infra*, Part IID.

<sup>8</sup> See SUBSTANCE ABUSE AND MENTAL HEALTH ADMIN., SUBSTANCE ABUSE AND MENTAL ILLNESS PREVENTION (2019), <https://www.samhsa.gov/prevention> (stating that substance use and mental disorders can make daily activities difficult and impair a person's ability to work, interact with family and fulfil other major life functions).

<sup>9</sup> See NAT'L INST. ON DRUG ABUSE, OVERDOSE DEATH RATES 1 (FIG. 1) (2019), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

<sup>10</sup> CTR. FOR DISEASE CONTROL & PREVENTION, INCREASES IN DRUG AND OPIOID OVERDOSE DEATHS – UNITED STATES, 2000-2014 (2016), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

<sup>11</sup> CTR. FOR DISEASE CONTROL & PREVENTION, CHANGES IN OPIOID PRESCRIBING PATTERNS (2018), <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

have ceased prescribing opioid analgesics altogether.<sup>12</sup> Other healthcare providers have become more guarded in their opioid prescribing practices.<sup>13</sup>

In the United States, the demand for illicit heroin and fentanyl rose due to restricted access to prescription opioids.<sup>14</sup> Consequently, the greater demand has yielded increases in illicit drug supply, abuse, addiction, and overdoses.<sup>15</sup> Illicit opioids (e.g., analog fentanyl and heroin) are now the most common substances found in drug overdose fatalities.<sup>16</sup> Not all individuals who consume these substances have intended to do so. Analog fentanyl is often mixed with heroin or cocaine or pressed into counterfeit pills without the user's knowledge.<sup>17</sup> The Drug Enforcement Administration (DEA) has issued public warnings that pills being sold on the black market such as oxycodone, for example, are actually counterfeit drugs containing illicit fentanyl.<sup>18</sup> Pharmaceutical fentanyl is 50 times more potent than heroin and 100 times more potent than morphine.<sup>19</sup> An extremely deadly fentanyl analog detected in the U.S., carfentanil, is

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<sup>12</sup> see Richard Lawhern, *Stop Persecuting Doctors for Prescribing Opioids for Chronic Pain*, Stat News (June 28, 2019), <https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/>.

<sup>13</sup> Gery P. Guy, Jr., et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, 66 MMRW 697, 700 (2017)(describing the decreases in opioid prescribing levels due to studies that showed potential for overdose risk).

<sup>14</sup> See RICHARD J. BONNIE, ET AL., PAIN MGMT. AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 217 (2017), <https://www.ncbi.nlm.nih.gov/books/NBK458661/>.

<sup>15</sup> See *id.* at 2.

<sup>16</sup> Holly Hedegaard, *Drugs Most Frequently Involved Drug Overdose Deaths, 2011-2016*, 67 NAT'L VITAL STATISTICS REPORTS 1, 4 (2018) (finding fentanyl accounted for 29% of all overdose deaths in 2016 and heroine accounted for 25% of overdose deaths).

<sup>17</sup> See R. Matthew Gladden et al., *Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths – 27 States, 2013-2014*, 65 MMRW 837, 837-38 (2016).

<sup>18</sup> See Times Staff, *DEA Warns Pills Being Sold on El Paso Streets as Oxycodone Actually Contain Fentanyl*, EL PASO TIMES (Mar. 2, 2019), <https://www.elpasotimes.com/story/news/crime/2019/03/02/pills-sold-el-paso-streets-oxycodone-actually-contain-fentanyl/3039711002/>.

<sup>19</sup> Gladden, *supra* note 17, at 838.

estimated to be 10,000 times more potent than morphine.<sup>20</sup>

The demand for non-opioid substances of abuse has also increased, and stimulant- and benzodiazepine-related overdoses are on the rise.<sup>21</sup> Almost 16 percent of college students say they misuse prescription stimulants, often in the quest for better grades.<sup>22</sup> From 2014 to 2016, the number of overdose deaths involving cocaine nearly doubled from 5,892 to 11,316.<sup>23</sup> The number of overdose deaths involving methamphetamine increased 3.6-fold from 1,887 deaths in 2011 to 6,762 deaths in 2016.<sup>24</sup>

Twenty percent of college students say it is somewhat or very easy to obtain sedatives, which they report using most often for sleep or anxiety relief.<sup>25</sup> An estimated 1.7 million Americans aged 12 or older misuse prescription tranquilizers, including benzodiazepines and muscle relaxants.<sup>26</sup> More than 30 percent of overdoses involving opioids also involve benzodiazepines, and 23 percent of individuals who died of an opioid-related overdose also tested positive for benzodiazepines.<sup>27</sup>

Let us not forget the harms of legal, non-controlled, non-prescription substances of abuse.

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<sup>20</sup> See Julie K. O'Donnell et al., *Trend in Death Involving Heroin and Synthetic Opioids Excluding Methadone, and Law Enforcement Drug Product Reports, by Census Region – United States, 2006-2015*, 66 MMWR 897, 902 (2017).

<sup>21</sup> See Sarah Karlin-Smith and Brianna Ehley, *5 Unintended Consequences of Addressing the Opioid Crisis*, POLITICO (May 8, 2018), <https://www.politico.com/story/2018/05/08/opioid-epidemic-consequences-502619> (finding that deaths involving cocaine increased 52.4% between 2015 and 2016); Marcus A. BachHuber et al., *Increasing Benzodiazepine Prescriptions and Overdose Mortality in the United States*, 106 AM. J. PUBLIC HEALTH 686, 686-87 (2016).

<sup>22</sup> See OHIO STATE UNIVERSITY, COLLEGE PRESCRIPTION DRUG STUDY 2018 RESEARCH BRIEF - STIMULANT USE 1 (2018), <https://cssl.osu.edu/posts/632320bc-704d-4eef-8bcb-87c83019f2e9/documents/cpds-brief-stimulants-final.pdf>.

<sup>23</sup> See Hedegaard, *supra* note 16, at 4.

<sup>24</sup> See Hedegaard, *supra* note 16, at 4.

<sup>25</sup> See OHIO STATE UNIVERSITY, COLLEGE PRESCRIPTION DRUG STUDY KEY FINDINGS 2 (2018), <https://cssl.osu.edu/posts/632320bc-704d-4eef-8bcb-87c83019f2e9/documents/cpds-2018-key-findings-final.pdf>.

<sup>26</sup> See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2017 NATIONAL SURVEY ON DRUG USE AND HEALTH 16 (2018).

<sup>27</sup> See NAT'L INSTITUTE ON DRUG ABUSE, BENZODIAZEPINES AND OPIOIDS (2018), <https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids>.

More than 88,000 Americans die from alcohol-related causes annually.<sup>28</sup> Cigarette smoking contributes to more than 480,000 deaths annually.<sup>29</sup> The FDA has declared the use of e-cigarettes, which contain addictive nicotine, an epidemic among teens with use increasing 78 percent from 2017 to 2018.<sup>30</sup>

### **B. The Federal Government Is Still Focusing Intensely on Reducing Opioid Prescribing**

Policy efforts to address drug abuse, addiction, and overdose in the U.S. remain largely focused on restricting access to opioid analgesics.<sup>31</sup> On top of existing reductions in opioid analgesic prescribing, the federal government is seeking to cut nationwide opioid prescription fills by an additional one-third by 2021.<sup>32</sup>

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), enacted on October 24, 2018, illuminates the federal focus on reducing exposure to opioid analgesics.<sup>33</sup> The provisions of the SUPPORT Act that further restrict access to prescription pain relievers include:

- Granting the U.S. Food and Drug Administration (FDA) authority to require alterations to opioid analgesic packaging (e.g., blister packs);<sup>34</sup>
- Developing guidance for hospitals on how to reduce opioid analgesic use;<sup>35</sup> and
- Granting additional authority to the DEA to change nationwide prescription opioid quotas.<sup>36</sup>

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<sup>28</sup> NAT'L INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, ALCOHOL FACTS AND STATISTICS (2018), <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics>.

<sup>29</sup> CTR. FOR DISEASE CONTROL & PREVENTION, SMOKING AND TOBACCO USE (2018), [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/tobacco\\_related\\_mortality/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm) (including deaths from second hand smoke).

<sup>30</sup> Karen A. Cullen et al., *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011-2018*, 67 MMRW 1276, 1276 (2018).

<sup>31</sup> *See, e.g.*, SUPPORT Act, Pub. L. No. 115-271 (2018).

<sup>32</sup> Press Release, The White House, President Donald J. Trumps Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand (Oct. 24, 2018).

<sup>33</sup> *See generally* SUPPORT Act, Pub. L. No. 115-271 (2018).

<sup>34</sup> *See* SUPPORT Act, Pub. L. No. 115-271, § 3041 (2018).

<sup>35</sup> *See* SUPPORT Act, Pub. L. No. 115-271, § 6092 (2018).

<sup>36</sup> *See* SUPPORT Act, Pub. L. No. 115-271, § 3282 (2018).

The SUPPORT Act supplemented preexisting federal efforts with the same objective. Current high-profile federal initiatives include: the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain in primary care,<sup>37</sup> the Department of Justice (DOJ) Opioid Fraud and Abuse Detection Unit,<sup>38</sup> Prescription Interdiction & Litigation (PIL) Task Force,<sup>39</sup> and the Prescription Opioid Strike Force.<sup>40</sup>

## 1. DOSE AND DURATION LIMITS

The CDC published a guideline for opioid prescribing for chronic pain in primary care settings in 2016.<sup>41</sup> The guideline suggests limits on the dose and duration of opioid prescriptions to prevent patients from developing OUD.<sup>42</sup> At least 33 states have since enacted dosage- or duration-limiting laws for opioid analgesic prescriptions.<sup>43</sup>

## 2. AGGRESSIVE DOJ ENFORCEMENT

In 2017, the DOJ established the Opioid Fraud and Abuse Detection Unit to mine prescribing and dispensing data to identify suspicious patterns and practices, then target and prosecute individuals who contribute to the overdose epidemic.<sup>44</sup> In February 2018, the DOJ

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<sup>37</sup> Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016*, 65 MMRW 1 (2016).

<sup>38</sup> Press Release, Department of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Protection Unit (Aug. 2, 2017) [hereinafter Fraud and Abuse Detection Unit].

<sup>39</sup> See Press Release, Department of Justice, Attorney General Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018) [hereinafter PIL].

<sup>40</sup> Press Release, Department of Justice, Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Task Force to Focus on Illegal Opioid Prescriptions (Oct. 25, 2018) [hereinafter ARPOST].

<sup>41</sup> See generally Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016*, 65 MMRW 1 (2016).

<sup>42</sup> See *id.* at 15.

<sup>43</sup> See *Prescribing Policies: States Confront Opioid Epidemic*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Oct. 31, 2018), <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>.

<sup>44</sup> See Fraud and Abuse Protection Unit, *supra* note 38.



expanded upon the Opioid Fraud and Abuse Detection Unit, bringing together senior DOJ officials under the umbrella of the PIL Task Force “to use all criminal and civil tools at its disposal” to crack down on manufacturers, distributors, pharmacies, pain management clinics, drug testing facilities, and individual health care providers.<sup>45</sup> In October 2018, the DOJ formed the Prescription Opioid Strike Force to prosecute medical professionals and others involved in the illegal prescription and distribution of opioids.<sup>46</sup> The Federal Bureau of Investigation (FBI) and U.S. Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) are part of the Strike Force.<sup>47</sup>

The Department of Justice as well as state and local law enforcement have found success convicting opioid prescribers for unambiguously criminal misconduct, including murder if their patients die of an overdose involving the opioids they prescribed.<sup>48</sup> Dr. Hsiu-Ying “Lisa” Tseng and Dr. Michael Alson Smith are two examples of “dirty docs” who have been convicted.<sup>49</sup>

In 2016, Dr. Tseng, an osteopathic physician licensed in California and referred to as “Dr. Feelgood,” was sentenced to 30 years to life in prison for second-degree murder of three of her patients who had fatal overdoses.<sup>50</sup> She appealed, and in December 2018, California’s Second District Court of Appeals upheld her conviction, finding overwhelming evidence of her knowledge of risk and reckless indifference to her patients’ lives in her prescribing practices.<sup>51</sup> Tseng was reportedly the first U.S. doctor convicted of murder for improperly prescribing controlled medications.<sup>52</sup>

In February 2019, Dr. Smith, a former North Carolina physician, was sentenced to three

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<sup>45</sup> See PIL, *supra* note 39.

<sup>46</sup> See ARPOST, *supra* note 40.

<sup>47</sup> See *id.*

<sup>48</sup> See, e.g., *People v. Tseng*, 241 Cal. Rptr. 3d 194, 208 (Cal. Ct. App. 2018); Press Release, Doctor Convicted of Three Murders in Prescription Drug Overdose Case (Oct. 30, 2015), <https://www.dea.gov/press-releases/2015/10/30/doctor-convicted-three-murders-prescription-drug-overdose-case>.

<sup>49</sup> See, e.g., *id.*

<sup>50</sup> See Felice J. Freyer, *Doctor Charged with Manslaughter in Opioid Overdose Death*, BOS. GLOBE (Dec. 11, 2018), <https://www.bostonglobe.com/metro/2018/12/11/doctor-charged-with-manslaughter-opioid-overdose-death/2h5j03vXdfHBDZqPiQDZVN/story.html>.

<sup>51</sup> See *People v. Tseng*, 241 Cal. Rptr. 3d 194, 208 (Cal. Ct. App. 2018).

<sup>52</sup> Press Release, Doctor Convicted of Three Murders in Prescription Drug Overdose Case (Oct. 30, 2015), <https://www.dea.gov/press-releases/2015/10/30/doctor-convicted-three-murders-prescription-drug-overdose-case>.

years in federal prison after pleading guilty to illegal drug distribution, health care fraud, and aggravated identity theft in connection with the illegal distribution of controlled medications to at least seven patients in exchange for sex acts in 2017.<sup>53</sup> DOJ prosecutors alleged that Smith coerced patients to engage in sexual acts by threatening to stop prescribing controlled medication.<sup>54</sup> Prosecutors further alleged that Smith submitted fraudulent claims to, and was paid by, North Carolina Medicaid and Medicare, for medical services he did not provide during the office visits in which sex acts with patients took place.<sup>55</sup>

The DOJ is aggressively fulfilling its vow to “use every criminal, civil, and regulatory tool possible to target, prosecute and shut down” entities whose conduct it deems unlawful.<sup>56</sup> During a 45-day “surge” in 2018, the DOJ made 28 arrests and took 337 other investigative and administrative actions, including executing searches, conducting inspections, obtaining voluntary surrenders of DEA registrations, and issuing orders to show cause why registration should not be revoked and immediate suspension orders.<sup>57</sup>

On February 8, 2019, the DOJ announced that its PIL Task Force had, for the first time, obtained an *ex parte* temporary restraining order (TRO) from the U.S. District Court for the Middle District of Tennessee to stop two pharmacies, their owner, and three pharmacists from dispensing opioids and other controlled medications.<sup>58</sup> The defendants were not provided notice or an opportunity to appear before the court before it issued the TRO.<sup>59</sup> According to the unsealed complaint, the pharmacies and pharmacists allegedly filled prescriptions for controlled

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<sup>53</sup> Joe Marusak, *NC Doctor Who Traded Drugs for Sex with Patients Receives Prison Sentence*, CHARLOTTE OBSERVER (Feb. 21, 2019), <https://www.charlotteobserver.com/news/local/crime/article226567114.html>.

<sup>54</sup> Press Release, Department of Justice, Former North Carolina Physician Pleads Guilty to Drug Distribution, Health Care Fraud, and Aggravated Identify Theft Charges (June 1, 2018), <https://www.justice.gov/usao-wdnc/pr/former-north-carolina-physician-pleads-guilty-drug-distribution-health-care-fraud-and>.

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

<sup>56</sup> Press Release, Drug Enforcement Administration, DEA Surge and Drug Diversion Investigations Lead to 28 Arrests and 147 Revoked Registrations (April 2, 2018), <https://www.dea.gov/press-releases/2018/04/02/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked>.

<sup>57</sup> *Id.*

<sup>58</sup> T.R.O. at 2, 3, *United States v. Oakley Pharmacy, Inc.*, No. 2:19-cv-00009 (M.D. Tenn. Feb. 7, 2019).

<sup>59</sup> T.R.O. at 1, *United States v. Oakley Pharmacy, Inc.*, No. 2:19-cv-00009 (M.D. Tenn. Feb. 7, 2019) (indicating the temporary restraining order was under seal).

medications outside the ordinary course of professional conduct without having verified that the prescriptions were issued for a legitimate medical need.<sup>60</sup> Specifically, the complaint alleged that the defendants routinely dispensed opioids in high doses, in dangerous combinations with other controlled medications, and to patients who traveled long distances to obtain and fill prescriptions.<sup>61</sup>

### C. FEDERAL RAIDS ARE NOT LIMITED TO PRESCRIBERS AND DISPENSERS OF OPIOID ANALGESICS

DOJ and its federal enforcement partners are also targeting prescribers of FDA approved medications used to treat OUD.<sup>62</sup> Such medications include methadone, naltrexone, and buprenorphine.<sup>63</sup> Presently, only one-third of substance use disorder treatment programs offer medication.<sup>64</sup>

Methadone is an FDA approved controlled opioid.<sup>65</sup> When used to treat OUD it may be dispensed only in federally regulated methadone clinics.<sup>66</sup> Naltrexone is not a controlled medication and has a relatively low potential for diversion and abuse.<sup>67</sup> Naltrexone-assisted treatment cannot begin until an individual has stopped using opioids for seven to 10 days.<sup>68</sup>

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<sup>60</sup> Complaint at 1, *United States v. Oakley Pharmacy, Inc.*, No. 2:19-cv-00009 (M.D. Tenn. Feb. 7, 2019).

<sup>61</sup> *See id.* at 29-30, 33.

<sup>62</sup> *See* Maia Szalavitz, *The Feds Are Raiding the Offices of Doctors Who Prescribe Addiction Medication*, VICE (June 6, 2018), [https://www.vice.com/en\\_us/article/8xevwb/dea-raids-addiction-doctors](https://www.vice.com/en_us/article/8xevwb/dea-raids-addiction-doctors) (describing the FBI raid of Dr. Stuart Gitlow home and office).

<sup>63</sup> SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN, MEDICATION ASSISTED TREATMENT (2019), <https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat>.

<sup>64</sup> Sheila Kaplan, *F.D.A. to Expand Medication-Assisted Therapy for Opioid Addicts*, N.Y. TIMES (Feb. 25, 2018), <https://www.nytimes.com/2018/02/25/science/fda-medication-assisted-therapy.html?module=ArrowsNav&contentCollection=Health&action=keypress&region=FixedLeft&pgtype=article>

<sup>65</sup> SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., METHADONE (2015), <https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>.

<sup>66</sup> *Id.*

<sup>67</sup> SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., CLINICAL USE OF EXTENDED-RELEASE INJECTABLE NALTREXONE IN THE TREATMENT OF OPIOID USE DISORDER: A BRIEF GUIDE 6 (2015).

<sup>68</sup> *Id.* at 12-13.

Naltrexone's effects can yield a sudden reduction in tolerance to opioids.<sup>69</sup> After a patient receives treatment with naltrexone, the use of previously tolerated doses of opioids could lead to overdose.<sup>70</sup>

Buprenorphine is a controlled opioid that effectively fills opiate receptors in the brain, thereby reducing opioid withdrawal symptoms and cravings without increasing opioid sensitivity and the risk of overdose.<sup>71</sup> Buprenorphine is safer than commonly prescribed opioid analgesics because of a phenomenon called the "ceiling effect," which prevents intoxication and respiratory depression among opioid-tolerant individuals and reduces the possibilities for both abuse and overdose.<sup>72</sup> To prevent diversion and abuse of buprenorphine, the Drug Addiction Treatment Act of 2000 (DATA 2000) requires providers who seek authority to prescribe buprenorphine to patients with OUD to obtain a waiver.<sup>73</sup> DATA 2000 also limits the number of patients they may treat at any one time.<sup>74</sup>

Opioid-tolerant individuals have a lower likelihood of overdosing on buprenorphine than other prescription or illicit opioids,<sup>75</sup> and individuals who obtain buprenorphine on the black-market use it primarily to relieve OUD withdrawal symptoms.<sup>76</sup> Relatively few people use

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<sup>69</sup> See AMY GIBSON AND LOUISA DEGENHARDT, NAT'L DRUG & ALCOHOL RESEARCH CENTRE, MORTALITY RELATED TO NALTREXONE IN THE TREATMENT OF OPIOID DEPENDENCE: A COMPARATIVE ANALYSIS, xviii (2005).

<sup>70</sup> NAT'L DRUG AND ALCOHOL RESEARCH CTR., MORTALITY RELATED TO NALTREXONE IN THE TREATMENT OF OPIOID DEPENDENCE: A COMPARATIVE ANALYSIS xii (2005) (finding that the lack of naltrexone exposes a naltrexone-maintained patient to overdose risk).

<sup>71</sup> NAT'L DRUG AND ALCOHOL RESEARCH CTR., MORTALITY RELATED TO NALTREXONE IN THE TREATMENT OF OPIOID DEPENDENCE: A COMPARATIVE ANALYSIS 10 (2005). See also, Sonia Mendoza, et al. *Shifting Blame: Buprenorphine Prescribers, Addiction Treatment, and Prescription Monitoring in Middle-Class America*, 53 TRANSCULT PSYCHIATRY 465 (2016) (linking the FDA's approval of buprenorphine with the increased use of opioids by middle-class America).

<sup>72</sup> See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., CLINICAL GUIDELINES FOR THE USE OF BUPRENORPHINE IN THE TREATMENT OF OPIOID ADDICTION 15 (2004).

<sup>73</sup> *Id.*, at 133.

<sup>74</sup> *Id.*

<sup>75</sup> See Jake Harper, *Black Market for Suboxone Gives Some a Glimpse of Recovery*, KAISER HEALTH NEWS (Oct. 9, 2018), <https://khn.org/news/black-market-for-suboxone-gives-some-a-glimpse-of-recovery/>.

<sup>76</sup> See *id.*

buprenorphine to get high.<sup>77</sup> For these and other reasons, practitioners are calling for the deregulation of buprenorphine for the treatment of OUD.<sup>78</sup> Nevertheless, the DOJ investigates and prosecutes prescribers of buprenorphine for OUD using the same tactics it uses in pursuit of prescribers and dispensers of opioid analgesics.<sup>79</sup>

#### **D. THE DEPARTMENT OF JUSTICE HAS RAIDED SOME OF AMERICA'S MOST REPUTABLE PHYSICIANS**

The professionals whose conduct the DOJ deems unlawful are, in some cases, among the most reputable physicians in the U.S.<sup>80</sup> Some of these professionals have presided over the organizations that draft and publish guidelines and other medical-scientific literature that form the basis of the medical standard of care.<sup>81</sup>

##### **1. DR. LYNN WEBSTER, PAST PRESIDENT OF THE AMERICAN ACADEMY OF PAIN MEDICINE**

In 2010, the DEA raided the Utah clinic of Dr. Lynn Webster,<sup>82</sup> a physician with board certifications in anesthesiology, pain medicine, and addiction medicine.<sup>83</sup> Webster lectures extensively on the subject of preventing opioid abuse and criminal diversion in the treatment of pain and has authored more than 300 scientific abstracts, manuscripts, journal articles, and books.<sup>84</sup> He is a past president of AAPM,<sup>85</sup> which develops clinical practice guidelines for use

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<sup>77</sup> *See id.*

<sup>78</sup> *See id.* (quoting a doctor who believes more regulation will cause addicts to turn to the street).

<sup>79</sup> Press Release, Five Pennsylvania Physicians Charged with Unlawfully Distributing Buprenorphine and Defrauding Medicare and Medicaid (May 3, 2018), <https://www.justice.gov/opa/pr/five-pennsylvania-physicians-charged-unlawfully-distributing-buprenorphine-and-defrauding>

<sup>80</sup> *See* Daphne Chen & Eric Schulzke, *Two Utah Doctors Caught in Spotlight of Opioid Lawsuits*, DESERET NEWS (June 6, 2017), <https://www.deseretnews.com/article/865681412/Two-Utah-doctors-caught-in-spotlight-of-opioid-lawsuits.html>.

<sup>81</sup> *See id.*

<sup>82</sup> Christopher Moraff, *Feds' Pill Crackdown Drives Pain Patients to Heroin*, DAILY BEAST (Apr. 15, 2016), <https://www.thedailybeast.com/feds-pill-crackdown-drives-pain-patients-to-heroin>.

<sup>83</sup> *Who is Dr. Lynn Webster*, DR. LYNN WEBSTER, <http://www.lynnwebstermd.com/about/> (last visited Jul. 17, 2019).

<sup>84</sup> *Id.*

of opioids in the treatment of pain drawing upon clinicians' expertise and literature reviews.<sup>86</sup>

The DOJ spent four years investigating Webster, during which time media attention negatively impacted his practice.<sup>87</sup> Specifically, in a December 2013 CNN report, Dr. Sanjay Gupta referred to Webster repeatedly as "Dr. Death."<sup>88</sup> In June 2014, the DOJ announced that it would not prosecute Webster.<sup>89</sup> "My reputation was tarnished forever," Webster said in 2016.<sup>90</sup>

## 2. DR. FOREST TENNANT, EDITOR-IN-CHIEF OF PRACTICAL PAIN MANAGEMENT

In 2017, DEA agents raided the home and offices of Dr. Forest Tennant after having already investigated the pain physician for two years.<sup>91</sup> For a decade, Tennant served as editor-in-chief of the *Practical Pain Management* medical journal, which provides research insights and information on best practices in pain medicine.<sup>92</sup> Tennant also served as mayor of West Covina, California.<sup>93</sup> In 2017, Tennant's peers honored him with a lifetime achievement award for his contributions to pain medicine.<sup>94</sup>

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<sup>85</sup> *AAPM Council of Past Presidents*, AM. ACAD. PAIN MGMT., <https://painmed.org/about/board/council-of-past-presidents> (last visited Jul. 17, 2019).

<sup>86</sup> *Id.*

<sup>87</sup> *See Moraff*, *supra* note 81.

<sup>88</sup> *Id.*

<sup>89</sup> Lynn Webster, *DEA Ends Investigation of Pain Doctor*, DR. LYNN WEBSTER (Sept. 4, 2014), <http://www.lynnwebstermd.com/dea-ends-investigation-of-pain-doctor/>.

<sup>90</sup> *Moraff*, *supra* note 81.

<sup>91</sup> Pat Anson, *DEA Raids Dr. Forest Tennant's Patient Clinic*, PAIN NEWS NETWORK (Nov. 16, 2017), <https://www.painnewsnetwork.org/stories/2017/11/16/dea-raids-forest-tennants-pain-clinic>.

<sup>92</sup> *About Forest Tennant, MD, DrPH*, PRAC. PAIN MGMT., <https://www.practicalpainmanagement.com/author/2391/tennant> (last visited July 17, 2019); *About Practical Pain Management*, PRAC. PAIN MGMT., <https://www.practicalpainmanagement.com/about> (last visited Jul. 17, 2019).

<sup>93</sup> Brian Day & Stephanie K. Baer, *DEA Targets Former West Covina Mayor in Opioid Investigation*, SAN GABRIEL VALLEY TRIB. (Nov. 16, 2017), <https://www.sgvtribune.com/2017/11/16/dea-targets-former-west-covina-mayor-in-opioid-investigation/>.

<sup>94</sup> Jodi Godfrey, *Forest Tennant, MD, DrPH, Honored for a Lifetime of Achievement in Pain Medicine*, PRAC. PAIN MGMT., <https://www.practicalpainmanagement.com/meeting->

Tennant typically treated individuals with cancer or other complex conditions who otherwise had difficulty obtaining effective treatment.<sup>95</sup> Months after the raid, the DEA reportedly had not found sufficient evidence to charge Tennant with a crime, but he retired nonetheless in 2018 due to the stress the ongoing investigation caused.<sup>96</sup> One patient of Tennant said, “I believe many of Dr. Tennant’s patients will die because they will never find another doctor to treat their painful condition.”<sup>97</sup>

### **3. DR. STUART GITLOW, PAST PRESIDENT OF THE AMERICAN SOCIETY OF ADDICTION MEDICINE**

In March 2018, FBI agents raided the Rhode Island medical office and home of Dr. Stuart Gitlow.<sup>98</sup> Gitlow is a board-certified addiction psychiatrist and the immediate past president of ASAM.<sup>99</sup> ASAM is a medical society representing over 6,000 addiction medicine professionals and is one of only five national associations that Congress has approved to provide the training that physicians must complete to obtain a federal waiver to treat OUD with buprenorphine.<sup>100</sup> ASAM formulated the *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, which recommends standards and identifies best practices for addiction treatment practitioners. As of July 2019, the DOJ’s investigation of Gitlow remained active.<sup>101</sup>

### **4. DR. RALPH T. REACH, PAST PRESIDENT OF THE TENNESSEE SOCIETY OF ADDICTION**

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summary/forest-tennant-md-drph-honored-lifetime-achievement-pain-medicine (last visited Jul. 17, 2019).

<sup>95</sup> Pat Anson, *Dr. Forest Tennant Retiring Due to DEA Scrutiny*, PAIN NEWS NETWORK (Mar. 26, 2018), <https://www.painnewsnetwork.org/stories/2018/3/26/dr-forest-tennant-retiring-due-to-dea-scrutiny>.

<sup>96</sup> T.C. Kelly, *Has the Opioid Crisis Resulted in the Unfair Prosecution of Doctors?*, FREEADVICE (Apr. 19, 2018), <https://www.freeadvice.com/news/Litigation/has-the-opioid-crisis-resulted-in-the-unfair-prosecution-of-doctors.htm>.

<sup>97</sup> Anson, *supra* note 89.

<sup>98</sup> Russ Olivo, *City Doctor’s Home, Office Raided by FBI*, THE CALL (Mar. 19, 2018), [https://www.woonsocketcall.com/news/city-doctor-s-home-office-raided-by-fbi/article\\_1e4270a0-2bb5-11e8-be84-b7f0c2501d63.html](https://www.woonsocketcall.com/news/city-doctor-s-home-office-raided-by-fbi/article_1e4270a0-2bb5-11e8-be84-b7f0c2501d63.html).

<sup>99</sup> *Id.*

<sup>100</sup> 21 U.S.C. § 823 (g)(2)(G)(ii)(IV) (2012).

<sup>101</sup> Barnes phone conversation w/ Dr. Gitlow, Feb. 2019.

## MEDICINE

In May 2018, the DEA raided and searched the home and clinics of Dr. Ralph T. Reach, a past president of the Tennessee Society of Addiction Medicine and a member of ASAM's legislative committee who helped draft Tennessee's OUD treatment law.<sup>102</sup> As of March 2019, despite the fact that Reach had not been convicted of or even charged with a crime, he was unable to find a job practicing medicine. "No one will employ me as long as I am under investigation," he said.

## II. ANALYSIS

### A. INDISCRIMINATE RAIDS ARE DESTRUCTIVE

DOJ raids and searches of professionals' homes and medical clinics interrupt the delivery of health care, put patients' lives at risk, and unjustly destroy careers and livelihoods.<sup>103</sup> They also create confusion and fear among professionals serving or considering serving similar patient populations.<sup>104</sup> A reluctance to practice and prescribe controlled medications when medically necessary is especially troublesome given rising rates of suicide, the availability of increasingly lethal black-market alternatives, and in the case of medications for OUD, the federal objective of increasing, rather than decreasing, their prescribing.<sup>105</sup>

#### 1. INABILITY OF STABLE PATIENTS TO OBTAIN NECESSARY MEDICATIONS

Confused about new state dose and duration limits and fearing criminal and civil liability, some prescribers "report feeling pressure to lower patient doses, even for patients who have been on stable regimens of opioids for years without trouble."<sup>106</sup> According to Dr. Julian Grove, a pain specialist licensed to practice in Arizona, "[a] lot of practitioners are reducing opioid medications, not from a clinical perspective, but more from a legal and regulatory perspective for

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<sup>102</sup> Julie Miller, *Raids Cause Larger Concern for MAT Prescriber*, BEHAV. HEALTHCARE EXECUTIVE (May 31, 2018), <https://www.behavioral.net/article/policy/raids-cause-larger-concern-mat-prescribers>.

<sup>103</sup> See Moraff, *supra* note 81.

<sup>104</sup> See *id.*

<sup>105</sup> See *id.*

<sup>106</sup> Will Stone, *Patients with Chronic Pain Feel Caught in an Opioid-Prescribing Debate*, KAISER HEALTH NEWS (Aug. 1, 2018), <https://www.healthleadersmedia.com/clinical-care/patients-chronic-pain-feel-caught-opioid-prescribing-debate>.



fear of investigation. No practitioner wants to be the highest prescriber.”<sup>107</sup>

The Comprehensive Addiction and Recovery Act of 2016 (CARA) required DHHS, the Department of Veterans Affairs (VA), and the Department of Defense (DOD) to convene the Pain Management Best Practices Inter-Agency Task Force (Task Force) to identify gaps in best practices adopted by federal agencies for pain management.<sup>108</sup> In May 2019, the Task Force published a final report, which stated, “regulatory oversight has also led to fears of prescribing among some clinicians, with some refusing to prescribe opioids even to established patients on a stable opioid regimen.”<sup>109</sup> The report states that tightening the availability of opioid analgesics has “led to unintended consequences, such as patient abandonment and forced tapering.”<sup>110</sup>

On March 6, 2019, more than 300 medical experts, including three former Directors of the Office of National Drug Control Policy, sent a letter to the CDC urging the agency to investigate increases in illicit opioid use and suicide following involuntary opioid taper or discontinuation premised upon the CDC’s recommendation.<sup>111</sup> The experts asked the CDC to issue a bold clarification that the guideline does not endorse mandated involuntary dose reduction or discontinuation.<sup>112</sup> On April 9, 2019, the FDA warned that abrupt opioid discontinuation can cause severe harm, including withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.<sup>113</sup> The following day, the CDC issued a clarification stating that the guideline recommends tapering opioid dosage “**only** when patient harm outweighs

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

<sup>108</sup> *Charter: Pain Management Best Practices Inter-Agency Task Force*, U.S. DEP’T HEALTH & HUMAN SERVS., <https://www.hhs.gov/ash/advisory-committees/pain/charter/index.html> (last visited Jul. 17, 2019).

<sup>109</sup> *Pain Management Best Practices Inter-Agency Task Force, Final Report on Pain Management Best Practices Inter-Agency Task Force Report*, 12, U.S. DEP’T HEALTH & HUMAN SERVS. (May 6, 2019), <https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf> (last visited Jul. 17, 2019).

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

<sup>111</sup> Letter from Health Professionals for Patients in Pain (HP3), to Ctrs. for Disease Control & Prevention (Mar. 6, 2019), <https://healthprofessionalsforpatientsinpain.org/the-letter-1>

<sup>112</sup> *Id.*

<sup>113</sup> *FDA Identifies Harm Reported From Sudden Discontinuation of Opioid Pain Medicines and Requires Label Changes to Guide Prescribers on Gradual, Individualized Tapering*, FOOD & DRUG ADMIN. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes> (last visited Jul. 19, 2019).

patient benefit of opioid therapy.”<sup>114</sup>

## 2. RELEGATION TO RISKY STREET DRUGS

Patients who cannot access medically necessary controlled medications may turn to the black market in attempts to obtain relief from their untreated symptoms.<sup>115</sup> At a time when counterfeit pills can be made to look like regulated pharmaceutical pain relievers,<sup>116</sup> a patient desperate for treatment could unwittingly ingest deadly analog fentanyl. Synthetic opioids, which include fentanyl and its analogs, contributed to nearly 30,000 overdose deaths in 2017, an increase of more than 9,000 over 2016.<sup>117</sup>

## 3. SUICIDE

Nearly 45,000 lives are lost in the U.S. each year to suicide,<sup>118</sup> making it the tenth leading cause of death nationwide.<sup>119</sup> The number of Americans who died by suicide after having medically necessary opioid pain relievers tapered without their consent or denied altogether is

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<sup>114</sup> Letter to Daniel P. Alford, from Robert R. Redfield, Director, Ctr. For Disease Control & Prevention (April 10, 2019) *available at* <https://img1.wsimg.com/blobby/go/3d70257f-a143-4a5b-b9df-f7d265df0d3d/downloads/Alford%20Final%20.pdf?ver=1556148791199>; *see also*, Press Release, *CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain*, Ctrs. for Disease Control & Prevention (Apr. 24, 2019) (updated on June 5, 2019), <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html> (noting that the CDC’s 2019 Guideline “does not support abrupt tapering or sudden discontinuation of opioids.”).

<sup>115</sup> *2017 CDC Survey Results*, PAIN NEWS NETWORK, <https://www.painnewsnetwork.org/2017-cdc-survey/> (last visited Jul. 17, 2019).

<sup>116</sup> Katie Zezima, *Counterfeit Opioid Pills Are Tricking Users – Sometimes with Lethal Results*, WASH. POST (Nov. 19, 2017), [https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users--sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb\\_story.html](https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users--sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb_story.html).

<sup>117</sup> Christopher Ingraham, *Fentanyl Use Drove Drug Overdose Deaths to a Record High in 2017, CDC Estimates*, WASH. POST (Aug. 15, 2018), [https://www.washingtonpost.com/business/2018/08/15/fentanyl-use-drove-drug-overdose-deaths-record-high-cdc-estimates/?utm\\_term=.4707dbf14be0](https://www.washingtonpost.com/business/2018/08/15/fentanyl-use-drove-drug-overdose-deaths-record-high-cdc-estimates/?utm_term=.4707dbf14be0).

<sup>118</sup> *Suicide Rising Across the US*, CTNS. FOR DISEASE CONTROL & PREVENTION: VITAL SIGNS (June 2018), <https://www.cdc.gov/vitalsigns/pdf/vs-0618-suicide-H.pdf>.

<sup>119</sup> Melanie Heron, *Deaths: Leading Causes for 2016*, 67 NAT’L VITAL STATS. REP., at 8 (July 26, 2018), [https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67\\_06.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_06.pdf).

unknown.<sup>120</sup> Researchers from the CDC looked at over 123,000 suicides in 18 states between 2003 and 2014 and discovered that approximately 10 percent of those who died either had chronic pain in their medical records or mentioned it in suicide notes.<sup>121</sup>

## B. ROUGHSHOD RAIDS ARE COUNTERPRODUCTIVE

While the federal government intends to decrease opioid analgesic prescription fills by an additional one-third by 2021,<sup>122</sup> that is not the case with medications to treat OUD.<sup>123</sup> The federal government has prioritized increasing patient access to medication for the treatment of OUD, as well as boosting the number of health care professionals who prescribe medication for OUD.<sup>124</sup>

### 1. CONGRESSIONAL INTENT

CARA expanded the types of providers who may treat individuals with buprenorphine for

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<sup>120</sup> Elizabeth Llorente, *As Doctors Taper or End Opioid Prescriptions, Many Patients Driven to Despair, Suicide*, FOX NEWS (Dec. 10, 2018), <https://www.foxnews.com/health/as-opioids-become-taboo-doctors-taper-down-or-abandon-pain-patients-driving-many-to-suicide>.

<sup>121</sup> See Pat Anson, *One in 10 Suicides Linked to Chronic Pain*, PAIN NEWS NETWORK (Sept. 12, 2018), <https://www.painnewsnetwork.org/stories/2018/9/12/one-in-10-suicides-linked-to-chronic-pain>; Emiko Petrosky et al., *Chronic Pain Among Suicide Decedents, 2003 to 2014: Findings From the National Violent Death Reporting System*, ANNALS OF INTERNAL MED. (Oct. 2, 2018), <http://annals.org/aim/fullarticle/2702061/chronic-pain-among-suicide-decedents-2003-2014-findings-from-national>.

<sup>122</sup> See *Fact Sheets: President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand*, WHITE HOUSE (Oct. 24, 2018), <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand-2/>.

<sup>123</sup> See *Information about Medication-Assisted Treatment (MAT)*, FOOD & DRUG ADMIN. (Feb. 14, 2019), <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>; *FDA in Brief: FDA Finalizes New Policy to Encourage Widespread Innovation and Development of New Buprenorphine Treatments for Opioid Use Disorder*, FOOD & DRUG ADMIN. (Feb. 6, 2018), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-finalizes-new-policy-encourage-widespread-innovation-and-development-new-buprenorphine>.

<sup>124</sup> OFFICE OF NAT'L DRUG CTL. POLICY, EXEC. OFFICE OF THE PRESIDENT, NATIONAL DRUG CONTROL STRATEGY, at 9 (2019), <https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf>.

ODU to include nurse practitioners and physician assistants.<sup>125</sup> The SUPPORT Act of 2018 made two additional changes intended to expand access to buprenorphine for OUD.<sup>126</sup> First, it enabled clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to obtain a waiver to prescribe buprenorphine for OUD.<sup>127</sup> Second, it allowed federally waived practitioners to immediately start treating 100 OUD patients at a time with buprenorphine (skipping the initial 30 patient limit) if the practitioner is board certified in addiction medicine or addiction psychiatry, or if the individual practices in a qualified setting.<sup>128</sup>

## 2. PRACTITIONER CONCERNS

Only 63,071 practitioners in the U.S. have waivers permitting them to prescribe buprenorphine for OUD.<sup>129</sup> Many of those practitioners seldom, if ever, use it.<sup>130</sup> Federal regulations controlling the prescribing of buprenorphine for OUD are considered deterrents to greater use of the medication.<sup>131</sup> More specifically, physicians without a federal waiver to prescribe buprenorphine for OUD report a concern that the DEA will intrude on their practice if they obtain a waiver.<sup>132</sup>

DOJ raids of practitioners who prescribe buprenorphine for OUD exacerbate, rather than alleviate, apprehensions related to federal regulation and scrutiny.<sup>133</sup> As Dr. Margaret Jarvis, a

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<sup>125</sup> *Buprenorphine Patient Limit*, CTR. FOR U.S. POLICY (Feb. 3, 2019), <https://centerforuspolicy.org/buprenorphine-patient-limit/>.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Practitioner and Program Data*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/physician-program-data> (last visited Jul. 17, 2019).

<sup>130</sup> Christine Vestal, *Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs*, PEW CHARITABLE TRUSTS (Jan. 15, 2016), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/15/few-doctors-are-willing-able-to-prescribe-powerful-anti-addiction-drugs>.

<sup>131</sup> Emily Cassel, *This Drug Could Help End Opioid Addiction*, VICE (June 9, 2017), [https://tonic.vice.com/en\\_us/article/43yp3g/this-drug-could-help-end-opioid-addiction](https://tonic.vice.com/en_us/article/43yp3g/this-drug-could-help-end-opioid-addiction).

<sup>132</sup> C. HOLLY A. ANDRILLA ET AL., OVERCOMING BARRIERS TO PRESCRIBING BUPRENORPHINE FOR THE TREATMENT OF OPIOID USE DISORDER: RECOMMENDATIONS FROM RURAL PHYSICIANS, 35 J. RURAL HEALTH 113, 117 (2019).

<sup>133</sup> Szalavitz, *supra* note 62.

psychiatrist and the vice president of ASAM, said after the raids of ASAM physicians Gitlow and Reach, “[i]n terms of having a chilling effect, this is bad.”<sup>134</sup> The chilling effect of DOJ raids of OUD treatment providers undermines the federal government’s express goal of increasing the number of practitioners who prescribe them.<sup>135</sup>

### C. TWO KEY ELEMENTS OF CONTROLLED SUBSTANCE PRESCRIBING CASES ARE MEDICAL IN NATURE

Under the federal Controlled Substances Act (CSA), the DOJ has the authority to investigate and prosecute controlled medication prescribers and dispensers.<sup>136</sup> In cases involving prescribers brought under the CSA, federal courts determine criminal liability based on whether (1) the practitioner knowingly and intentionally furnished a prescription for a controlled medication; (2) the practitioner’s behavior served a “legitimate medical purpose”; and (3) the practitioner acted within “the usual course of medical practice.”<sup>137</sup> Steps two and three of this test require an assessment of the medical condition of the individual who received the prescription and an evaluation of whether the treatment the professional provided to the patient was consistent with the standards of the profession.<sup>138</sup>

## III. POLICY RECOMMENDATION

### A. LICENSING BOARDS ARE WELL EQUIPPED TO EVALUATE MEDICAL NEED AND PATIENT CARE

Broadly speaking, the mission of state health-profession licensing boards is to keep patients safe.<sup>139</sup> These boards are typically composed of licensed practitioner and non-practitioner members.<sup>140</sup> Most health-profession licensing boards have a staff that includes an executive director, investigators, and attorneys, with legal services provided by the state’s

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<sup>134</sup> *Id.*

<sup>135</sup> Moraff, *supra* note 81.

<sup>136</sup> MICHAEL C. BARNES & STACEY L. SKLAVER, ACTIVE VERIFICATION AND VIGILANCE: A METHOD TO AVOID CIVIL AND CRIMINAL LIABILITY WHEN PRESCRIBING CONTROLLED SUBSTANCES, 15 DEPAUL J. HEALTH CARE L. 93, 102 (2013).

<sup>137</sup> *Id.* at 103.

<sup>138</sup> *Id.* at 104.

<sup>139</sup> FED’N ST. MED. BOARDS, <http://www.fsmb.org/> (last visited Jul. 17, 2019).

<sup>140</sup> *Consumer FAQ*, FED’N ST. MED. BOARDS, <https://www.fsmb.org/consumer-faq/> (last visited Jul. 17, 2019).

attorney general office.<sup>141</sup> Complaints or reports regarding health professionals are often anonymous and may be submitted to licensing boards by patients, caregivers, law enforcement, or concerned citizens, such as members of the news media.<sup>142</sup>

When a board receives an allegation regarding a licensed health professional potentially violating the law, regulations, or the medical standard of care, the board's staff reviews the allegations and decides whether to investigate.<sup>143</sup> Licensed practitioners have a right to due process when allegations against them are brought to the licensing board.<sup>144</sup> In instances when the alleged conduct threatens patients with immediate harm, such as sexual misconduct or substance-related impairment, boards may issue an emergency suspension of the practitioner's license until an investigation of the practitioner is completed.<sup>145</sup>

After an investigation, the staff submits its findings to the board for review, possible hearings, and action.<sup>146</sup> The board may impose discipline, including suspension or revocation of the license to practice.<sup>147</sup> Final board orders may include findings of fact, conclusions of law, and final decrees or stipulations.<sup>148</sup>

Health-profession licensing boards' responsibilities include providing guidance to licensees on best practices or specific medical topics.<sup>149</sup> Their members and staff have knowledge of the medical standard of care and best practices, and the vast majority of them have non-practitioner members to represent the interests of the public.<sup>150</sup> Licensing boards' processes provide accused professionals investigative transparency and an opportunity to be heard. For these reasons, licensing boards should be the first to investigate allegations in which medical

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<sup>141</sup> *Id.*

<sup>142</sup> *See Understanding the Enforcement Process*, VA. DEPT'T OF HEALTH PROFS., <https://www.dhp.virginia.gov/media/dhpweb/docs/enforcement/enfBrochure.pdf>.

<sup>143</sup> *See id.*

<sup>144</sup> *U.S. Medical Regulatory Trends and Actions*, FED'N ST. MED. BOARDS, <http://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf> (last visited July 17, 2019).

<sup>145</sup> *Id.*

<sup>146</sup> *See Understanding the Enforcement Process*, *supra* note 140.

<sup>147</sup> *Consumer FAQ*, *supra* note 138.

<sup>148</sup> *U.S. Medical Regulatory Trends and Actions*, *supra* note 142.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

need and patient care are at issue. Given that criminal liability in federal CSA prescribing cases hinges upon whether the prescriber's behavior served a legitimate medical need and whether the practitioner provided patient care consistent within the ordinary course of professional practice, licensing boards should be the first to investigate suspected controlled-medication prescribing misconduct.

**B. CONGRESS SHOULD REQUIRE A STATE MEDICAL LICENSING BOARD DETERMINATION BEFORE FEDERAL AGENTS MAY INVESTIGATE A PRESCRIBER**

Congress should amend federal law to require that federal investigators and prosecutors obtain a referral from a state professional licensing board before instituting, aiding in, or defending a criminal investigation, indictment, or prosecution or civil action against a state-licensed health care professional or pharmacist in which medical need or patient care, including the prescribing or dispensing of controlled medications, is at issue. The licensing board referral should be premised upon a final order of the full board whose factual findings expressly include misconduct that warrants criminal investigation.

**C. STATE LEGISLATURES SHOULD REQUIRE A LICENSING BOARD REFERRAL BEFORE LAW ENFORCEMENT MAY INVESTIGATE A PRESCRIBER**

Similarly, state legislatures should amend their laws to require that state law enforcement, including the attorney general and political subdivision prosecutors, sheriffs' offices, and police departments, obtain a referral from a state professional licensing board before instituting, aiding in, or defending a criminal investigation, indictment, or prosecution or civil action against a state-licensed health care professional or pharmacist in which medical need or patient care, including the prescribing or dispensing of controlled medications, is at issue. The licensing board referral should be premised upon a final order of the full board whose factual findings expressly include misconduct that warrants criminal investigation.

**D. CONGRESS SHOULD AUTHORIZE AND APPROPRIATE FEDERAL FUNDING FOR STATE HEALTH-PROFESSION LICENSING BOARDS**

In recent years, Congress has allocated a significant amount of federal funding in response to the overdose crisis.<sup>151</sup> Overall funding for treatment initiatives increased from \$7.9 billion in fiscal year (FY) 2013 to \$10.6 billion in FY 2017.<sup>152</sup> Prevention efforts were funded at

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<sup>151</sup> LISA N. SACCO & ERIN BAGALMAN, R44987, CONG. RESEARCH SERV., THE OPIOID EPIDEMIC AND FEDERAL EFFORTS TO ADDRESS IT: FREQUENTLY ASKED QUESTIONS (Oct. 18, 2017).

<sup>152</sup> *Economic Aspects of the Opioid Crisis: Hearing Before the U.S. Cong. Joint Econ. Comm.*, 115th Cong. (2017) (statement of Lisa N. Sacco, Analyst, Congressional Research Service).

around \$1.5 billion in FY 2017, up from \$1.27 billion in FY 2013.<sup>153</sup> Law enforcement funding for opioid-related efforts increased from \$8.8 billion in FY 2013 to \$9.3 billion in FY 2017.<sup>154</sup>

To support state professional licensing boards in expeditiously investigating complaints, disciplining or rehabilitating noncompliant health professionals, and referring potentially criminal misconduct to law enforcement, Congress should redirect federal opioid-related funding away from the DOJ to HHS. HHS should then provide grants to states to bolster the budgets of health-profession licensing boards. Directing to state licensing boards \$930 million, just ten percent of FY 2017 funding for law enforcement efforts to reduce opioid abuse, would create a “surge,” radically bolstering state-board resources. This approach would enable state health-profession licensing boards to efficiently investigate and, if necessary, act upon allegations in which medical need and patient care are at issue.

### CONCLUSION

Prescription-opioid-related overdose deaths are on the decline while illicit-opioid-related deaths ravage families and communities. Nonetheless, the federal government continues to focus largely on reducing access to prescription opioid medications. As part of this effort, the DOJ has instituted several initiatives targeting health care providers, including a 45-day “surge” in which the DOJ took action against 365 individuals whose conduct it deemed unlawful.

Not all health care professionals subject to the DOJ’s searches and seizures are “dirty docs.” In fact, some of them are nationally recognized leaders not just in pain management, but also in addiction medicine.<sup>155</sup>

The DOJ’s indiscriminate raids of health care providers can put patients’ lives at risk by leaving them without access to medically necessary treatments, destroy the livelihoods of physicians and other professionals who have not been convicted of or even charged with a crime, and discourage other health care providers from practicing in the same field of medicine.<sup>156</sup> This chilling effect is especially troublesome given that Congress has prioritized increasing the number of health care providers who prescribe buprenorphine to treat OUD.<sup>157</sup>

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<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Szalavitz, *supra* note 62; Mike Stankiewicz, *DOJ Raids Could Be Making Opioid Crisis Worse: Report*, FIERCEHEALTHCARE (May 11, 2018), <https://www.fiercehealthcare.com/hospitals-health-systems/doj-standing-way-trump-s-opioid-task-force>.

<sup>156</sup> Szalavitz, *supra* note 62; Mike Stankiewicz, *supra* note 153.

<sup>157</sup> 42 C.F.R. 8.610.



Licensing boards are made up of licensed practitioners and staffed by individuals with specialized knowledge of the health professions. Their investigative processes are transparent and provide the accused an opportunity to be heard. A referral from a state health-profession licensing board should, therefore, be a prerequisite to law enforcement investigations of health care providers in which medical need and patient care are at issue.