

# Just Say No: The Case Against the Reclassification of Buprenorphine

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## JUST SAY NO: THE CASE AGAINST THE RECLASSIFICATION of BUPRENORPHINE

Ameet Sarpatwari, Ph.D., M.Phil.\*

*“These three concerns—for individual functioning, public safety, and public health—provide the rationale for . . . treatment. They anchor the policy discussion in the recognition that multiple and competing objectives are being pursued. This recognition should help to achieve the appropriate trade-offs that lead to sound and effective public policy.”<sup>1</sup>*

### INTRODUCTION

George C. sits inside the cramped examination room of Dr. Michael Hayes, Director of the Detoxification Center at Maryland General Hospital in West Baltimore.<sup>2</sup> A once promising three-sport high school athlete, he turned to heroin following his mother’s death in 1978.<sup>3</sup> Following over eighteen attempts at treatment, George finally concluded that methadone would be of no help to him.<sup>4</sup> It simply put him in a daze: “I started getting methadone in the disco era and woke up from it when it was hip-hop.”<sup>5</sup> However, in 2001, Dr. Hayes intro-

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<sup>1</sup> COMM. ON FED. REG. OF METHADONE TREATMENT, DIVISION OF BIOBEHAVIORAL SCI. & MENTAL DISORDERS, INST. OF MED., FEDERAL REGULATION OF METHADONE TREATMENT 21 (Richard A. Rettig & Adam Yarmolinsky eds., 1995).

<sup>2</sup> Stephen Janis, *Wonder Drug: Buprenorphine’s Advocates Say it Could Revolutionize Addiction Treatment Here in the Nation’s Heroin Capital and Wonder Why it’s Taking So Long*, BALT. CITY PAPER (Mar. 24, 2004), <http://www2.citypaper.com/story.asp?id=7033>.

<sup>3</sup> *Id.*

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

<sup>5</sup> *Id.* While dizziness and drowsiness are recognized side effects of both methadone and buprenorphine, see Rasmin Benyamin et al., *Opioid Complications and Side Effects*, 11 PAIN PHYSICIAN, S105, S105 (2008), most patients do not experience either symptom once they have reached an appropriate, stable dose. See Brief for Respondents at 37– 38, N.Y. City Transit Authority v. Beazer, 440 U.S. 568 (1979)

duced George to buprenorphine.<sup>6</sup> The sublingually administered partial opioid agonist changed his life.<sup>7</sup> It not only helped him minimize his cravings but also afforded him freedom and stability, which enabled him to create his own home-improvement business.<sup>8</sup> George now visits the Hospital once a month to pick up his prescription, which he notes is “no different than taking [his] anti-depressant medication.”<sup>9</sup>

The Substance Abuse and Mental Health Services Administration (“SAMHSA”) estimates that 359,000 Americans age twelve years or older were, like George, heroin dependent or abusive in 2010, a 67.8% increase from 2002.<sup>10</sup> An additional 1.9 million people were

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(No. 77-1427) (noting that the directors of all the major methadone treatment programs in New York “unanimously affirmed, that after a short adjustment period, persons maintained on methadone exhibit no side effects of consequence and are entirely capable of normal functioning”). The primary focus of this Comment is to evaluate the public health impact that buprenorphine reclassification would have and, thus, on the decreased convenience and increased stigma of buprenorphine treatment, not its comparative side effects.

<sup>6</sup> Janis, *supra* note 2. In the United States, Reckitt Benckiser markets buprenorphine as Subutex or Suboxone (one part naloxone per four parts buprenorphine). Press Release, Reckitt Benckiser, US FDA Marketing Approval for Reckitt Benckiser's Subutex & Suboxone (Oct. 9, 2002), *available at*

<http://www.rb.com/site/RKBR/Templates/MediaInvestorsGeneral2.aspx?pageid=168&cc=GB>. In 2009, the FDA licensed Roxane Laboratories to manufacture generic Subutex. *Drugs*, U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicalApprovalReports/ANDAGenericDrugApprovals/ucm189606.htm> (last visited Dec. 30, 2011).

<sup>7</sup> Janis, *supra* note 2. An agonist is a drug that is able to activate a cellular receptor owing to its resemblance to the natural transmitter or hormone. PETER N. BENNETT ET AL., *CLINICAL PHARMACOLOGY* 76 (10th ed. 2010). A partial agonist, meanwhile, exhibits agonistic and antagonistic properties, resulting in a lower response at full receptor occupancy. *Id.* at 77. “An opioid is any agent that activates opioid receptors,” and therefore includes both naturally (e.g., opium) and synthetically (e.g., heroin) derived products. *What is the Difference Between “Opioids” and “Opiates,”* The Nat’l Alliance of Advocates for Buprenorphine Treatment,

[http://www.naabt.org/faq\\_answers.cfm?ID=3](http://www.naabt.org/faq_answers.cfm?ID=3) (last visited Dec. 30, 2012).

<sup>8</sup> Janis, *supra* note 2.

<sup>9</sup> *Id.*

<sup>10</sup> CTR. BEHAV. HEALTH STAT. & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN., RESULTS FROM THE 2010 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS 72 (2011) [hereinafter CBHSQ-SAMHSA], *available at*

<http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.pdf>. Results.pdf. CBHSQ-SAMHSA defines substance dependence and abuse in accordance with the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (“DSM-IV”). *Id.* at 69. The DSM-IV, in turn, defines these terms as follows:

Substance Dependence: “A maladaptive pattern of substance use, leading to

dependent on or abusive of prescription pain-relievers,<sup>11</sup> predominantly opioids like hydrocodone (e.g., Vicodin) and oxycodone (e.g., Oxycontin), and meperidine (e.g., Demerol).<sup>12</sup> Despite these figures, available pharmacotherapies for opioid-dependent individuals remain largely limited to methadone or buprenorphine.<sup>13</sup> Whereas treatment with the Schedule II controlled substance, methadone, is heavily regulated and restricted to approved programs and hospital-based pharmacies, Congressional enactment of the Drug Addiction Treatment Act of 2000 (“DATA”) enabled office-based physicians to receive certification to prescribe the Schedule III controlled substance, buprenorphine.<sup>14</sup> Proponents of DATA argue that it effectively removed two

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clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same 12-month period: 1. tolerance, as defined by either of the following: a. a need for markedly increased amounts of the substance to achieve intoxication or desired effect[;] b. markedly diminished effect with continued use of the same amount of the substance[;] 2. withdrawal, as manifested by either of the following: a. the characteristic withdrawal syndrome for the substance . . . [;] b. the same of (or a closely related) substance to relieve or avoid withdrawal symptoms[;] 3. the substance is often taken in larger amounts or over a longer period than was intended[;] 4. there is a persistent desire or unsuccessful efforts to cut down or control substance use[;] 5. a great deal of time is spent in activities necessary to obtain the substance . . . , use the substance . . . , or recover from its effects[;] 6. important social, occupational, or recreational activities are given up or reduced because of substance use[;] 7. the substance use is continued despite knowledge of having had a persistent or recurrent physical or psychological problem that was likely to have been caused or exacerbated by the substance . . . .” AM. PSYCHIATRIC ASS’N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 181 (4th ed. 2000).

Substance Abuse: “A. A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following occurring at any time during the same 12-month period: 1. recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home . . . [;] 2. recurrent substance use in situations in which it is physically hazardous . . . [;] 3. recurrent substance-related legal problems . . . [;] 4. continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance . . . [and] B. The symptoms have never met the criteria for Substance Dependence for this class of substance.” *Id.* at 181–82.

<sup>11</sup> CBHSQ-SAMHSA, *supra* note 10, at 72.

<sup>12</sup> See *DrugFacts: Prescription and Over-the-Counter Medications*, NAT’L INST. ON DRUG ABUSE, <http://www.nida.nih.gov/infofacts/painmed.html> (last visited Dec. 30, 2012).

<sup>13</sup> *NIDA InfoFacts: Heroin*, NAT’L INST. ON DRUG ABUSE, <http://www.nida.nih.gov/infofacts/heroin.html> (last visited Dec. 30, 2012).

<sup>14</sup> See Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL’Y 49, 53 (2010).

major obstacles to the treatment of opioid dependence: inconvenience and social stigma.<sup>15</sup> However, the specter of buprenorphine rescheduling has reappeared as a result of recent media focus on diversion,<sup>16</sup> the use of prescription drugs for illicit recreational purposes.

This Comment aims to examine the true extent of buprenorphine diversion and, thus, the public health impact that its reclassification as a Schedule II controlled substance would likely have. Part I details the increasing dependence on and abuse of opioids among vulnerable populations in the United States (“U.S.”).<sup>17</sup> Part II contextualizes this growing public health crisis, tracing the increased criminalization of narcotics by the federal government in the Twentieth Century.<sup>18</sup> Narrowing this scope, Part III elaborates upon the emergence of buprenorphine,<sup>19</sup> its comparative advantage over methadone in the treatment of opioid dependence,<sup>20</sup> and its treatment within the aforementioned regulatory regime.<sup>21</sup> Finally, in Part IV, this Comment concludes by assessing the scope of buprenorphine diversion, using a cost-benefit calculus to demonstrate that the detrimental impact of rescheduling on patients like George and society at large heavily outweighs its potential benefit.<sup>22</sup>

## I. OPIOID DEPENDENCE & ABUSE: AN ESCALATING NATIONAL PROBLEM

Opioid dependence and abuse is both a significant and growing public health concern in the U.S. As highlighted above, SAMHSA estimates that 359,000 Americans age twelve-years or older were heroin dependent or abusive in 2010, a 67.8% increase from 2002.<sup>23</sup> An esti-

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<sup>15</sup> See *id.* at 54.

<sup>16</sup> See Abby Goodnough & Katie Zezima, *When Children’s Scribbles Hide a Prison Drug*, N.Y. TIMES, May 27, 2011, at A1; *infra* Part IV.A.

<sup>17</sup> See *infra* Part I.

<sup>18</sup> See *infra* Part II. In ordinary parlance, the term “narcotics” is synonymous with “drugs,” which includes the active elements of opium poppy and coca (i.e., opium and cocaine, respectively) and their derivatives. TROY DUSTER, THE LEGISLATION OF MORALITY: LAW, DRUGS, AND MORAL JUDGMENT 30–31 (1970).

<sup>19</sup> See *infra* Part III.A.

<sup>20</sup> See *infra* Part III.B.

<sup>21</sup> See *infra* Part III.C.

<sup>22</sup> See *infra* Part IV.

<sup>23</sup> CBHSQ-SAMHSA, *supra* note 10, at 72. CBHSQ-SAMHSA admittedly does not specify whether this increase in heroin-dependent or abusive Americans is statistically significant (i.e., whether one can state with a predefined level of certainty that the difference in the proportion of heroin-dependent or abusive individuals between 2010 and 2002 is real and not due to chance). See *id.* Regardless, a growing

mated 417,000 members of this cohort, moreover, received treatment for heroin use during this time.<sup>24</sup> Although the proportion of first-time users did not significantly differ between 2009 and 2010, the mean age at first-use significantly declined (i.e., 25.5 vs. 21.3 years, respectively),<sup>25</sup> creating a longer window of opportunity for the development of addiction and, consequentially, infections associated with intravenous drug use such as human immunodeficiency virus (“HIV”), hepatitis C (“HCV”), and endocarditis.

The burden of heroin abuse and dependence, moreover, has been disproportionately borne by vulnerable segments of society. In a cross-sectional investigation utilizing data from the Self-Help in Eliminating Life-threatening Diseases (“SHIELD”) Study and the U.S. Census, Williams and Latkin uncovered a significant positive association (Odds Ratio [OR] [95% Confidence Interval (CI)] = 1.59 [1.06–2.15]) between neighborhood poverty and heroin, crack, or cocaine use in Baltimore, Maryland.<sup>26</sup> They further observed that social support and ties to employed persons were independently protective of such use (ORs [95% CIs] = 0.80 [0.69–0.92] and 0.47 [0.24–0.92], respectively),<sup>27</sup> underscoring the strong socioeconomic dimension to the problem.<sup>28</sup> Indeed, the vicious cycle of social isolation associated with heroin use has been hypothesized to explain, at least in part, the find-

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problem may be defined in both absolute (e.g., numbers) and relative (e.g., proportions) terms. Indeed, absolute measures are on occasion more important for public health practitioners, who are often charged with allocating scarce resources for the greatest good. *See generally* Tanja A.J. Howeling et al., *Using Relative and Absolute Measures for Monitoring Health Inequalities: Experiences from Cross-National Analyses on Maternal and Child Health*, 6 INT’L J. EQUITY HEALTH 15 (2007).

<sup>24</sup> CBHSQ-SAMHSA, *supra* note 10, at 78.

<sup>25</sup> *Id.* at 52.

<sup>26</sup> Chyvette T. Williams & Carl A. Latkin, *Neighborhood Socioeconomic Status, Personal Network Attributes and Use of Heroin and Cocaine*, 32 AM. J. PREVENTIVE MED. S203, S203 (2007). “If the underlying statistical model is correct and there is no bias, a confidence interval derived from a valid analysis will, over unlimited repetitions of the study, contain the true parameter with a frequency no less than its confidence level (often 95% is the stated level, but other levels are also used).” A DICTIONARY OF EPIDEMIOLOGY 49 (Miquel Porta ed., Oxford University Press 5th ed. 2008) [hereinafter DICTIONARY OF EPIDEMIOLOGY].

<sup>27</sup> Williams, *supra* note 26, at S203.

<sup>28</sup> Opioid dependence and abuse among pregnant women raises a unique and complex collection of issues, including sexism, racism, and the best interests of both the fetus and existing sibling(s). For an excellent and comprehensive overview of these topics, *see* Ellen M. Weber, *Child Welfare Interventions for Drug-Dependent Pregnant Women: Limitations of a Non-Public Health Response*, 75 U.M.K.C. L. REV. 790 (2007).

ing that heroin users are nearly fourteen times more likely to commit suicide than their peers.<sup>29</sup>

Equally powerful has been the role of race. Evidence suggests that the rates of illicit drug use among African Americans and whites are comparable.<sup>30</sup> However, Cooper et al. reported that the former cohort was 1.4 to 3.7 times more likely than the latter to engage in injection drug use in urban areas.<sup>31</sup> While this discrepancy may be explained in part by socioeconomic differences, there exist gross and unconscionable racial disparities in the rates of arrest and imprisonment for drug offenses.<sup>32</sup> In a 2008 study, Human Rights Watch reported that African Americans constituted 53.5% of all persons imprisoned for drug offenses in 2003 despite comprising only 12.8% of the total population.<sup>33</sup> Notably, African American males were roughly twelve times more likely to face jail time for such offenses than their white counterparts.<sup>34</sup> As Professor Michael Tonry notes,

Urban black Americans have borne the brunt of the War on Drugs. They have been arrested, prosecuted, convicted, and imprisoned at increasing rates since the early 1980s, and grossly out of proportion to their numbers in the general population or among drug users. By every standard, the war has been harder on blacks than on whites; that this was predictable makes it no less regrettable.<sup>35</sup>

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<sup>29</sup> Shane Darke & Jonathan Ross, *Suicide Among Heroin Users: Rates, Risk Factors, and Methods*, 97 ADDICTION 1383, 1385 (2002).

<sup>30</sup> See CBHSQ-SAMHSA, *supra* note 10, at 21.

<sup>31</sup> Hannah Cooper et al., *Racial/Ethnic Disparities in Injection Drug Use in Large US Metropolitan Areas*, 15 ANNALS EPIDEMIOLOGY 326, 331 (2005).

<sup>32</sup> See RYAN S. KING, THE SENT'G PROJECT, DISPARITY BY GEOGRAPHY: THE WAR ON DRUGS IN AMERICA'S CITIES (2008), available at [http://sentencingproject.org/doc/publications/dp\\_drugarrestreport.pdf](http://sentencingproject.org/doc/publications/dp_drugarrestreport.pdf); but see Erik Eckholm, *Reports Find Racial Gaps in Drug Arrests*, N.Y. TIMES (May 6, 2008), <http://www.nytimes.com/2008/05/06/us/06disparities.html> (noting one expert who "said it made sense for police to focus more on fighting visible drug dealing in low-income urban areas, largely involving members of minorities, than on hidden use in suburban homes, more often by whites, because the urban street trade is more associated with violence and other crimes and impairs the quality of life").

<sup>33</sup> See HUMAN RIGHTS WATCH, TARGETING BLACKS 4 (2008), available at <http://www.hrw.org/en/node/62236/section/8>.

<sup>34</sup> *Id.*

<sup>35</sup> MICHAEL H. TONRY, MALIGN NEGLECT—RACE, CRIME, AND PUNISHMENT IN AMERICA 105 (1995).

In recent years, the opioid epidemic has been fuelled by an increased misuse of prescription pain-relievers. SAMHSA estimates that 1.9 million Americans twelve years or older were prescription pain-reliever dependent or abusive in 2010;<sup>36</sup> 745,000 people, moreover, received treatment for prescription pain-reliever use during this time.<sup>37</sup> Troublingly, the popularity of these drugs among adolescents and young adults appears high.<sup>38</sup> The Monitoring the Future Project reported the annual prevalence of Vicodin and Oxycontin use to be 8.0% and 5.1% among twelfth-graders, respectively.<sup>39</sup> Only marijuana was misused more frequently.<sup>40</sup> In evaluating trends in the use of prescription pain-relievers since 1975, the group concluded, “While the rise in use appears to have halted, most rates remain reasonably near to recent peak levels . . . . [C]learly use of most . . . narcotics other than heroin . . . has become a larger part of the nation’s drug abuse problems.”<sup>41</sup>

The aggregate cost of such dependence and abuse is staggering. Mark et al. calculated that heroin addiction resulted in \$21.9 billion in lost productivity and associated criminal, medical, and social welfare costs in 1996 alone.<sup>42</sup> Birnbaum et al., meanwhile, conservatively estimated that prescription pain-reliever misuse costs totalled \$8.6 billion in 2006.<sup>43</sup> While opioid dependence and abuse has, thus, imparted an unequivocally heavy financial toll, the unquantifiable pain and suffering it has inflicted on addicts and their friends and family may constitute its greatest cost of all. Marie-Louise Kenny, who lost two of her brothers to overdoses within the span of three weeks, powerfully captured this sentiment, observing that “[h]eroin destroys lives. Not only

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<sup>36</sup> CBHSQ-SAMHSA, *supra* note 10, at 72.

<sup>37</sup> *Id.* at 78.

<sup>38</sup> See Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 *DRUG & ALCOHOL DEPENDENCE* 103, 104 (2006) (noting that “opioid analgesic abuse is mostly concentrated in adolescents and young adults”).

<sup>39</sup> LLOYD D. JOHNSTON ET AL.; *MONITORING THE FUTURE; NATIONAL SURVEY RESULTS ON DRUG USE, 1975–2010—VOLUME I: SECONDARY SCHOOL STUDENTS 2010 22* (2011).

<sup>40</sup> Compton & Volkow, *supra* note 38, at 103.

<sup>41</sup> JOHNSTON ET AL., *supra* note 39, at 23.

<sup>42</sup> Tami L. Mark et al., *The Economic Costs of Heroin Addiction in the United States*, 61 *DRUG & ALCOHOL DEPENDENCE* 195, 203 (2001).

<sup>43</sup> Howard G. Birnbaum et al., *Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001: A Societal Perspective*, 22 *CLINICAL J. PAIN* 667, 671 (2006).

the lives of the people who take it, but the future of those who are left behind.”<sup>44</sup>

## II. NARCOTIC REGULATION IN THE UNITED STATES: A CRIMINALIZED DRUG POLICY

### A. *The Harrison Act, Doremus & Webb: Opening the Door to Federal Intervention*

Over the course of the Twentieth Century, however, the federal government adopted and strengthened a drug policy that emphasized prohibition and criminalization over public health.<sup>45</sup> Congress laid its foundation with passage of the Harrison Narcotics Act of 1914 (“Harrison Act”), which “required manufacturers and sellers of narcotics to register with the federal government and to pay a tax on each transaction.”<sup>46</sup> Despite explicitly permitting physicians, dentists, and veterinarians to continue prescribing such drugs in the course of their professional practice,<sup>47</sup> the Harrison Act was quickly interpreted as a prohibitionist tool by its enumerated enforcers, the Department of the Treasury, which “[staked] out the position that the administration of drugs by a physician to an addict in order to prevent the suffering of physical withdrawal was not the good-faith practice of medicine.”<sup>48</sup> Professor Troy Duster highlights the sudden and seemingly drastic nature of this policy shift, remarking that only years earlier “anyone could go to his corner druggist and buy grams of morphine or heroin for just a few pennies.”<sup>49</sup> Scholars theorize that a host of influences likely contributed to this newfound approach to narcotics regulation, including, but not limited to, the Progressive Movement, geopolitical concerns, and xenophobia.<sup>50</sup>

The Supreme Court wasted little time wading into the debate, deciding the companion cases *United States v. Doremus* and *Webb v.*

<sup>44</sup> MARY KENNY, *DEATH BY HEROIN: RECOVERY BY HOPE* 22 (2000).

<sup>45</sup> For an illuminating and rigorous discussion of the divergence of U.S. drug policy from that of the United Kingdom in the 20th Century, 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 (2011).

<sup>46</sup> *Id.* at 274.

<sup>47</sup> Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785, 786, *repealed by* 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 (2006)).

<sup>48</sup> Boldt, *supra* note 45, at 279–80.

<sup>49</sup> DUSTER, *supra* note 18, at 3.

<sup>50</sup> See Boldt, *supra* note 45, at 269–77.

*United States* in 1919.<sup>51</sup> In *Doremus*, the federal government brought charges against a registered physician for issuing heroin to a patient in maintenance of his addiction.<sup>52</sup> The Court held that the Harrison Act constituted a valid exercise of Congressional Power under Article I, Section 8 (i.e., the Taxing and Spending Clause) of the Constitution and, in so doing, gave at least tacit approval to the prohibitory prerogative of the Department of the Treasury: “The act may not be declared unconstitutional because its effect may be to accomplish another purpose as well as the raising of revenue.”<sup>53</sup> The Court was more explicit in *Webb*, in which the defendant-appellant regularly sold morphine to habitual users.<sup>54</sup> The United States Court of Appeals for the Sixth Circuit had posed for the Justices the following question:

If a practicing and registered physician issues an order for morphine to an habitual user thereof, the order not being issued by him in the course of professional treatment in the attempted cure of the habit, but being issued for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use, is such order a physician's prescription under exception (b) of [Section] 2 [of the Act]?<sup>55</sup>

Speaking for the Court, Justice Day responded firmly in the negative, holding that “to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required.”<sup>56</sup> As Professor Ellen Weber notes, these companion rulings effectively precluded the ambulatory treatment of opioid addiction for the remainder of the Century.<sup>57</sup>

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<sup>51</sup> See 249 U.S. 86 (1919); 249 U.S. 96 (1919).

<sup>52</sup> *Doremus*, 249 U.S. at 90.

<sup>53</sup> *Id.* at 94.

<sup>54</sup> *Webb*, 249 U.S. at 97–98.

<sup>55</sup> *Id.* at 99.

<sup>56</sup> *Id.* at 99–100.

<sup>57</sup> Weber, *supra* note 14, at 60 n.70 (citing DAVID F. MUSTO, THE AMERICAN DISEASE 119–20 (3d. ed. 1999)); *but see* *United States v. Jin Fuey Moy*, 241 U.S. 394, 402 (1916) (holding that the Harrison Act did not bar a physician from issuing morphine to a patient addicted to opium only three years earlier).

*B. The War on Drugs: A Further Rejection of Medicalization*

The federal movement rejecting the medicalization of opioid dependence and abuse gained intensity over the following decades.<sup>58</sup> In 1930, the Department of the Treasury consolidated the functions of the Federal Narcotics Control Board and the Narcotic Division under the newly created Federal Bureau of Narcotics (“FBN”), selecting Harry J. Anslinger as its first commissioner.<sup>59</sup> Over his thirty-two-year reign, Anslinger championed a highly criminalized U.S. drug policy, effectively lobbying Congress to create federal “narcotics farms,” criminalize the sale of cannabis, and enact harsh mandatory minimum prison sentences for drug offenses.<sup>60</sup> The American Medical Association (“AMA”) and American Bar Association (“ABA”) lamented the resulting dearth of resources for the study of opioid dependence and abuse amidst this regulatory climate, noting in a joint 1961 report:

The narcotic drug addict because of his physical and psychological dependence on drugs and because of his frequently abnormal personality patterns should be as much a subject of concern to medicine and public health as to those having to do with law enforcement. But the ordinary doctor is not presently well equipped to deal with the problems of the narcotic addict, and even his authority to do so is in doubt.

The role of medicine and public health in dealing with drug addiction and the drug addict should be clarified. There must be a new determination of the limits of good medical practice in the treatment of drug addiction, and an objective inquiry into the question whether existing enforcement policies, practices and attitudes, as well as existing laws, have unduly or improperly interfered with good medical practice in this area. As part of this evaluation, con-

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<sup>58</sup> Boldt, *supra* note 45, at 285.

<sup>59</sup> LESLEY STONE & SUSAN C. KIM, *Domestic Public Health Law, in PRINCIPLES OF ADDICTIONS AND THE LAW: APPLICATIONS IN FORENSIC, MENTAL HEALTH, AND MEDICAL PRACTICE* 97, 99 (2010).

<sup>60</sup> *Id.* at 99–101.

sideration should also be given to the possibility of helping both the addict and persons formerly addicted through open clinic facilities as well as in closed institutions such as Lexington and Fort Worth.<sup>61</sup>

Instead of heeding these recommendations, however, the federal government heightened its assault, culminating in President Richard Nixon's infamous declaration of "War on Drugs" and passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("CDAPCA").<sup>62</sup> CDAPCA replaced the Harrison Act and classified narcotics into five schedules (i.e., Schedules I–V) according to their abuse and treatment potentials and their psychological and physiological effects.<sup>63</sup> Whereas Schedule I controlled substances are a) easily abused, b) not generally accepted for treatment, and c) widely perceived as unsafe;<sup>64</sup> Schedule V controlled substances a) have a low potential for abuse, b) are commonly used in treatment, and c) demonstrate a minimal risk of dependence.<sup>65</sup> Narcotics classed within higher schedules are subject to increased restrictions; therefore, while phenobarbital, a Schedule IV controlled substance, may be prescribed to and refilled by patients up to five times within a six-month period,<sup>66</sup> no prescriptions are permitted for the Schedule I narcotic, heroin.<sup>67</sup> Notably, authority for the classification of drugs under the CDAPCA rests with the Drug Enforcement Agency ("DEA"), acting under the auspices of the Department of Justice ("DOJ") and not the Department of Health and Human Services ("HHS").<sup>68</sup> Although Congress has subse-

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<sup>61</sup> C. JOSEPH STETLER ET AL., JOINT COMM. OF THE AM. BAR ASS'N & THE AM. MED. ASS'N, DRUG ADDICTION, CRIME OR DISEASE? FINAL REPORT OF THE JOINT COMMITTEE OF THE AMERICAN BAR ASSOCIATION AND THE AMERICAN MEDICAL ASSOCIATION ON NARCOTIC DRUGS 3 (1961) (internal numbering omitted), *available at* [http://druglibrary.net/schaffer/Library/studies/dacd/final\\_report.htm](http://druglibrary.net/schaffer/Library/studies/dacd/final_report.htm).

<sup>62</sup> Boldt, *supra* note 45, at 286.

<sup>63</sup> The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91–513, 84 Stat. 1236, 1247–52.

<sup>64</sup> 21 U.S.C. §§ 812(b)(1)(A–C) (2006).

<sup>65</sup> *Id.* §§ 812(b)(5)(A–C).

<sup>66</sup> *See id.* § 829(b)(2)(E).

<sup>67</sup> *See id.* § 829.

<sup>68</sup> *See* 21 C.F.R. § 1308.42 (2012); 21 U.S.C. § 811(a). In making a determination, the DEA must evaluate eight factors: the a) history of and b) potential for abusing the narcotic; c) the severity of this abuse; the narcotic's d) pharmacological effects, e) risk of dependence, and f) threat to public health; g) the regulatory status of its successor substance; and g) the depth of the existing evidence base. 21 U.S.C. §§ 811(c)(1–8).

quently modified CDAPCA,<sup>69</sup> its substance remains largely intact today.<sup>70</sup>

### III. BUPRENORPHINE

#### *A. Emergence of a Novel Treatment*

Near the peak of this war, a promising new drug arrived on the scene.<sup>71</sup> In 1981, the FDA granted the pharmaceutical company Reckitt Coleman, now Reckitt Benckiser, approval to market the partial opioid agonist, buprenorphine, as a hospital-based analgesic.<sup>72</sup> By this time, researchers had already documented its potential as a possible alternative to methadone; Drs. Nancy Mello and Jack Mendelson, for example, reported a statistically significant ( $p < 0.001$ ), dose-dependent reduction in heroin use in a ten day randomized controlled trial (“RCT”) among ten heroin-dependent men.<sup>73</sup> Nevertheless, it was not until 2002 that the FDA officially indicated buprenorphine for the treatment of opioid dependence.<sup>74</sup>

In October that year, Reckitt Benckiser received licensing approval for two distinct high-dose buprenorphine formulations: Subutex and Suboxone.<sup>75</sup> While Subutex consists of the single active ingredient, burprenorphine, Suboxone contains both buprenorphine and na-

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<sup>69</sup> See, e.g., Psychotropic Substances Act of 1978, Pub. L. No. 95–633, 92 Stat. 3768; Controlled Substances Penalties Amendment Acts of 1984, Pub. L. No. 98–473, 98 Stat. 2068; The Chemical Diversion and Trafficking Act of 1988, Pub. L. No. 100–690, 102 Stat. 4312.

<sup>70</sup> Compare The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91–513, 84 Stat. 1236, 1242–84, with 21 U.S.C. §§ 801–971.

<sup>71</sup> Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. 62,354, 62,354 (Oct. 7, 2002).

<sup>72</sup> *Id.*

<sup>73</sup> Nancy K. Mello & Jack H. Mendelson, *Buprenorphine Suppresses Heroin Use by Heroin Addicts*, 207 SCIENCE 657, 658 (1980). Drs. Mello and Mendelson reported a 45% and 69%–98% decrease in heroin use at buprenorphine doses of four and eight milligrams a day, respectively. *Id.* An RCT is defined as “[a]n epidemiological experiment in which subjects in a population are randomly allocated into groups . . . to receive an experimental preventive or therapeutic . . . intervention.” DICTIONARY OF EPIDEMIOLOGY, *supra* note 26, at 206. Owing to their minimization of bias, “RCTs are generally regarded as the most scientifically rigorous method of hypothesis testing available in epidemiology and medicine.” *Id.*

<sup>74</sup> Press Release, Reckitt Benckiser, *supra* note 6.

<sup>75</sup> *Id.*

loxone, an opioid antagonist, in a four-to-one ratio, respectively.<sup>76</sup> *In vivo* studies revealed higher bioavailability of buprenorphine upon sublingual administration.<sup>77</sup> However, naloxone proved considerably more potent if injected, blocking “the euphoric/analgesic effects of buprenorphine in opioid-dependent individuals.”<sup>78</sup> These findings led many health professionals to speculate that Suboxone would serve as an effective diversion control product.<sup>79</sup>

### *B. Comparative Advantage in the Treatment of Opioid Dependence*

Both formulations are arguably more attractive than methadone in the treatment of opioid dependence. First, buprenorphine exhibits comparable efficacy to methadone; in a head-to-head RCT of these drugs, Johnson et al. documented a similar percentage of participants with twelve or more consecutive opioid-negative urine analyses (26% vs. 28%, respectively) as well as analogous levels of self-reported intra-study opioid use (four times per week for both cohorts) and post-study opioid dependence (thirty-four vs. thirty-eight points, respectively, on a one-hundred point scale of increasing severity).<sup>80</sup> Likewise, in a meta-analysis of five RCTs, Drs. Linda Gowing, Robert Ali, and Jason White uncovered a non-statistically significant relative risk (“RR”) of the completion of withdrawal among patients on both pharmacotherapies (RR [95% CI] = 1.18 [0.93-1.49]).<sup>81</sup>

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<sup>76</sup> Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. 62,354, 62,354 (Oct. 7, 2002).

<sup>77</sup> Michael A. Yokell et al., *Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review*, 4 CURRENT DRUG ABUSE REV. 28, 30 (2011).

<sup>78</sup> *Id.*

<sup>79</sup> See Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. at 62,355 (summarizing comments submitted by both the American Society of Addiction Medicine [“ASAM”] and the California Society of Addiction Medicine [“CSAM”], which posited a low risk of Suboxone diversion).

<sup>80</sup> Rolley E. Johnson et al., *A Comparison of Levomethadyl Acetate, Buprenorphine, and Methadone for Opioid Dependence*, 343 NEW ENG. J. MED. 1290, 1295 (2000).

<sup>81</sup> Linda Gowing, Robert Ali & Jason M. White, *Buprenorphine for the Management of Opioid Withdrawal*, 1 COCHRANE DATABASE SYSTEMATIC REV., 2009, at 1, 13. A meta-analysis is “[a] statistical analysis of results from separate studies, examining sources of difference in results among studies, and leading to a quantitative summary of the results if the results are judged sufficiently similar to support such synthesis.” DICTIONARY OF EPIDEMIOLOGY, *supra* note 26, at 154. See also Richard P. Mattick et al., *Buprenorphine Versus Methadone Maintenance Therapy: A Ran-*

Second, buprenorphine poses a smaller risk of adverse events. As a partial opioid agonist, it exhibits a ceiling effect or plateau of its agonistic effects (e.g., euphoria, sedation, and respiratory distress), even at high doses.<sup>82</sup> Yokell et al. illustratively note that “[i]n experimental settings, doses up to 70 times the recommended analgesic dose were well tolerated in non-dependent males who had previous experience with opioids.”<sup>83</sup> The potential for abuse and overdose, though present, is, thus, smaller in comparison with pure agonists such as methadone.<sup>84</sup>

Finally, from a patient perspective, buprenorphine carries less social stigma and is significantly more accessible than methadone. As part of a recent, albeit inconsistent and fractured, movement to steer federal drug policy toward a more medicalized model,<sup>85</sup> Congress passed DATA, which enabled physicians to obtain certification to prescribe Schedule III, IV, and V narcotics for the treatment of opioid dependence.<sup>86</sup> Its impact, Professor Weber argues, has been revolutionary:

Significantly more patients can be treated for opioid dependence through the prescription of buprenorphine in an office-based practice than in federally regulated opioid treatment programs that prescribe and dispense methadone. The patients who seek office-based care tend to be younger, have fewer years of opiate dependence, and have lower rates of intravenous drug use . . . than persons who receive treatment in methadone programs. [They] . . . avoid both the stigma associated with obtaining care in a spe-

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*domized Double-Blind Trial with 405 Opioid-Dependent Patients*, 98 ADDICTION 441, 446–47 (2003) (failing to uncover a statistically significant differences in the intra-study percentages of morphine-free urine samples and levels of self-reported heroin use between opioid-dependent patients administered buprenorphine and methadone).

<sup>82</sup> Yokell et al., *supra* note 77, at 29.

<sup>83</sup> *Id.* (citing Sharon L. Walsh et al., *Clinical Pharmacology of Buprenorphine: Ceiling Effects at High Doses*, 55 CLINICAL PHARMACOLOGY & THERAPEUTICS 569, 577 [1994]) (emphasis added).

<sup>84</sup> *Id.* at 31.

<sup>85</sup> See Boldt, *supra* note 45, at 345 (arguing that recent federal drug policy has been a “mixed picture”).

<sup>86</sup> Children's Health Act of 2000, Pub. L. No. 106-310, § 3502, 114 Stat. 1101, 1222–27 (2000) (codified at 21 U.S.C. § 823(g) (2006 & West Supp. 2009)).

cialty methadone clinic, and the strict daily attendance regimen imposed on patients . . . . Finally, the co-location of addiction treatment in a primary care practice facilitates the treatment of co-occurring health conditions.<sup>87</sup>

### C. Regulatory History: From Schedule V to III

Despite these comparative advantages, the anticipated increase in diversion that would result from the expansion in indication prompted the DEA to re-categorize buprenorphine from Schedule V to Schedule III just two days prior to the release of Subutex and Suboxone into the market.<sup>88</sup> The move was ostensibly premised on “numerous scientific studies” and “years of human experience.”<sup>89</sup> Specifically, the DEA highlighted two paramount concerns. First, it claimed that despite posing a limited risk of physical dependence, buprenorphine more closely resembles pure agonists in the subjective feelings of pleasure and euphoria it elicits.<sup>90</sup> Second, it cited multiple studies that revealed that the four-to-one ratio of buprenorphine to naloxone in Suboxone does not effectively precipitate withdrawal symptoms among non-opioid dependent or abusive individuals when administered intravenously;<sup>91</sup> in other words, the drug does not sufficiently punish people who seek to use it illicitly.

## IV. A COST-BENEFIT ANALYSIS: THE STRONG CASE AGAINST RESCHEDULING

### A. The Threat of Rescheduling

While buprenorphine has remained a Schedule III controlled substance, the media has recently shone light on the issue of its diversion.<sup>92</sup> In May of 2011, for example, *The New York Times* ran a feature

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<sup>87</sup> See Weber, *supra* note 14, at 54.

<sup>88</sup> See Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. 62,354, 62,354 (Oct. 7, 2002); Press Release, Reckitt Benckiser, *supra* note 6.

<sup>89</sup> Schedules of Controlled Substances: Rescheduling of Buprenorphine from Schedule V to Schedule III, 67 Fed. Reg. at 62,354.

<sup>90</sup> *Id.* at 62,357–58.

<sup>91</sup> *Id.* at 62,359.

<sup>92</sup> See, e.g., Doug Donovan & Fred Schulte, “Bupe” Seizures Rise as Treatment Use Grows, BALT. SUN (Apr. 18, 2008), [http://articles.baltimoresun.com/2008-04-18/news/0804180065\\_1\\_buprenorphine-lab-data-seizures](http://articles.baltimoresun.com/2008-04-18/news/0804180065_1_buprenorphine-lab-data-seizures); Cinderella, Snow

story on the purportedly growing problem of Suboxone smuggling in prisons “from New Mexico to Maine.”<sup>93</sup> The article quoted Major Francine Breton, Administrator of the Cumberland County Jail in Portland, Maine, who stated, “It’s become a crisis in here, to be honest with you. It’s the drug of choice right now.”<sup>94</sup> Two months later, the *Burlington Free Press* echoed her concern while further highlighting the potential inadequacy of current waiver requirements for primary care physicians.<sup>95</sup>

This increased media attention followed on the heels of heightened inter- and intra-governmental scrutiny of the adequacy of the existing buprenorphine regulatory regime. In 2006, the World Health Organization (“WHO”) Expert Committee on Drug Dependence formally weighed the merits of reclassifying buprenorphine from a Schedule III substance under the Convention on Psychotropic Substances of 1971 to a Schedule I narcotic under the Single Convention on Narcotic Drugs of 1961,<sup>96</sup> a move that would, in the words of the American Psychiatric Association (“APA”), have “a chilling effect on access . . . to the extent that international drug scheduling influences individual countries’ choices of how to control buprenorphine.”<sup>97</sup> The Committee justified its proffer, in part, on “reports of diversion, seizures, and abuse of buprenorphine in various countries.”<sup>98</sup> Although the proposal was ultimately rejected,<sup>99</sup> the federal government has subsequently considered a variety of steps that it can take to mitigate diver-

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*White Implicated in Jail Smuggling Ring*, THE SMOKING GUN (Mar. 29, 2011), <http://www.thesmokinggun.com/buster/drug-smuggling/cinderella-snow-white-drug-smuggling-904832>; *Prison Inmates Try to Smuggle Drug Via Colouring Book: Three Prison Inmates and Their Loved Ones Have Been Charged with Attempting to Smuggle Drugs into a US Jail on the Pages of a Children's Colouring Book*, TELEGRAPH (Mar. 29, 2011), <http://www.telegraph.co.uk/news/worldnews/northamerica/usa/8414951/Prison-inmates-try-to-smuggle-drug-via-colouring-book.html>.

<sup>93</sup> See Goodnough & Zezima, *supra* note 16.

<sup>94</sup> *Id.*

<sup>95</sup> Sam Hemingway, *Suboxone Succeeds in Aiding Opiate Addicts, but too Many are Abusing it Instead*, BURLINGTON FREE PRESS (July 27, 2011), <http://www.burlingtonfreepress.com/article/20110727/NEWS02/110726034/Suboxone-succeeds-aiding-opiate-addicts-too-many-abusing-instead>.

<sup>96</sup> WHO EXPERT COMM. ON DRUG DEPENDENCE, THIRTY-FOURTH REPORT 5–8 (2006).

<sup>97</sup> Jim Rosack, *APA Opposes WHO Proposal to Tighten Buprenorphine Controls*, 4 PSYCHIATRIC NEWS, March 3, 2006, at 2, 2.

<sup>98</sup> WHO EXPERT COMM. ON DRUG DEPENDENCE, *supra* note 96, at 6.

<sup>99</sup> *Id.* at 7–8.

sion.<sup>100</sup> Combined, these actions raise legitimate concerns regarding the specter of buprenorphine reclassification as a Schedule II controlled substance.

*B. Diversion: More Than Meets the Eye*

Two facts militate against such a move. First, although buprenorphine diversion has been well documented, it does not rise to the level of significant public health concern in the U.S. In an international literature review, Yokell et al. uncovered data inversely tying the frequency of illicit buprenorphine use to heroin accessibility.<sup>101</sup> In Finland, for example, “A sharp increase in the misuse of buprenorphine coincided with a notable decrease in 2001 in the availability of heroin.”<sup>102</sup> Arguably owing to this diminished market, Aalto et al. report that twenty-nine of thirty opioid-dependent patients (97%) they evaluated in a 2007 study listed buprenorphine as their primary drug of choice.<sup>103</sup> Heroin, however, is readily accessible in the U.S., particularly in metropolitan areas.<sup>104</sup> The frequency of diversion has therefore been low; in fact, buprenorphine “generally ranked as the least-abused or misused opioid among those studied (examples of other opioids with higher rates of abuse in the U.S. include heroin, oxycodone, hydrocodone, methadone, morphine, and fentanyl).”<sup>105</sup>

Second, the demand for diversion appears to stem principally from individuals who lack access to treatment and, consequentially, use buprenorphine therapeutically. In a recent study by Bazazi et al., for example, a majority of injecting and non-injecting opioid-abusers reported illicitly using Suboxone to reduce withdrawal symptoms.<sup>106</sup>

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<sup>100</sup> See Doug Donovan & Fred Schulte, *Strategies to Control Bupe Abuse Outlined*, BALT. SUN (Feb. 23, 2008), [http://articles.baltimoresun.com/2008-02-23/news/0802230293\\_1\\_buprenorphine-heroin-drug-treatment](http://articles.baltimoresun.com/2008-02-23/news/0802230293_1_buprenorphine-heroin-drug-treatment).

<sup>101</sup> Yokell et al., *supra* note 77, at 32.

<sup>102</sup> *Id.*

<sup>103</sup> Mauri Aalto et al., *Buprenorphine Misuse in Finland*, 42 SUBSTANCE USE & MISUSE 1027, 1027 (2007).

<sup>104</sup> U.S. DEP'T JUSTICE NAT'L DRUG INTELLIGENCE CTR., NATIONAL DRUG THREAT ASSESSMENT 2 (2011).

<sup>105</sup> Yokell et al., *supra* note 77, at 33.

<sup>106</sup> Alexander R. Bazazi et al., *Illicit Use of Buprenorphine/Naloxone Among Injecting and Noninjecting Opioid Users*, 5 J. ADDICTION MED. 175, 177 (2011). See also Raminta Daniulaityte, Russel Falck & Robert G. Carlson, *Illicit Use of Buprenorphine in a Community Sample of Young Adult Non-Medical Users of Pharmaceutical Opioids*, 122 DRUG & ALCOHOL DEPENDENCE 201, 204 (2012) (reporting that half of respondents took buprenorphine illicitly to reduce withdrawal symptoms).

Although expressing a strong interest in treatment, they faced significant barriers: “Cost and difficulty of finding a prescribing physician were commonly reported reasons for why interested participants were unable to access . . . treatment.”<sup>107</sup> These observations are consistent with SAMHSA’s findings in a Vermont case study that “buprenorphine diversion and abuse are not widespread, but rather tend to be concentrated in certain small population groups within the state . . . [that] may reflect lack of access to addiction treatment.”<sup>108</sup> Diversion, thus, appears primarily fuelled by efforts at harm reduction and may paradoxically be solved through greater, *not reduced*, access to buprenorphine (i.e., outpatient-based pharmacotherapy), a prescription rooted in history. Increased concern over buprenorphine diversion parallels heightened public outcry over illicit drug use in the early Twentieth Century.<sup>109</sup> One influential reading of U.S. drug policy posits that the restrictions placed upon the ability of physicians to treat opioid dependence and abuse, in at least partial response to this outcry,<sup>110</sup> precipitated the development on an illegal market and, possibly, to an increased number of opioid dependent individuals.<sup>111</sup>

These facts clearly reveal a paucity of risk posed by buprenorphine diversion at present and, thus, the marginal benefits of rescheduling that would come at the price of overwhelming costs. Not only would a substantially smaller number of opioid-dependent individuals be treated, those continuing to be so would be forced to forgo the benefits currently accruable from coupling addiction therapy to primary care services.<sup>112</sup>

## CONCLUSION

The reclassification of buprenorphine as a Schedule II controlled substance would ultimately represent a significant and damaging regression in federal drug policy.<sup>113</sup> Opioid-dependence and abuse

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<sup>107</sup> Bazazi et al., *supra* note 106, at 179.

<sup>108</sup> CTR. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., DIVERSION AND ABUSE OF BUPRENORPHINE: A BRIEF ASSESSMENT OF EMERGING INDICATORS—RESULTS OF THE VERMONT CASE STUDY 5 (2006).

<sup>109</sup> See Boldt, *supra* note 45, at 271.

<sup>110</sup> See *id.* at 275–76.

<sup>111</sup> See PETER CONRAD, *DEVIANCE AND MEDICALIZATION: FROM BADNESS TO SICKNESS* 127 (Temple Univ. Press 1992).

<sup>112</sup> See Weber, *supra* note 14, at 54.

<sup>113</sup> See *supra* Part II, Part III.B & Part IV.B.

constitutes a growing public health epidemic,<sup>114</sup> which can only be tackled through enhanced access to pharmacotherapies.<sup>115</sup> The scope of and demand for burprenorphine diversion serve, if anything, to confirm this fact.<sup>116</sup>

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<sup>114</sup> *See supra* Part I.

<sup>115</sup> *See supra* Part IV.B.

<sup>116</sup> *See id.*