Does it Fit?—A Look at Addiction, Buprenorphine, and the Legislation Trying to Make it Work

Alan Gordon, M.D. a
Alexandra A. Gordon, J.D. b

I. INTRODUCTION

Even in 2016, our understanding of addiction continues to be distorted by a deep-rooted stigma and a lack of delineation among substances and their unique characteristics that have varying effects on the brain, such as stimulating, sedating, soothing or numbing. Some substances are more likely to result in tolerance and physical dependence. Other substances are more likely to stimulate a more typical reward response and association with immediate gratification. To be sure, there are personality profiles, whether simply innate or related to other underlying psychiatric disorders, which are more susceptible to impulsive behavior for immediate gratification.

The words “addict,” “alcoholic,” and even terminology such as “substance dependence” or “abuse” are thought of pejoratively. I am addicted to my morning coffee (caffeine), and many of us have other addictions. Mark Twain was quoted saying, “I’m like Mark Twain’s quote: ‘Quitting smoking is easy . . .’” How do we judge one

---

a Clinical Associate Professor of Psychiatry, The Warren Alpert Medical School of Brown University; Chief of Clinical Addiction Rehabilitation Programs, Butler Hospital, Providence, Rhode Island. Salute to Suffolk University Law School for highlighting this national crisis at this time.

b Associate, Morrison Mahoney LLP; J.D., Suffolk University Law School; M.B.A., Suffolk University; B.S., The Wharton School, University of Pennsylvania. Ms. Gordon may be contacted at aagordonl@suffolk.edu.

addiction as better or worse than another? Is it based on whether the addiction is legal or whether the addiction is causing harm to ourselves or others?

This article will explore the history of addiction to opioids and the corresponding legislative attempts to limit access to opioids. It will further examine how the general public frequently regards addiction recovery as the complete cessation of or abstinence from opiate use, without regard for the essential stabilizing and therapeutic benefits of medications, such as buprenorphine and methadone. This article will conclude with a look at current and proposed legislation on the use of buprenorphine, and analyze whether it fits within the clinical setting.

II. WHAT IS ADDICTION AND WHERE DOES IT COME FROM?

A. History of Addiction

The first mention of intoxicating fluids goes as far back as Genesis 9:20-22, where “Noah plants a vineyard at the base of Mount Ararat, consumes the wine and becomes drunken.” Mayflower cargo included crude opium and Europeans marveled at their mood elevation effects. Paracelsus (1493-1541) mixed opium and wine producing laudanum, finding the effect swifter and more potent, with the idea that a good thing can always be improved upon. Sydenham (1624-1689) also exploited the solubility of opium in alcohol. Sertürner (1804), experimenting with crude opium that

---

2 See discussion infra Part II.C.
3 See discussion infra Part II.D.
4 See discussion infra Part IV.
7 Id.
8 Id.
had mixed alkaloids, isolated morphine, which acted faster and was more soluble. The Standard American Dispensary (1818) noted that habitual use of opium could lead to "addiction, tremors, paralysis, stupidity, and general emaciation."10

In 1860, the hypodermic needle was invented, improving on the delivery system for opium. Bayer Pharmaceuticals (1874) isolated diacetylmorphine for asthma and bronchitis, thus creating heroin. Soon after, it was noted that heroin could relieve everything from pains associated with teething, to labored breathing, to the aches of the elderly. Now, Bayer Pharmaceuticals is recognized for marketing aspirin for pain. In the 19th century, heroin became the standard medication in America's West. American physicians traveled with two saddlebags that contained the following treatment options: (1) bandages, catheters and splints; (2) laudanum for pain, emotional distress, diarrhea, and "women's ills;" (3) quinine for fevers; (4) calomel as emetic; and (5) whiskey.16

B. Heroin Addiction since the 1960s

Heroin addiction became a significant public policy concern in the United States in the 1950s and 1960s. From 1950 to 1961, heroin-related deaths increased five-
fold from 7.2 per 10,000 deaths to 35.8 per 10,000 deaths. Seventy-five percent of these deaths were of individuals aged fifteen through thirty-five. During this time, heroin overdose became the leading cause of death in New York City for young adults. The average age of death from heroin overdose was twenty-nine.

The public opinion of heroin addiction, and narcotics use in general, continued to decline in the decades that followed. Newspapers began reporting that soldiers in Vietnam were addicted to heroin, inciting domestic fear of what would happen when those addicted soldiers returned home. Further tainting public perception of heroin addiction, President Richard Nixon called heroin drug use “public enemy number one,” and from that point forward, heroin addiction was not simply a medical condition, but rather something to be feared and eradicated.

Despite public opinion, narcotic manufacturers continued to aggressively promote narcotics, regardless of the potential addictive side effects. An early Parke-Davis advertisement stated that “[n]arcotic products could make the coward brave, the silent eloquent, and render the sufferer insensitive to pain.” However, pharmaceutical

18 Id.
19 Id.
20 Id.
21 See infra notes 22-23 (discussing publicity on heroin use).
23 Id. (describing the American government’s response to heroin addiction).
24 Id. (highlighting the events that transformed the public’s view of heroin addiction).
companies began to pay the price for their unscrupulous advertising.\textsuperscript{26} Purdue Pharma, the maker of OxyContin, was successfully sued for $24 million in a lawsuit that accused the company of misleading the public about the addictiveness of the powerful prescription drug.\textsuperscript{27} The Connecticut-based company has had approval from the Food and Drug Administration ("FDA") since 1995 to market OxyContin, a type of opioid that has pain-relieving qualities similar to the illegal drug heroin.\textsuperscript{28}

C. Opioid Addiction in Modern Climate

What is the usual route to developing dependence on opioid products? Introduction to opioid narcotics frequently starts with legitimate prescriptions for acute pain, usually from a primary care physician.\textsuperscript{29} The effects of medications like Vicodin, oxycodone, and Percocet include not only the numbing of pain; they also include a soothing quality and have been described as having mood elevation effects.\textsuperscript{30} As Parke-Davis once stated, these drugs "make the coward brave, the silent eloquent and render the sufferer insensitive to pain."\textsuperscript{31} If not legally obtained, introduction is often initially causally related to prescription narcotics received from friends and family.\textsuperscript{32}

The most problematic component of opioid usage is that the physical dependence starts silently without any indication to the user that there are negative consequences. There are no hangovers, and there are usually no noted effects on alertness, coordination, or any other measures of negative changes in behavior. Constipation is the most frequent adverse effect, and can be severe and, in fact, ironically, has prevented many possible opioid abusers from continuing their use. By the time the user loses easy access to available narcotic medication, a dependence and withdrawal syndrome may develop. There is individual variability on how soon, or whether this may happen, but there are no indicators as to who is vulnerable. This is purely a physical phenomenon. The chronology described above has very little to do

---


34 See Tony P. George, M.D. & Thomas R. Kosten, M.D., *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 ADDICTION SCI. & CLINICAL PRAC. 13, 15 (2002), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/pdf/spp-01-1-13.pdf (discussing positive neurological effects of opioids as incentive for continuing use). As a result of the beneficial side effects of opioids, the withdrawal symptoms of patients who develop tolerance to opioid drug use are more severe, and often trigger the user to return to the use of the drug. *Id.* at 16.


36 See Esposito, supra note 33. “Physical dependence can set in in as few as five days for someone taking several daily doses.” *Id.*

37 See id. (reasoning users who medicate for longer period are more prone to dependence and tolerance).

38 See Jette Hojsted & Per Sjogren, Review, *Addiction to Opioids in Chronic Pain Patients: A Literature Review*, 11 EUROPEAN J. PAIN 490, 491 (2007) (discussing physical dependence on opioids). “Physical dependence is an expected consequence of prolonged use, but sometimes physical dependence may develop after the use of a dependency-producing drug for only 48 hours.” *Id.*
with people deciding to use a narcotic substance recreationally, for sensation-seeking, or out of desire to experiment with mind-altering effects.\textsuperscript{39}

Once the dependence and consequent withdrawal syndrome has developed, unless recognized and medically treated, the dependent person is trapped in a vicious cycle of pursuing access to narcotics through nontraditional means.\textsuperscript{40} This frequently means illegal activities, and is a pathway to the destruction of the social fabric of the narcotic seeker’s world, impacting many. When the cost of obtaining illegal narcotics becomes too high, cheaper and more potent heroin becomes the option that can be used by nasal inhalation, or by even more powerful intravenous injection, which also carries the risk of infections like Hepatitis C and HIV.\textsuperscript{41} More recently, drug dealers have been adding fentanyl to heroin, which creates a much more potent narcotic.\textsuperscript{42}

\textsuperscript{39}See Gillian A. Beauchamp, M.D. et al., Commentary, Moving Beyond Misuse and Diversion; The Urgent Need to Consider the Role of Iatrogenic Addiction in the Current Opioid Epidemic, 104 AM. J. PUB. HEALTH 2023, 2023 (2014) (discussing a shifting focus on the role healthcare providers play in the current opioid epidemic). “Largely unaddressed is that some individuals transition to nonmedical use and addition despite their intention to use medications only as directed and only for pain relief.” Id.

\textsuperscript{40}See NAT’L INST. ON DRUG ABUSE, RESEARCH REPORT SERIES: PRESCRIPTION OPIOIDS AND HEROIN 1, 2 (2015), available at https://www.drugabuse.gov/sites/default/files/rx_and_heroin_rrs_layout_final.pdf (discussing drug overdose deaths involving opioid pain relievers). “Of those who began abusing opioids in the 2000s, 75 percent reported that their first opioid was a prescription drug.” Id. at 2. Additionally, “nearly 80 percent of heroin used reported using prescription opioids prior to heroin.” Id.

\textsuperscript{41}Id. “In a recent survey of patients receiving treatment for opioid abuse, accessibility was one of the main factors identified in the decision to start using heroin.” Id. at 4. Availability is a key factor that “contributes to the popularity of a drug.” Id. Some opioid users have indicated that their transition from the use of opioid pills to heroin was made easier through initially smoking or snorting heroin before moving towards intravenous injection. NAT’L INST. ON DRUG ABUSE, supra note 40, at 5. “Because heroin is often injected, the upsurge in use also has implications for HIV, hepatitis C (HCV), and other injection-related illnesses.” Id. at 4.

\textsuperscript{42}See Mindy J. Hull, M.D. et al, Fatalities Associated With Fentanyl and Co-Administered Cocaine or Opiates, 52 J. FORENSIC SCI. 1383, 1383 (2007) (examining deaths associated with illicit fentanyl use). “Fentanyl hydrochloride is a synthetic narcotic analgesic and Schedule II controlled substance used medically in the treatment of severe and chronic pain.” Id. “Fentanyl is estimated to be 30-50 times more potent than heroin.” Id. Overdose deaths have been caused by heroin laced with fentanyl. Id. The street names of “Drop Dead,” “Flatline,” and “Lethal Injection” have been used to describe this potent mixture. Id.
What is this withdrawal syndrome that is so powerful that persons go to such
great lengths to relieve? The best analogy is the experience of a severe bout of the flu.\textsuperscript{43} This is something that we all have experienced and survived: the chills, the bone aches, the loss of energy, and the lack of focus. It is inherent in our psyche that the flu is time-limited, has few options for symptom relief, and is simply something to endure. The course of the flu is approximately seven days, and there is an internal time clock that understands that this will be time-limited. Imagine, however, experiencing similar symptoms, without the concept of these symptoms being time-limited, and you are capable of obtaining a narcotic, which will immediately bring relief. It is beyond my certainty how long I would be able to endure this state without searching for relief beyond what was available. If there is something to the idea that some have a greater vulnerability to being impulsive and a need for more immediate gratification, then the risk would be much higher.

Again, we do know that substance use disorders do exist and that there is a strong genetic predisposition, as marked by the much higher frequency of family members prone to substance use disorders.\textsuperscript{44} It is important to conceptualize the


\textsuperscript{44} See Family History and Genetics, NCADD, https://ncadd.org/about-addiction/family-history-and-genetics (last modified Apr. 25, 2015). Although, there has not been a confirmed “addiction gene,” there are numerous studies that have shown addiction and genetics are correlated. \textit{Id.} “Research conducted on twins and adopted children has shown the impact of genetics in relation to alcohol and drug dependence, and in recent years, researchers have identified numerous genes as affecting risk for dependence on alcohol and drugs.” \textit{Id.} See also Molly J. Dingel et al., \textit{Framing Nicotine Addiction as a “Disease of the Brain”: Social and Ethical Consequences}, 92 SOC. SCI. Q. 1363, 1367 (Dec. 2011), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589175/pdf/nihms417000.pdf (stating NIDA study concluded forty to sixty percent of addiction was because of genetics); \textit{Substance}
affliction of narcotic dependence through the spectrum of a medical disorder. The person who has become dependent on opioids is no different to the diabetic who has become dependent on insulin. Once the dependence has been established, it should be of little consequence whether the diabetic developed the disorder from initially abusing alcohol and inflaming her pancreas or through another mechanism. All chronic medical illnesses are based on a combination of genetic vulnerability and lifestyle factors.45

D. Treating Addiction in the Clinical Setting

Episodic, recreational use of a narcotic substance, for sensation-seeking or experimenting with mind-altering effects, is not the usual chronology, and is not the basis of the current crisis. Today, there are treatments for opioid dependence that are extremely successful in terms of opioid replacement therapy.46 Methadone maintenance has been shown to be an effective therapy.47 Methadone, however, is only available for maintenance in clinics that have requirements that greatly restrict a normal lifestyle.48

---

45 See Margaret E. Sears & Stephen J. Genuis, Environmental Determinants of Chronic Disease and Medical Approaches: Recognition, Avoidance, Supportive Therapy and Detoxification, 2012 J. ENVTL. PUB. HEALTH 1, 2 (2012), available at http://www.hindawi.com/journals/jeph/2012/356798/ (explaining that causes of chronic disease vary by “germs” and “modifiable factors”); Julia James, Chronic Disease: Genes Matter, But So Does Environment, SCOPE, (Oct. 22, 2010), http://scopeblog.stanford.edu/2010/10/22/genes_matter_but_so_does_environment/ (indicating that although we are predisposed by genetics, environment is a major factor).

46 See Scott Farnum, Treating Opiate Addiction with Replacement Therapy, HBO, https://www.hbo.com/addiction/treatment/343_treating_opiate_addiction.html (last visited Apr. 3, 2016). Replacement therapy is a long-term process that requires uses of other medications. Id. Methadone and buprenorphine are common medications used with replacement therapy. Id.

47 See Sasha Uhlmann et al., Methadone Maintenance Therapy Promotes Initiation of Antiretroviral Therapy Among Injection Drug Users, 105 SOC'Y FOR STUDY ADDICTION 907, 911 (May 2010). A few studies have shown that methadone is an effective medication for replacement therapy. Id. Because of this, the World Health Organization has established methadone as one of the best medicines. Id. See also Methadone Replacement Therapy, PHARMACEUTICAL SERVICES (Nov.18, 2013), http://www.pharmacy.gov.my/v2/en/content/methadone-replacement-therapy.html (explaining the process of obtaining and using methadone).

48 See Lamberson v. Pennsylvania, 963 F. Supp. 2d 400, 402 (M.D. Pa. 2013) (explaining how clinics providing methadone maintenance treatment are subject to "exact regulatory
Methadone is also a full opioid agonist with much greater risk of morbidity and mortality. 49

Since 2000, the introduction of buprenorphine products has provided a much safer option available in a physician’s office after the prescriber has completed the additional training and obtained the designated waiver. 50 Unfortunately, many restrictions and stipulations are associated with this waiver, and have resulted in insufficient physicians showing a willingness to prescribe. 51 For example, some provide limitations on the number of patients who can be treated, and others impose requirements for monitoring, which can be intimidating and invite very close scrutiny from the Drug Enforcement Agency (“DEA”). 52 The paradox is that there are no such standards”). See also Adrian Preda, M.D., Opioid Abuse Treatment & Management, MEDSCAPE, http://emedicine.medscape.com/article/287790-treatment (last updated Mar. 16, 2016) (discussing role of clinics in stabilizing lifestyle of drug abusers and addicts).


51 See Notification of Intent to Use Schedule III, IV, or V Opioid Drugs, supra note 50 (providing waiver application layout).

52 See RAND CORPORATION, POLICIES TO SUPPORT A BETTER TREATMENT FOR HEROIN AND PRESCRIPTION OPIOID ABUSE 2-3 (2015), available at http://www.rand.org/content/dam/rand/pubs/research_briefs/RB9800/RB9871/RAND_RB9...
requirements for prescribing for opioid agonists like Percocet and oxycodone. There is also no evidence to suggest that buprenorphine products are the primary cause of opioid overdoses. For example, a review of opioid overdoses in Rhode Island in 2015 suggests that there are no examples where buprenorphine products were considered the primary cause. The few cases that included buprenorphine products were situations of consumption of many of the agents that could also be implicated. It is reasonable to consider buprenorphine products as having significant harm reduction qualities.

This is a time when the nation, and in particular New England, is recognizing that it has an epidemic, an emergency that requires immediate action, and there have been many legislative initiatives to address the issue. Many of these initiatives include requiring more scrutiny from physicians prescribing buprenorphine products, including using a prescription monitoring program, limiting the number of patients that a prescriber may treat, and requiring additional treatment and monitoring. While requiring careful prescribing and monitoring of buprenorphine products is understandable, the auditing of these physicians has been so intense as to intimidate

871.pdf, 2015 (detailing current state of buprenorphine waivered physicians). See also infra notes 94-96 (referencing legislation proposals at the state level).


55 Id.

56 Id.

physicians from participating, and has eliminated resources that could be used for focusing on physicians prescribing more potent narcotics in irresponsible ways.\textsuperscript{58} It is the hope that better understanding will lead to a greater focus on legislative initiatives.

III. OPIATE LEGISLATION

A. History of Opiate Legislation

Opiate laws in the United States date back to the early 1900s, with the Pure Food and Drug Act of 1906.\textsuperscript{59} Until the Controlled Substances Act of 1970, the focus on such legislation was eliminating access to all opiates.\textsuperscript{60} However, in recognition of the use of drugs for legitimate medical purposes, the Controlled Substances Act of 1970 ranked all drugs, including opiates, into Schedules and regulated practitioners’ ability to

\textsuperscript{58} See supra note 57 and accompanying text (noting the qualifications a physician must abide by to prescribe buprenorphine).


\textsuperscript{60} See also Regulatory Information: Federal Food and Drug Acts of 1906, FDA, http://www.fda.gov/RegulatoryInformation/Legislation/ucm148690.htm (last visited Mar. 30, 2016) (providing the scope, intent, and text of the Act). The purpose of the Pure Food and Drug Act of 1906 was to regulate food, drug, medicine, and liquor trafficking, and to prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” Id.
Some opiates, like heroin, were designated as Schedule I drugs due to the high potential for abuse, lack of accepted medical use treatment in the United States, and “lack of accepted safety for use of the drug or other substance under medical supervision.”62 However, others, like methadone, were given the lower Schedule II designation due to the high potential for abuse, risk of severe psychological or physical dependence, and accepted medical use for treatment in the United States.63

In response to the increasing concern over addiction to methadone, Congress enacted the Narcotic Addict Treatment Act of 1974, once again seeking to limit the public’s access to opioid medications—this time, Methadone—by placing strict limits on practitioners’ ability to prescribe Methadone to treat opioid addiction.64 Practitioners who distributed narcotic medications for “maintenance treatment” or “detoxification treatment” were required to register separately for that purpose, making it more difficult to become a licensed practitioner.65 For the first time, the legislature defined “maintenance treatment” as “the dispensing, for a period in excess of twenty-one days, a narcotic drug in the treatment of an individual for dependence on heroin or other morphine-like drugs,” and “detoxification treatment” as “the dispensing, for a period not in excess of twenty-one days of a narcotic drug in decreasing doses to an individual

---

63 21 U.S.C. §§ 801(1), 812 (2012). See also U.S. National Library of Medicine, Methadone, NIH.GOV, https://www.nlm.nih.gov/medlineplus/druginfo/meds/a682134.html#why (last modified Aug. 15, 2014) (defining methadone and describing its uses and dangers). Methadone is a narcotic used to treat narcotic addiction. Id. It is commonly used to reduce withdrawal symptoms in individuals addicted to heroin or other narcotic drugs. Id. Outside the drug addiction realm, it may also be used to treat severe and chronic pain in individuals who cannot be treated with other pain medications. Id.
65 Id. § 823(g)(1) (explaining how practitioners must obtain registration from attorney general to treat narcotic addicts).
in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state.”

The Drug Addiction Treatment Act of 2000 expanded on the Narcotic Addict Treatment Act of 1974, for the first time enabling qualified physicians to prescribe and dispense narcotics for the purpose of treating opioid addiction from their own offices. This eliminated the need to seek care from specialized drug treatment clinics (i.e. Methadone clinics), and enabled these qualified practitioners to treat opioid addiction similarly to any other ailment from the privacy of their offices. The Drug Addiction Treatment Act of 2000 established the current regulations governing how a practitioner becomes licensed to prescribe narcotics as part of an opioid treatment regimen.

In 2002, the FDA approved two new drugs, Suboxone (buprenorphine hydrochloride and naloxone hydrochloride) and Subutex (buprenorphine hydrochloride), for the treatment of opioid addiction. On the day before their release, the Drug Enforcement Administration (“DEA”) reclassified the drugs as Schedule III drugs from their previous designation as Schedule V drugs. This rescheduling was

67 21 U.S.C. § 823 (g)(2)(B) (discussing the conditions under which the requirements for dispensing narcotic drugs for treatment are waived). See also Laws: Learn About the Laws Concerning Opioids, supra note 59 (discussing the history of legislative acts aimed at regulating and prohibiting the use of opioids).
68 Laws: Learn About the Laws Concerning Opioids, supra note 59.
69 See 21 U.S.C. § 823 (g)(2) (discussing current regulations under the act). See also infra Part B Current Buprenorphine Legislation and Regulation (discussing the way buprenorphine is currently regulated and dispensed).
based on the recommendation of the Department of Health and Human Services that buprenorphine has a lower potential for abuse than Schedule I and Schedule II drugs; it has a currently accepted medical use in treatment in the United States, and buprenorphine may lead to “moderate or low physical dependence or high psychological dependence.”

B. Current Buprenorphine Legislation and Regulation

Distribution of buprenorphine as part of treatment for opioid addiction is currently regulated by the Drug Addiction Treatment Act of 2000 (“DATA 2000”). Providers who seek to prescribe buprenorphine as part of their treatment regimen for patients struggling with opioid addiction are required to undergo a series of registration

Schedule III drugs have a lower potential for abuse than Schedule I or Schedule II drugs. Id. Schedule III drugs are currently accepted for medical use in the United States; and, abuse of these drugs may lead to low to moderate physical dependence or high psychological dependence. Id. Some examples of Schedule III drugs include amphetamine and anabolic steroids. Id. See also 21 U.S.C. § 812 (2012). Examples of Schedule V drugs include compounds that contain:

1. Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
2. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
3. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit; and
5. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.


72 See Sarpatwari supra note 71, at 391 (reclassifying buprenorphine as a schedule III drug was not favorable).

steps. First, providers must hold a current state medical license, a valid DEA registration number, attest that he or she has the capacity to refer appropriate patients to counseling and non-pharmacologic therapies, certify that he or she will not have more than thirty patients (or 100 after the one-year mark), and meets one or more of the following conditions: (1) holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties; (2) holds an addiction certification from the American Society of Addiction Medicine; (3) holds a subspecialty board certification in addiction medicine from the American Osteopathic Association; (4) has completed not less than eight hours of training with respect to the treatment and management of opioid-addicted patients; (5) has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment; (6) has other training or experience, considered by the state medical licensing board; or (7) has other training or experience demonstrating the physician’s ability to treat and manage opioid-addicted patients.

Once meeting this significant threshold for registration, providers are limited to the number of patients to whom they may prescribe the medication. Providers who are DATA 2000 certified for less than one year may treat only thirty patients with buprenorphine at any one time. After the one-year mark, providers may treat up to

---

74 See Why are Doctors Limited to Only Helping 30/100 People at a Time?, NAABT.ORG, http://www.naabt.org/faq_answers.cfm?ID=46 (last visited Mar. 30, 2016). Under DATA 2000, providers are limited to physicians. Id. No other healthcare providers may apply for DATA 2000 certification to prescribe buprenorphine. Id.

75 See 30-100 Patient Limit, NAABT.ORG, http://www.naabt.org/30_patient_limit.cfm (last visited Mar. 30, 2016). Once DATA 2000 certified, providers are limited to treating only thirty patients with buprenorphine at any one time. Id. Providers who are DATA 2000 certified for more than one year may treat 100 patients with buprenorphine for opioid addiction and maintenance. Id.

76 Id.

77 See 30-100 Patient Limit, supra note 75 (describing the limit on the number of patients certain providers may treat).
100 patients with buprenorphine at any one time.\textsuperscript{78}

C. Proposed Buprenorphine Legislation

In September 2015, the Obama Administration announced a major shift in the policy surrounding the prescribing of buprenorphine to combat heroin and narcotic addiction.\textsuperscript{79} The goal was to remove some of the obstacles facing physicians seeking to treat patients with opiate addiction.\textsuperscript{80} This policy shift came months after Senator Edward Markey (D-Mass.) and Senator Rand Paul (R-Ky.) announced their support for proposed legislation, the Recovery Enhancement for Addiction Treatment Act ("TREAT Act"), which would make buprenorphine and other similar medications more accessible to opioid addicts.\textsuperscript{81}

The TREAT Act recognizes that deaths from drug overdoses, largely from prescription pain relievers, have increased exponentially in the United States since 2005.\textsuperscript{82} Moreover, abuse or misuse of opioid pain medications causes approximately 475,000 emergency visits annually, correlating to an increased burden on the healthcare

\textsuperscript{78} See 30-100 Patient Limit, supra note 75 (discussing under what circumstances the limit on patients treated by providers is expanded). Providers seeking to treat up to 100 patients with buprenorphine at any one time are required to submit additional notification of their intent to increase treatment levels. \textit{Id.}


\textsuperscript{80} See Cherkis & Grim, supra note 79 (detailing the new approach to treating opioid addiction).


\textsuperscript{82} See S. 1455 § 2 (detailing TREAT Act legislative findings).
system. This does not include the additional healthcare resources required for the
treatment of HIV, viral hepatitis, or other social harms related to opioid addiction.

Additionally, medication-assisted treatments, such as use of buprenorphine, is both
medically effective and a cost-effective means of treating opioid addiction that can
decrease overdose deaths and reduce transmission of HIV and viral hepatitis.

Under the proposed TREAT Act, the class of individuals permitted to seek
certification to prescribe buprenorphine is expanded from physicians to
“practitioners.” A qualifying practitioner under the TREAT Act may include a
physician, nurse practitioner, or physician’s assistant who meets a set of criteria similar
to the criteria previously required of physicians under DATA 2000. The physician
must be licensed under applicable state law, and must meet one or more of the
following requirements: (1) has board certification in addiction psychiatry from either
the American Board of Medical Specialties, the American Society of Addiction
Medicine, the American Osteopathic Association, or the American Board of Addiction

---

83 Id.
84 See Elinore F. McCance-Katz, Treatment of Opioid Dependence and Coinfection with HIV and Hepatitis C Virus in Opioid Dependent Patients: The Importance of Drug Interactions Between Opioids and Antiretroviral Agents, 41 CLIN. INFECT. DIS. (Supplement 1) S89-S95, S89 (2005), available at http://cid.oxfordjournals.org/content/41/Supplement_1/S89.full.pdf+html (discussing how HIV and Hepatitis C are common in opioid dependent injection drug users). See also S. 1455 § 2. The legislative findings do take note of secondary social harms and diseases attributable to opioid dependence, but do not include emergency room visits attributable to secondary effects in the figure that is stated. Id.
85 Id.
86 Id. § 3. Under the Controlled Substances Act, the term “practitioner” is defined as follows:

[A] physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Medicine; (2) has completed eight hours of training with respect to treating and managing opiate dependence for substance abuse disorders; (3) has participated as an investigator in clinical trial leading to the approval of a narcotic drug for maintenance or detoxification treatment; or (4) has other training and/or experience that demonstrates the physician’s ability to treat and manage opiate-dependent patients. These proposed requirements reflect a broadening of the qualifications necessary for a physician to become qualified to use narcotics to treat opiate addiction.

For the first time, nurse practitioners and physician assistants may also apply to become qualified subscribers and providers of medication assisted therapies for opiate addiction. In order to become a qualified nurse practitioner or physician assistant, the nurse practitioner or physician assistant must meet the following requirements: (1) be licensed under applicable state law; (2) be licensed to prescribe Schedule III, IV, or V medications for pain; (3) practice under the supervision of a licensed physician who is either qualified to prescribe narcotics for opiate addiction, or the physician and either the nurse practitioner or physician assistant practice in a qualified practice setting; and (4) has either completed at least twenty-five hours of training with respect to treating and managing opiate dependence for substance abuse disorders or has other training and/or experience that demonstrates the nurse practitioner’s or physician assistant’s ability to treat and manage opiate-dependent patients. In the alternative to the above,

88 See S. 1455 § 4 (amending the Controlled Substances Act).
89 See supra note 71 (providing background on the Drug Addiction Treatment Act of 2000).
90 See S. 1455 § 4. A “qualified practice setting” is defined as one or more of the following:

(I) A National Committee for Quality Assurance-recognized Patient-Centered Medical Home or Patient-Centered Specialty Practice.

(II) A Centers for Medicaid & Medicare Services-recognized Accountable Care Organization.
state-licensed nurse practitioners may also become qualified to prescribe narcotics for opiate addiction if they meet these criteria: (1) they are licensed under state law to prescribe Schedule III, IV, or V medications for pain; (2) they have training and/or experience that demonstrates a specialization in the treatment of opiate-dependent patients; (3) they prescribe opioid addition therapy in collaboration with a qualified physician; and (4) they practice in a qualified practice setting.91

The TREAT Act not only broadens the requirements for providers to qualify to prescribe narcotics for treatment of opioid addiction, but also increases the number of patients each individual provider may treat at any one time, thereby permitting an exponential increase in the availability of medication-assisted therapies for opioid addiction. Under the proposed TREAT Act, in the first year of certification, providers may treat up to 100 patients at any one time, which is an increase from the current thirty-patient limit.92 After one year of certification, providers may petition to treat an

91 *Id.* (describing the role of nurse practitioners with addiction treatments).
92 *See* S. 1455 § 3. *See also supra* Part B (discussing the distribution and current regulation of...
unlimited number of patients, which is an increase from the current 100-patient limit, provided that the practitioner complies with existing requirements, as well as the following: (1) agrees to participate in his/her state’s Prescription Drug Monitoring Program; (2) practices in a qualified practice setting; and (3) has completed at least 24 hours of training provided by an approved organization.93

In addition to the Obama Administration’s recent policy shift in favor of medication-administered therapies for opioid addiction, Presidential Candidate Hillary Clinton has similarly announced a $10 billion plan in favor of decreasing the stringent regulations on which providers may prescribe narcotics for opioid addiction, and in what quantities.94 Although not identical to the proposed TREAT Act, the general premise is the same: increase both the availability of the medications by increasing the number of qualified providers and the quantity of authorized prescriptions.95 Furthermore, Clinton’s proposal offers $7.5 billion in federal grant money over ten years

buprenorphine as part of treatment for opioid addiction).

93 See S. 1455. Approved Organizations include, but are not limited to, the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, and the American Psychiatric Association. Id.


95 See id. See also Hillary Clinton’s Initiative to Combat America’s Deadly Epidemic of Drug and Alcohol Addiction, THE BRIEFING, https://www.hillaryclinton.com/briefing/factsheets/2015/09/02/combat-addiction/ (last visited Mar. 28, 2016) (detailing Clinton’s proposal for combatting substance abuse in the U.S.). Clinton’s proposal sets out the following five goals for immediate Federal Action: (1) “enhance access to treatment,” (2) “ensure that federal law on insurance parity is being implemented and enforced,” (3) “encourage best practices for insurance coverage for substance use disorders,” (4) “promote better prescriber practices in Medicare and the Veterans Administration,” and (5) “direct the Attorney General to issue guidance on prioritizing treatment over incarceration for nonviolent low-level federal drug offenders.” Id.
to states that develop a comprehensive plan designed to assist in achieving federal goals for decreasing opioid addition and opioid addiction-related secondary concerns.96

At the state level, Massachusetts in particular, has pioneered legislation to address what Governor Charlie Baker has termed the “Opioid Epidemic in the Commonwealth.” Governor Baker announced Massachusetts’ “Action Plan to Address the Opioid Epidemic in the Commonwealth” on June 22, 2015.97 The goal of Governor Baker’s action plan is to reduce the magnitude and severity of harm related to opioid misuse and to decrease deaths due to opioid overdoses in Massachusetts.98 One of the initiatives includes removing barriers to treatment for patients covered by MassHealth by altering the prior authorization policies.99 Other initiatives directly address the use of medication-assisted treatment for patients with substance abuse disorders. For example, the action plan seeks to use the Department of Health to increase the number of office-based treatment programs as well as further integrate medication-assisted treatment into the clinical setting, which would include access to buprenorphine.100

96 See id. Clinton’s federal-level goals are to: (1) “empower communities to implement preventive programming for adolescents about drug use and addiction;” (2) “ensure that every person suffering from drug or alcohol addiction can obtain the comprehensive, ongoing treatment he or she needs, and stay in recovery;” (3) “ensure that all first responders have access to naloxone;” (4) “require licensed prescribers to have a minimum amount of training and to consult a prescription drug monitoring program before writing a prescription for controlled medications;” and, (5) “prioritize rehabilitation and treatment over prison for low-level and nonviolent drug offenses and end the era of mass incarceration.” Id.


98 Id. at 2 (stating the overall objectives of the plan).


100 See BAKER & POLITO, supra note 97, at 5.
However, Massachusetts' proposed action plan cannot function without coordination with the federal government. For that reason, in an effort to coordinate with the proposed TREAT Act, Governor Baker's action plan includes an initiative for a proposed partnership with the Drug Enforcement Administration to permit medical residents to prescribe buprenorphine. The action plan also echoes the TREAT Act in calling for an increase in (or removal of) the patient cap for buprenorphine prescriptions, and including nurse practitioners and physician assistants to the class of providers eligible to write prescriptions for the drug. As of January 8, 2016, many of the action plan's initiatives focused on increasing access to buprenorphine have not progressed, and are largely waiting on the stringent Federal regulations to lift. Encouragingly, the Commonwealth continues to encourage doctors to become DATA 2000 certified to increase the number of eligible buprenorphine prescribers, even though the number of patients each prescriber may treat remains limited.

IV. ANALYSIS

The assessment of the current legislation and the clinical climate of opioid addiction can be summed up in four simple words: it does not fit. The reason the legislation does not fit is largely because of how society views “addiction” and “recovery.” It may be difficult for some to understand how a patient is “recovered” from an opioid addiction if the patient remains reliant on another narcotic, i.e. buprenorphine, to remain in that state. It is this overall dichotomy that bred the

101 Id. at 6 (detailing plans to partner with DEA officials to permit prescription of buprenorphine).
102 Id. (outlining how to increase access to buprenorphine by partnering with federal leaders).
legislation currently in place—legislation that is focused on ceasing access to opioid and narcotics of any kind, rather than strategically and thoughtfully identifying those that are harmful and those that, when used appropriately, may be helpful.

In the clinical setting, a patient struggling with opioid addiction who seeks recovery faces her first hurdle when the seemingly insurmountable withdrawal symptoms strike. Those severe flu-like symptoms—the chills, the bone aches, the loss of energy and lack of focus—hit with no end in sight. In the current climate, options are limited to receiving treatment at specialized methadone clinics, which easily identifies the patient as an “addict” and carries its own stigma; fighting the withdrawal symptoms without assistance; searching out a clinician who carries DATA 2000 certification and has not reached her buprenorphine prescription limit; or forgoing recovery altogether and returning to addiction.

This path, however, is blocked by the current legislation, which is reflective of an outdated and naïve view of addiction. Of the four potential paths outlined above, seeking out a DATA 2000 certified physician who has not met her buprenorphine cap is arguably the most desirable. However, by a twist of fate, it is also the least available treatment option, thus creating a perfect storm of low supply and high demand, and

106 End the 30/100 Patient limits on Care: Why This Current Rationing Policy Must End, NAABT.ORG, http://www.naabt.org/reasons.cfm (last modified Sept. 13, 2015). The alternatives are not only inferior, but also potentially dangerous. Id. For example, ultra-rapid detox, or anesthesia-assisted rapid detoxification with naltrexone induction, has been associated with potentially life-threatening adverse effects. See Eric D. Collins et al., Anesthesia-Assisted vs. Buprenorphine-or Clonidine-Assisted Heroin Detoxification and Naltrexone Induction: A Randomized Trial, 294 JAMA 903, 903 (Aug. 2005), available at http://jama.jamanetwork.com/article.aspx?articleid=201451.
resulting in waiting lists, more selective providers, and a higher price.\textsuperscript{107} Patients who want to recover from their addiction are compelled to do so with inferior methods, or perhaps become disenchanted by the notion of recovery at all, and continue with their dangerous addiction. Even worse, patients may seek the drug illegally, and self-administer without the supervision of a certified physician, buying it off of other addicts who obtain the drug under the guise of recovery.\textsuperscript{108} This result is not unique to buprenorphine, or even medicine, but rather it harkens back to basic microeconomics and the dilemma created by high demand and low supply. With the supply kept at a minimum by federal and state regulation and demand increasing every day, prices increase and alternatives become popular. In this case, however, the alternatives are inferior and the increasing price takes the drug farther out of reach of those who truly need it.

If buprenorphine is the superior means of treating opioid addiction, then some may question why it is regulated at all. The answer is simple: at its core, buprenorphine is a narcotic and a Schedule III controlled substance.\textsuperscript{109} Patients may become addicted

\textsuperscript{107} See Hillary Clinton's Initiative Action Plan, supra note 95. Waiting lists in particular may be devastating because they compel those who are motivated to seek treatment for their addiction to seek out inferior forms of treatment. \textit{Id.} This goes against one of the National Institute on Drug Abuse's thirteen principles of effective treatment. \textit{Principles of Drug Addiction Treatment: A Research-Based Guide, NAABT.ORG} (Oct. 1999), http://www.naabt.org/documents/principals_of_drug_treatment.pdf. Specifically, Principle #2: Treatment needs to be readily available. \textit{Id.} at 3.

\textsuperscript{108} Interview with Abigail Simon, LICSW, in Cambridge, MA (Jan. 30, 2016). On buprenorphine in the clinical setting, Ms. Simon stated:

\textit{If used correctly and with a prescriber who meets once per week, it's a good replacement therapy. But there's a risk because people over prescribe and addicts sell it on the street. Also physicians take on too many patients because the reimbursement is high and patients pay out of pocket.}

\textit{Id.}

\textsuperscript{109} See Jeffrey Junig, \textit{Is Suboxone a Narcotic? ADDICTIONBLOG.ORG} (Mar. 3, 2014), http://prescription-drug.addictionblog.org/is-suboxone-a-narcotic/ (stating buprenorphine is a narcotic under most definitions); \textit{What is the Difference Between Buprenorphine, Subutex and Suboxone,}
to buprenorphine, although the risk is low.\textsuperscript{110} Furthermore, buprenorphine is not intended to be used in the clinical setting as a singular treatment; rather, it is most effective as an element of an overall treatment plan, including regular counseling.

The fact that buprenorphine is a narcotic being used to treat addiction to another narcotic also begs the question as to whether a patient is truly "recovered" from an addiction to narcotics if he is still dependent on buprenorphine to some extent. This question, in part, lies at the core of the existing legislation and its stringent regulations of use of buprenorphine. Historically, the legislative attempts to regulate narcotics were aimed at ceasing access.\textsuperscript{111} Why? Because narcotic addiction and drug overdoses were running rampant.\textsuperscript{112} Diseases like HIV/AIDS, Hepatitis B, and Hepatitis C were becoming more prevalent, largely in part due to the sharing of hypodermic needles.\textsuperscript{113} Therefore, in the mind of the general public, the best way to stop the problem was to cut off the source by limiting access to the very substance that was causing the problem.

Buprenorphine, therefore, creates a legislative quandary: it is a narcotic, which society dictates should be unavailable to the general public, but it is a narcotic that was proven to successfully treat the much more threatening narcotic addiction.

\begin{footnotes}
\item[111] See supra notes 59-60 and accompanying text (outlining the history of opiate laws in the U.S.); \textit{supra} note 63 (providing reasons for restrictions on methadone prescription access under Narcotics Addict Treatment Act of 1974). \textit{See also} Cherkis, \textit{supra} note 78 (explaining how TREAT Act would generally impact heroin access).
\item[112] See Joseph, et al., \textit{supra} note 17, at 347-349 (offering methadone treatment history and related issues). \textit{See also} \textit{supra} note 79 (offering TREAT Act's perspective on the relationship between prescription pain relievers and overdoses); \textit{supra} notes 97-100 and accompanying text (referencing how Massachusetts planned to address the opioid epidemic).
\item[113] See AGGRAWAL, \textit{supra} note 11 (detailing the effects that the hypodermic needle had on opium usage).
\end{footnotes}
Buprenorphine fell victim to the historic trend in legislation to treat all narcotics as "bad" by highly regulating and limiting the public's access to them.

However, legislation, like medicine, is not static, but evolves with time. The clear trend in opioid legislation is to turn away from the strict ideology that "all narcotics are bad," to the more nuanced policy that "some drugs are worse than others." This is largely reflective of the views of those in the medical community, and in the overall public, that combating narcotic addiction, overdoses, and the related medical problems is the ultimate goal. If the best chance of reaching that goal is to make another narcotic, such as buprenorphine, that has a low likelihood of addiction and a low potential for abuse, more readily available to the patient community, then that is what should be done. All narcotics are not the same. The proposed TREAT Act and corresponding state regulations recognize that the legislative and clinical focus need to shift away from traditional notions of combatting addiction and reflect the current clinical realities of the affliction.

V. CONCLUSION

It is important to understand opioid dependence in the context of other physical dependencies that are very common in all families and our society. However, it is important to have a good historical perspective. Society tends to make value judgments about different addictions and dependencies as being good or bad based on criteria that are not always scientifically based or that do not appreciate the innocent way that addiction occurs and touches on every family and socioeconomic group. The corresponding legislation is frequently slow to respond, inclined to be punitive, and provides as little resource as possible, essentially treating those who are afflicted as pariahs. Rather than allowing societal prejudices and delayed legislation to dictate our view of addiction and dependency, we must focus on the desired end result and work
backwards by treating those afflicted with the most appropriate and effective care available, even if it includes narcotics.