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*Supply and Demand: Navigating Emergency Regulatory Developments in the Fight
Against Opioid Use Disorder*

By Eva Bogdewic

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Introduction

The battle against opioid use disorder in the United States spans three centuries, beginning when American physicians recorded widespread morphine addiction in the years following the Civil War.¹ Regulatory attempts to curb the opioid crisis began in the early twentieth century, as did experimentation with—and stigmatization of—maintenance treatment.² This crisis has worsened considerably over the last several decades. Since 1999, overdose deaths from opioids have increased more than sixfold,³ claiming close to 500,000 American lives.⁴ This

¹ Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAGAZINE (Jan. 4, 2018), <https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/> (delineating the many evolutions of the opioid crisis in the United States from battlefield hospitals in the American Civil War and opium dens in San Francisco to the rise of heroin use in the aftermath of World War II to the commercial normalization of OxyContin in the early 2000s). *See also* Jonathan S. Jones, *The "Great Risk" of "Opium Eating": How Civil War-Era Doctors Reacted to Prescription Opioid Addiction*, YALE UNIV. LIBR. (Dec. 1, 2020), <https://library.medicine.yale.edu/blog/> (describing the rise of opioid addiction in the wake of the American Civil War and the threat of addiction that physicians began to understand at the time).

² Trickey *supra* note 1.

³ Claire Felter, *The U.S. Opioid Epidemic*, COUNCIL ON FOREIGN RELATIONS (last updated July 16, 2020, 8:00 AM), <https://www.cfr.org/backgrounder/us-opioid-epidemic>.

⁴ *Data Analysis and Resources*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed March 10, 2020), <https://www.cdc.gov/drugoverdose/data/analysis.html>.

is a consequence of three types of addictive opioid supply pools; prescription pills, heroin, and synthetic opioids; forming what is commonly known as the “triple wave” of opioid mortality in the United States.⁵

Today, more than two million Americans struggle with opioid use disorder (OUD).⁶ An estimated 8-12% of chronic pain opioid users develop OUD.⁷ Opioid prescriptions peaked in

⁵ The first wave, opioid prescription pills, began to rise in the 1990s; heroin is recognized to have risen in the mid-2000s; the third wave, synthetic opioids, flooded into the United States from China and Mexico in the mid-2010s. A partial cause of the explosion of heroin use was the insufficiency of prescription pills to appease the addictions of young heroin users, who instead found that heroin could be obtained cheaply with relative ease.

Daniel Ciccarone, *The Triple Wave Epidemic: Supply and Demand Drivers of the US Opioid Overdose Crisis*, 71 INT’L J. DRUG POLICY 183.

⁶ *Opioid Addiction 2016 Facts & Figures*, AMERICAN SOCIETY OF ADDICTION MEDICINE, <https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf> (noting, also, that as of 2015, 20.5 million Americans had some type of substance abuse disorder). *See also* THE COUNCIL OF ECONOMIC ADVISERS, *THE UNDERESTIMATED COST OF THE OPIOID CRISIS* (Nov. 2017) (estimating the economic cost of the opioid crisis in the United States to be approximately \$504 billion).

⁷ *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE (March 11, 2021), <https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis>. *See also* Oesterle, et al., *Medication-Assisted Treatment for Opioid-Use Disorder*, MAYO CLINIC,

2012 and declined between 2014 and 2019,⁸ falling 37.1%.⁹ In large part, this resulted from increased education and regulation surrounding the use of opioid analgesics to treat pain.¹⁰ However, opioid overdose deaths did not decline accordingly.¹¹ From 2013 to 2019, deaths from synthetic opioids increased twelvefold despite tightened regulation of opioid prescriptions and falling rates of prescription opioid deaths.¹² The illicit market willingly supplied what pharmacists and doctors would not, or could not, provide.¹³ This reality, and the realities of

[https://www.mayoclinicproceedings.org/article/S0025-6196\(19\)30393-3/pdf](https://www.mayoclinicproceedings.org/article/S0025-6196(19)30393-3/pdf) (stating that 30% of patients prescribed opioids misuse them).

⁸ *U.S. Opioid Dispensing Rate Maps*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed Dec. 7, 2020), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

⁹ American Medical Association, *Physicians' Progress Toward Ending the Nation's Drug Overdose and Death Epidemic* (2020), <https://www.ama-assn.org/system/files/2020-07/opioid-task-force-progress-report.pdf>.

¹⁰ *See, e.g.*, BRIAN T. YEH, CONG. RSCH. SERV., R45164, LEGAL AUTHORITIES UNDER THE CONTROLLED SUBSTANCES ACT TO COMBAT THE OPIOID CRISIS 29 (2018).

¹¹ *Data Analysis and Resources*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed March 10, 2020), <https://www.cdc.gov/drugoverdose/data/analysis.html>.

¹² *Tighter Regulation Lowers Targeted, but Not Overall, Opioid Use*, NATIONAL BUREAU OF ECONOMIC RESEARCH (Nov. 2020), <https://www.nber.org/bh/tighter-regulation-lowers-targeted-not-overall-opioid-use>; Daniel Ciccarone, *The Rise of Illicit Fentanyl, Stimulants and the Fourth Wave of the Opioid Crisis*, 34 CURRENT OPINION IN PSYCHIATRY 344.

¹³ Ciccarone, *supra* note 12.

addiction, remain today. Illicit opioids have never been as prevalent in the United States as they are now.

Recently, federal and state institutions have brought lawsuits against major corporations for their respective roles in perpetuating the opioid crisis.¹⁴ However, in the midst of the “third wave” of the opioid crisis, the greatest cause of opioid-related death is consumption of synthetic opioids, namely fentanyl. In 2019, fentanyl and other synthetic opioids were involved in 72.9% of all drug overdoses in the United States.¹⁵

To date, there are three FDA-approved medications used for medically assisted treatment (MAT) of OUD: methadone, buprenorphine, and naltrexone. Methadone is a Schedule II substance and a full opioid agonist without the euphoric effects of other opioid drugs. It is also the most strictly regulated of all three substances; methadone must be dispensed at an opioid

¹⁴ See Jan Hoffman, *Drug Distributors and J.&J. Reach \$26 Billion Deal to End Opioid Lawsuits*, N.Y. TIMES (July 21, 2021), <https://www.nytimes.com/2021/07/21/health/opioids-distributors-settlement.html>; Michael Balsamo & Anne D’Innocenzio, *Feds Sue Walmart Over Role in Opioid Crisis*, AP NEWS (Dec. 22, 2020); Jan Hoffman, *15 States Reach a Deal With Purdue Pharma, Advancing a \$4.5 Billion Opioid Settlement*, N.Y. TIMES (published July 8, 2021, updated July 10, 2021), <https://www.nytimes.com/2021/07/08/health/purdue-pharma-opioids-settlement.html>; OFF. OF THE DEPUTY ATT’Y GEN., PRESS RELEASE 10-1282, OPIOID MANUFACTURER PURDUE PHARMA PLEADS GUILTY TO FRAUD AND KICKBACK CONSPIRACIES (Nov. 24, 2020).

¹⁵ *Drug Overdose Deaths Remain High*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed March 3, 2021), <https://www.cdc.gov/drugoverdose/deaths/index.html>.

treatment program (OTP).¹⁶ Buprenorphine, a Schedule III substance and partial opioid agonist, must also be administered by an OTP, although certain medical practitioners may obtain special waivers, also known as “X-waivers,” to prescribe and dispense the substance.¹⁷ Naltrexone is a slow-release opioid antagonist while naloxone, also known as Narcan, it is a fast-acting opioid antagonist used solely for detoxification. Both drugs can be prescribed by any licensed physician to suspend the effects of opioids. Medically assisted treatment is highly effective in diminishing cravings and ending the vicious cycle of opioid abuse.¹⁸

Compliance with MAT is the most effective predictor of successful recovery from OUD.¹⁹ Unfortunately, OUD treatment disparities are severe. Only 21.5% of people with OUD

¹⁶ *Information About Medication-Assisted Treatment (MAT)*, FOOD & DRUG ADMIN. (current as of Feb. 14, 2019), <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>.

¹⁷ *See infra* part II(A).

¹⁸ Bertha K. Madras et al., *Improving Access to Evidence Based Medical Treatment for Opioid Used Disorder: Strategies to Address Key Barriers Within the Treatment System*, NAT’L ACADEMY OF MEDICINE, <https://nam.edu/improving-access-to-evidence-based-medical-treatment-for-opioid-use-disorder-strategies-to-address-key-barriers-within-the-treatment-system/>.

¹⁹ *Medications for Opioid Use Disorder Improve Patient Outcomes*, THE PEW CHARITABLE TRUSTS (Dec. 17, 2020), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes>.

underwent treatment from 2009 to 2013.²⁰ As of 2021, the U.S. has approximately 1,800 opioid treatment programs, meaning that the ratio of opioid addicts to treatment programs is more than one thousand to one.²¹

In the spring of 2020, COVID-19 reached the United States and spread rapidly in densely populated, urban areas, eventually claiming hundreds of thousands of American lives. Every state and territory closed its public schools and imposed restrictions on social gatherings; most forced “non-essential” commercial enterprises to close.²² The workforce that once boasted an

²⁰ Brendan Saloner, & Shankar Karthikeyan, *Changes in Substance Abuse Treatment Use Among Individuals with Opioid Use Disorders in the United States, 2004–2013*, 314 JAMA 1515; JONATHAN H. DUFF, CONG. RSCH. SERV., R45279, BUPRENORPHINE AND THE OPIOID CRISIS: A PRIMER FOR CONGRESS 2 (2018) (stating that as of 2015, only eighteen percent of those in need of MAT received it); see NAT’L INST. ON DRUG ABUSE, MEDICATIONS TO TREAT OPIOID USE DISORDER RESEARCH REPORT 14, <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview>; Utsha Khatri et al., *These Key Telehealth Policy Changes Would Improve Buprenorphine Access While Advancing Health Equity*, HEALTH AFFAIRS BLOG (Sep. 11, 2020), <https://www.healthaffairs.org/>. See also *Barriers to Addiction Treatment: Why Addicts Don’t Seek Help*, AM. ADDICTION CENTERS (last updated May 28, 2021), <https://americanaddictioncenters.org/rehab-guide/treatment-barriers>.

²¹ *Opioid Treatment Programs: A Key Treatment System Component*, PEW TRUSTS (July 16, 2021), <https://www.pewtrusts.org/>; *supra* note 6.

²² See *Reopening Plans and Mask Mandates for All 50 States*, N.Y. TIMES (last updated July 1, 2021), <https://www.nytimes.com/interactive/2020/us/states-reopen-map-coronavirus.html>.

unemployment rate of 3.5% suddenly grappled with an unemployment rate of 14.8%.²³ Fear, despair, and isolation swept across the nation and further exacerbated a myriad of already detrimental physical, mental, and behavioral health epidemics.²⁴ Access to healthcare became restricted as many hospitals were overwhelmed by the sheer volume of infected persons and practitioners employed social distancing measures to avoid spread of the virus.²⁵

The pandemic's impact on opioid use disorder and overdose deaths has been especially devastating. The number of overdose deaths rose 27% to 88,295 from September 2019 to August 2020.²⁶ The provisional drug overdose death count for 2020 is close to 90,000, with opioid-related deaths comprising 70-75% of these deaths.²⁷

Throughout the pandemic, the U.S. government implemented a number of emergency

²³ FALK, ET AL., CONG. RSCH SERV., R46554, UNEMPLOYMENT DURING THE COVID-19 PANDEMIC 2, <https://fas.org/sgp/crs/misc/R46554.pdf>.

²⁴ Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV 649, 716 (2020) (citing William Wan & Heather Long, 'Cries for Help': Drug Overdoses Are Soaring During the Coronavirus Pandemic, WASH. POST (July 1, 2020)).

²⁵ Robinson Meyer & Alexis Madrigal, *The U.S. Has Passed the Hospital Breaking Point*, THE ATLANTIC (Dec. 4, 2020), <https://www.theatlantic.com/health/>.

²⁶ Jesse C. Baumgartner & David C. Radley, *The Spike in Drug Overdose Deaths During the COVID-19 Pandemic and Policy Options to Move Forward*, TO THE POINT (Mar. 25, 2021), <https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward>.

²⁷ *Id.*

actions aimed at furthering efforts to combat the intensifying opioid crisis. Some of these changes may represent potential shifts in the landscape of the opioid crisis. In May 2021, President Biden signed a congressional act to extend an emergency scheduling order—originally enacted by the Drug Enforcement Agency (DEA) in 2018 and extended, for the first time in 2020—that maintained Schedule I status for fentanyl analogues under the Controlled Substances Act until October 2021.²⁸ Some fentanyl analogues are designed with minor structural changes intended specifically to circumvent the law,²⁹ and the temporary scheduling order has effectively prevented this.³⁰ Congress has hesitated to permanently enact the order.³¹

This supply-side action came in tandem with an increased focus on deregulation of MAT. In April 2021, the Department of Health and Human Services (HHS) issued guidance that removed training and certification requirements typically required for medical practitioners outside of an opioid treatment program (OTP) to prescribe and dispense buprenorphine. In response to the limitations on in-person healthcare services, HHS enacted other emergency measures to expand use of telemedicine to administer MAT. Specifically, qualified practitioners were permitted to initiate buprenorphine treatment without an in-person evaluation and prescribe

²⁸ See 21 C.F.R. § 1308.11.

²⁹ KRISTIN M. TENNYSON, ET AL., U.S. SENTENCING COMMISSION, FENTANYL AND FENTANYL ANALOGUES: FEDERAL TRENDS AND TRAFFICKING PATTERNS 7 (Jan. 2021).

³⁰ *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 3 (2019) (statement of Ms. Amanda Liskamm, Director of Opioid Enforcement and Prevention Efforts, U.S. Department of Justice).

³¹ *Id.*

buprenorphine and methadone for those patients already receiving the substances.³² In addition, HHS published guidance for states granting permission for OTPs to issue twenty-eight days of take-home methadone and buprenorphine to patients considered “stable.”³³

The Attorney General’s decision to temporarily schedule fentanyl-related substances, while effective in preventing the development and trafficking of new fentanyl analogues, diminishes the integrity of the drug scheduling process and creates unforeseen consequences for criminal justice. The DEA should expand opportunities for researchers to study fentanyl analogues so they can be properly scheduled in accordance with the Controlled Substances Act using a defensible methodology that promotes trust between the government, the American people, and the scientific community.

Efforts to regulate the supply side of the opioid epidemic will be fruitless if the demand of opioid addiction continues to grow and illicit fentanyl is more accessible than medically assisted treatments. The DEA should maintain its emergency removal of the X-waiver requirements for buprenorphine and reexamine the inflexibility of the opioid treatment program

³² Letter from Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, Drug Enforcement Agency, 2 (March 31, 2020); SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., FAQs: PROVISION OF METHADONE AND BUPRENORPHINE FOR THE TREATMENT OF OPIOID USE DISORDER IN THE COVID-19 EMERGENCY (April 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

³³ See Letter from Thomas W. Prevoznik, *supra* note 32, at 2 (March 31, 2020) (describing the emergency allowances for prescription of buprenorphine following a telephone call or video conference where an in-person evaluation would generally be required).

requirement. DEA and HHS should permanently preserve emergency measures expanding access to telemedical OUD treatment and prescription, granting discretion to physicians to treat their patients as they see fit to improve access for OUD patients otherwise limited by disability, lacking transportation access, or unable to meet the transaction costs of in-person visits.

Part I of this Comment discusses the temporary class scheduling of fentanyl analogues, its effectiveness, and its implications. Part II explores the operative removal of the X-waiver requirement during the pandemic and DEA's stringent requirements for opioid treatment programs. Part III of this Comment analyzes the emergency expansion of telemedicine and its impact on addressing OUD treatment disparities. Part IV addresses several administrative courses of action that DEA, HHS, and FDA might take to address the supply and demand components of the opioid crisis.

I. Temporary Class-Wide Scheduling of Fentanyl

Rates of opioid use disorder and overdose death correlate strongly with supply,³⁴ and over the last several decades, the federal government has made many attempts to reduce the supply of opiate drugs available to the public. In 2018, the DEA temporarily placed all fentanyl analogues into Schedule I. In April 2021, Congress extended the temporary order until October 2021.³⁵

The HHS, Substance Abuse Mental Health Services Administration (SAMHSA), the

³⁴ See generally Bryce Pardo, et al., *The Synthetic Opioid Surge in the United States: Insights from Mortality and Seizure Data*, RAND CORPORATION 3 (discussing supply-side indicators in the synthetic opioid market and their relationship to overdose rates).

³⁵ Pub. L. No. 115-114, 135 Stat. 264.

FDA, the DOJ, and the DEA are responsible for regulating controlled substances and enforcing the law. The FDA determines whether prescription drugs are safe and effective for their proposed use under the Controlled Substance Act of 1970 (CSA).³⁶ The FDA also determines whether certain substances have abuse potential such that they threaten public health. Such substances are regulated as “controlled substances” and placed into five different “schedules.”³⁷ Schedule I substances are those ruled to have no accepted medical use and high abuse potential; schedule II substances have high potential for abuse, but some medical utility; schedule III substances carry a lesser, but significant, risk of abuse and psychological dependence; and substances in schedules IV and V are purported to have low risk of abuse.³⁸ The drug scheduling process balances the interests of preventing abuse and addiction while recognizing the medical utility of certain controlled substances.

Fentanyl is a schedule II substance.³⁹ It is 50 times more powerful than heroin and 100 times more potent than morphine, and it only takes two milligrams of fentanyl to result in an overdose fatality.⁴⁰ As a full opioid agonist, fentanyl binds tightly to μ (mu) opioid receptors in

³⁶ 21 U.S.C. § 301.

³⁷ 21 C.F.R. §§ 1308.11-15; 21 U.S.C. § 802-12.

³⁸ CONTROLLED SUBSTANCE SCHEDULES, DEA, DIVERSION CONTROL DIV.,
<https://www.deadiversion.usdoj.gov/schedules/>.

³⁹ 21 C.F.R. §§ 1308.11-15; 21 U.S.C. § 812.

⁴⁰ U.S. GOV’T ACCOUNTABILITY OFF., GAO-21-499, SYNTHETIC OPIOIDS: CONSIDERATIONS FOR THE CLASS-WIDE SCHEDULING OF FENTANYL-RELATED SUBSTANCES 10 (2021).

the brain and inhibits neuronal pain signals.⁴¹ Fentanyl can depress the nervous system within minutes, making it incredibly powerful in treating breakthrough pain.⁴² Where pain is not present, this neurobiological reward system induces pleasure that can encourage repeated use and cause dependence.⁴³ High fentanyl plasma concentration can cause fatal respiratory depression.⁴⁴ Fentanyl's schedule II designation recognizes its ability to meet the legitimate needs of chronic pain and cancer patients.⁴⁵

Synthetic opioids are commonly consumed as counterfeit prescription pills containing lethal doses of fentanyl and fentanyl analogues sold illegally to unknowing users.⁴⁶ Just as

⁴¹ Jeffery Fudin, *Opioid Agonists, Partial Agonists, Antagonists: Oh My!*, PHARMACY TIMES (Jan. 6, 2018), <https://www.pharmacytimes.com/view/opioid-agonists-partial-agonists-antagonists-oh-my>.

⁴² Unlike other opioids, fentanyl can be administered in transmucosal fashion in the form of a film, spray, or patch. Theodore H. Stanley, *The Fentanyl Story*, 15 JOURNAL OF PAIN 1215, 1217-19 (Dec. 2014).

⁴³ Kosten & George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. PRAC. PERSP. 13, 14.

⁴⁴ *Id.* at 1223.

⁴⁵ Pat Anson, *How Opioid Hysteria Affects Cancer Patients*, PAIN NEWS NETWORK (May 25, 2021), <https://www.painnewsnetwork.org/stories/2021/5/25/how-opioid-hysteria-affects-cancer-patients>; *see also* Stanley, *supra* note 42.

⁴⁶ *Data Analysis and Resources*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed March 10, 2020), <https://www.cdc.gov/drugoverdose/data/analysis.html>. China is the

heroin was cheaper for addicts to obtain than prescription opioids in the early 2000s, and thus replaced the prescription drugs, fentanyl is cheaper and easier to obtain than both prescription opioids and heroin and has become the leading cause of opioid-related death.⁴⁷ Rates of opioid abuse have not increased drastically, but the introduction of fentanyl into the supply has made opioid abuse much more lethal than in previous years.⁴⁸ Scheduling determinations are typically made on an individual basis by a notice-and-comment rulemaking process that can take months to several years, so federal agencies cannot schedule the hundreds of different fentanyl analogues fast enough to be able to prosecute their manufacturers.⁴⁹

A. Legislative Background

The Harrison Narcotics Act of 1914 was the first deliberate attempt to regulate opiate

largest manufacturer and exporter of the illicit fentanyl that is distributed in the United States.

DRUG ENFORCEMENT AGENCY, DEA-DCT-DIR-009-20, FENTANYL FLOW TO THE UNITED STATES 2-3 (Jan. 2020); LIANA W. ROSEN & SUSAN V. LAWRENCE, CONG. RSCH. SERV., IF10890, ILLICIT FENTANYL AND CHINA’S ROLE (updated Jan. 29, 2021). *See* Daniel Ciccarone, *Fentanyl in the U.S. Heroin Supply: A Rapidly Changing Risk Environment*, 46 INT’L J. OF DRUG POLICY 107, 108 (describing the “positive supply shock” of synthetic opioids that began in 2013).

⁴⁷ Pardo, et al., *Understanding America’s Surge in Fentanyl and Other Synthetic Opioids*, RAND CORPORATION 3 (2019), https://www.rand.org/pubs/research_briefs/RB10091.html. *See also* Vanda Felbab-Brown, *Fentanyl and Geopolitics: Controlling Opioid Supply from China*, BROOKINGS INST. 1, 5.

⁴⁸ *Id.*

⁴⁹ Schwartzapfel *infra* note 91.

substances in response to rising rates of addiction.⁵⁰ A 1919 Supreme Court case determined that under the Harrison Narcotics Act, maintenance treatment, or the practice of using addictive substances to treat addicts, violated the law.⁵¹

Today, the CSA provides the statutory authority for DEA to make “schedule” determinations for drugs; it regulates the manufacture, possession, use, prescription, distribution, and import of substances.⁵² Certain CSA provisions control industry registration. These provisions require manufacturers, distributors, pharmaceutical companies, hospitals, pharmacies, and other practitioners to register with the DEA annually or triennially to manufacture or distribute controlled substances.⁵³ The registrations specify the extent of authorized engagement

⁵⁰ Samuel B. Waterman, *The Harrison Act and Medical Practice*, 25 GUILD PRAC. 1 (1966); see David T. Courtwright, *Preventing and Treating Narcotic Addiction—A Century of Federal Drug Control*, NEW ENGLAND J. OF MEDICINE (Nov. 26, 2015), <https://www.nejm.org/doi/full/10.1056/NEJMp1508818>; see also C. E. Terry, *The Harrison Anti-Narcotic Act*, 5 AM. J. PUBLIC HEALTH 518 (criticizing the Harrison Anti-Narcotic Act for failing to impose more severe restrictions of the prescription of opium, calling the physician “the greatest single factor in drug addict formation”).

⁵¹ See Scott, *The Pleasure Principle: A Critical Examination of Federal Scheduling of Controlled Substances*, 29 Sw. U. L. REV. 447, 455 (2000) (citing *Webb v. United States*, 249 U.S. 96, 99-100 (1919)).

⁵² 21 U.S.C. §§ 801-971. H.R. REP. No. 91-1444 (1970); *id.* (citing *Touby v. United States*, 500 U.S. 160 (1991)).

⁵³ 21 U.S.C. § 821-32.

and include a multitude of obligations.⁵⁴ Other CSA provisions delineate trafficking regulations, including production, distribution, and possession offenses and penalties.⁵⁵

A controlled substance can be scheduled, rescheduled, or removed from schedule control by an administrative process or by an act of Congress.⁵⁶ The legislative process for scheduling substances is far more direct.⁵⁷ The DEA’s schedule determinations are contingent on medical and scientific evaluations by the HHS Secretary who delegates the responsibility of performing these evaluations to the FDA.⁵⁸ The basic criteria for scheduling are also known as the “Eight Factor Analysis.”⁵⁹ The FDA’s schedule recommendations are binding, but the DEA has discretion to implement the recommendation.⁶⁰ DEA drug scheduling is subject to the notice-

⁵⁴ 21 U.S.C. § 821-32.

⁵⁵ 21 U.S.C. § 841-90.

⁵⁶ See JOANNA R. LAMPE, CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 117TH CONGRESS 8 (2019).

⁵⁷ *Id.* at 2.

⁵⁸ 21 U.S.C. § 811(a); 28 C.F.R. § 0.100(b).

⁵⁹ 21 U.S.C. § 811(c); U.S. FOOD & DRUG ADMIN., ASSESSMENT OF ABUSE POTENTIAL OF DRUGS: GUIDANCE FOR INDUSTRY 10-11 (2017). The eight factors specified in this subsection of the CSA are, “[the substance’s] actual or relative potential for abuse;” “scientific evidence of its pharmacological effect, if known;” “the state of current scientific knowledge regarding the drug or other substance;” “its history and current pattern of abuse;” “the scope, duration, and significance of abuse;” and “what, if any, risk there is to the public health.”

⁶⁰ See LAMPE, *supra* note 57, at 9.

and-comment rulemaking process.⁶¹ The Comprehensive Crime Control Act of 1984 created the legal authority for the Attorney General, in certain circumstances, to issue emergency scheduling orders.⁶²

Scheduling impacts research of controlled substances. Researchers conducting studies on controlled substances require approval from the FDA and DEA.⁶³ Ironically, one of the factors considered in FDA scheduling evaluations is, “the state of current scientific knowledge regarding the drug.”⁶⁴ These determinations require research that produces evidence that is widely accepted by the scientific community.⁶⁵ This is widely considered a gordian knot of drug scheduling determinations: the lack of credible research surrounding a controlled substance can prevent further research of the substance.⁶⁶ However, because the entire class of fentanyl analogues is controlled collectively, researchers may apply and obtain approval to study the entire class of substances rather than having to submit applications on a substance-by-substance

⁶¹ *Id.*

⁶² *Id.* at 10.

⁶³ 21 U.S.C. § 823. *See also* Michael H. Andreae, et al., *An ethical exploration of barriers to research on controlled drugs*, 16 AM J. BIOETHICS 36; JOANNA R. LAMPE, CONG. RSCH. SERV., LSB10404, AN EXPIRATION DATE FOR TEMPORARY CONTROL OF FENTANYL ANALOGUES 2 (2021); *Touby v. United States*, 500 U.S. 160 (1991).

⁶⁴ 21 U.S.C. § 811(c).

⁶⁵ 21 U.S.C. § 811(c).

⁶⁶ *See generally* Elena Quattrone, *The “Catch-22” of Marijuana [Il]legalization*, 22 BU J. SCIENCE & TECH. L. 299.

basis.⁶⁷

B. Temporary Scheduling Authority

Section 202 of the CSA, or 21 U.S.C. 811(h), gives the U.S. Attorney General legal authority to enact a temporary scheduling order.⁶⁸ The legislative history of this statutory authority demonstrates that Congress intended to prevent the development of new variations of illicit psychotropic substances.⁶⁹ In fact, the very first time the DEA issued an emergency scheduling order in 1985, it used the authority to schedule 3-methylfentanyl.⁷⁰ To justify its decision, the DEA provided evidence of thirty-one overdose deaths that resulted from consumption of the synthetic fentanyl analogue.⁷¹ Since then, the DEA has used this authority to control other “designer drugs” like 3,4-methylenedioxymethamphetamine (MDMA) analogues and synthetic cannabinoids.⁷² In order to exercise this authority, the DEA must demonstrate that the substance is an “imminent hazard” to public health and safety.⁷³ In making an emergency

⁶⁷ *Supra* note 30 at 31; *supra* note 40 at 17.

⁶⁸ 21 U.S.C. § 811(h); 21 C.F.R. § 1308.49 (2021).

⁶⁹ Olivia Castillo, *Kratom Crackdown: How DEA Abused Its Emergency Scheduling Authority under the Controlled Substances Act*, 72 U. MIAMI L. REV. 972, 996-97 (2018); *see also* Am. Pharm. Ass'n v. Weinberger, 377 F. Supp. 824, 830 (D.D.C. 1974), *aff'd sub nom.* Am. Pharm. Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976).

⁷⁰ Castillo, *supra* note 62, at 998.

⁷¹ *Id.* (citing 50 Fed. Reg. 11,690 (March 25, 1985)).

⁷² *Id.* at 998-1001.

⁷³ 21 U.S.C. § 811(h)(3).

scheduling determination, the Attorney General is required to consider “actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.”⁷⁴

Temporary scheduling orders are not subject to judicial review and the substance may only be rescheduled by legislative action.⁷⁵ Generally, a temporary scheduling order will expire two years after it is issued, but the Attorney General may further extend the order for another year after this time.⁷⁶

In February 2018, the DEA issued such an order on fentanyl and fentanyl analogues, placing them in schedule I.⁷⁷ Then, in February 2020, Congress voted to extend the order for another year.⁷⁸ In April 2021, Congress voted to extend the temporary scheduling order until

⁷⁴ 21 U.S.C. § 811(h)(3).

⁷⁵ LAMPE, *supra* note 63, at 2; Touby v. United States, 500 U.S. 160 (1991). *See also* John Hudack & Grace Wallace, *How to Reschedule Marijuana and Why It’s Unlikely Anytime Soon*, THE BROOKINGS INSTITUTION (Feb. 13, 2015), <https://www.brookings.edu/blog/fixgov/2015/02/13/how-to-reschedule-marijuana-and-why-its-unlikely-anytime-soon>.

⁷⁶ 21 U.S.C. § 811(h)(2).

⁷⁷ *See* LAMPE, *supra* note 56, at 2.

⁷⁸ *See* 21 C.F.R. § 1308.11(h) (stating, “The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule fentanyl-related substances that are not currently listed in any schedule of the Controlled Substances Act (CSA) and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers in schedule I”).

October 2021.⁷⁹ Congress expressed intent to use the order to “[deter] traffickers, manufacturers, and those distributing [fentanyl analogues].”⁸⁰ Congresswoman Cathy Rodgers acknowledged that extending the temporary order amounted to “kicking the can down the road.”⁸¹

The DEA has the authority, apart from the temporary order, to control fentanyl analogues under existing law.⁸² The 1986 Controlled Substance Analogue Enforcement Act (Analogue Act) provides the regulatory framework for control of controlled substance analogues.⁸³ The Analogue Act sets forth three criteria under which controlled substance analogues can be controlled under the CSA; one that is chemically similar to a controlled substance; has a “stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to a controlled substance;” or which a person intends to have an effect on the central nervous system that is substantially similar to a controlled substance.⁸⁴ *United States v. Forbes*⁸⁵ held that one substance is not substantially similar to another if it is not chemically similar,

⁷⁹ Extending Temporary Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 115-114, 135 Stat. 264.

⁸⁰ 167 Cong. Rec. H2025, H2025 (April 21, 2021) (statement by Rep. Pallone of New Jersey).

⁸¹ *Id.* (statement by Rep. Rogers of Washington).

⁸² *See* 21 U.S.C. § 813.

⁸³ Yandiel Muniz, *Designer Drugs and the Federal Analog Act*, FIU L. REV (Mar 11, 2017), <https://law.fiu.edu/2017/03/11/designer-drugs-federal-analog-act/>.

⁸⁴ 21 U.S.C. § 813; *McFadden v. United States*, 576 U.S. 186, 193-94 (2015) (clarifying the knowledge standard for violating the Analogue Act).

⁸⁵ 806 F. Supp. 232 (D. Colo. 1992).

cannot be synthesized from the other, and it does not have the same or similar effects as the other.⁸⁶ In other words, the Analogue Act's rule is conjunctive: the government must prove both the chemical similarity and the physiological similarity of the substance to the controlled substance.⁸⁷ Under the temporary order, Schedule I includes a definition of "fentanyl-related substance[s]" that includes a non-exclusive list of several types of structural modifications that might qualify.⁸⁸

C. Predicted Outcomes of Class-Wide Scheduling

The DEA has scheduled a scattering of fentanyl-related substances individually through administrative rulemaking.⁸⁹ Of course, the DEA can continue to schedule fentanyl analogues this way.⁹⁰ The DEA can also regulate controlled substance analogues using the analogue provisions under 21 U.S.C. § 813 and definitions under 21 U.S.C. § 802 (32), but the process of prosecuting these cases and getting a court to declare a substance as an analogue is time and

⁸⁶ *Forbes*, 806 F. Supp. 232 (D. Colo. 1992) (finding that since alphanethyltryptamine (AET) is a primary amine and dimethyltryptamine (DMT) and diethyltryptamine (DET) are tertiary amines, DMT and DET are not chemical analogues of AET).

⁸⁷ *Id.*

⁸⁸ 21 C.F.R. § 1308.11(a); *compare* 21 C.F.R. § 1308.11(e). 21 C.F.R. § 1308.11(h)(i).

⁸⁹ 21 C.F.R. § 1308.11.

⁹⁰ *See supra* note 10.

resource intensive.⁹¹ The reduced prosecutorial burden under the temporary order, according to law enforcement, is effective in reducing the number of new chemical variations of fentanyl in the illicit market.⁹² The DEA may have the authority to permanently schedule the class of fentanyl analogues if Congress does not do so, but HHS must first perform an eight-factor analysis of, presumably, the entire class of fentanyl analogues.⁹³

Maintaining the order does not align with the DEA's obligations under the CSA to evaluate substances based on their medical value and potential for abuse. Class-wide scheduling of fentanyl includes thousands of substances, some of them not even realized yet. Fentanyl analogues are not unilaterally harmful — chemical structure does not automatically predict likelihood of abuse or addiction.⁹⁴ Some of the fentanyl analogues that fall under the umbrella of

⁹¹ Beth Schwartzapfel, *Biden Could Have Taken the War on Drugs Down a Notch. He Didn't.*, THE MARSHALL PROJECT (June 16, 2021, 6:00 AM), <https://www.themarshallproject.org/>. See LAMPE, *supra* note 57; LAMPE, *supra* note 63.

⁹² Victor W. Weedn, et al., *Fentanyl-related Substance Scheduling as an Effective Drug Control Strategy*, WILEY ONLINE LIBRARY, <https://onlinelibrary.wiley.com/doi/full/10.1111/1556-4029.14712>.

⁹³ See *supra* note 10 at 16.

⁹⁴ Comer et al., *Potential Unintended Consequences of Class-Wide Drug Scheduling Based on Chemical Structure: A Cautionary Tale for Fentanyl-Related Compounds*, 221 DRUG AND ALCOHOL DEPENDENCE 1, 3 (April 2021) (stating that the “main problem with class-wide bans is that potentially thousands of compounds are defined solely by their chemical structures without regard for their pharmacological activity. As such, an antagonist (i.e., a medication that could be

this class scheduling order may not actually be harmful or have the same psychogenic effect as fentanyl. Designation as a schedule I substance means that the substance has no medical or therapeutic use, which may not be the case for all fentanyl compounds.⁹⁵ Licit fentanyl can be a lifesaving medical drug and is unique in serving the needs of patients in extreme circumstances.⁹⁶ Critics argue that fentanyl analogues will remain illegal under the Controlled Substances Act even if they are not permanently placed into Schedule I or II.⁹⁷

Critics of the class-wide order further argue that since it lowers the prosecutorial burden of proof, it will result in unfair outcomes for criminal defendants.⁹⁸ Class-wide scheduling could impose mandatory minimum sentences for drug offenders where the substance in question is not necessarily harmful, which some classify as overcriminalization akin to other policies born out of an ongoing war on drugs.⁹⁹

used to reverse an overdose but would not produce a drug “high”) could be mistakenly included in the class-wide ban”).

⁹⁵ See LAMPE, *supra* note 56, at 3.

⁹⁶ See Stanley *supra* note 42.

⁹⁷ Ronald Newman & Aamra Ahmad, *Vote “No” on H.R. 2630, Extending the Temporary Emergency Scheduling of Fentanyl Analogues Act*, AMERICAN CIVIL LIBERTIES UNION (April 20, 2021), <https://www.aclu.org/>.

⁹⁸ *Supra* note 40 at 58.

⁹⁹ As of December 2020, only eight individuals were prosecuted under the temporary scheduling order. *Id. Groups Urge US to End Emergency Scheduling of Fentanyl-related Substances*, HUMAN RIGHTS WATCH (April 8, 2021), <https://www.hrw.org/news/2021/04/08/groups-urge-us->

Many scholars, scientists, and activists have criticized legislative and administrative scheduling, asserting that kratom, psilocybin, marijuana, and other substances previously placed in Schedule I have medical benefits that ought to render them, at most severe, Schedule II substances.¹⁰⁰ Many of these substances may provide promising alternatives to opioid analgesics for pain management or addiction treatment.¹⁰¹ Maintaining the thin rope of this temporary scheduling order serves to further delegitimize both the legislative and administrative scheduling processes. Establishing more robust, transparent, and defensible methodologies for making schedule determinations will restore trust between the DEA, HHS, the American public, and the scientific community. More importantly, subjecting the decision to judicial review preserves the system of checks and balances that the framers intended.

end-emergency-scheduling-fentanyl-related-substances#. *See also* 167 Cong. Rec. H2025, H2027 (April 21, 2021) (statement by Ms. Jackson Lee, Representative from Texas).

¹⁰⁰ *American Kratom Association: HHS Rescinds Scheduling Recommendation for Kratom But FDA Failed to Notify the Public for 2 ½ Years*, PRNEWswire (Jan. 28, 2021), <https://www.prnewswire.com/news-releases/american-kratom-association-hhs-rescinds-scheduling-recommendation-for-kratom-but-fda-failed-to-notify-the-public-for-2--years-301217770.html>; Jack E. Henningfield, et al., *The Abuse Potential of Kratom According to the 8 Factors of the Controlled Substances Act: Implications for Regulation and Research*, 235 PSYCHOPHARMACOLOGY 573; Matthew W. Johnson, et al., *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143; Hudack & Wallace *supra* note 75.

¹⁰¹ *See* Castillo, *supra* note 69, at 977-984.

II. Regulatory Barriers to Opioid Use Disorder Treatments

Maintenance treatment; or the practice of supplementing a harmful, addictive substance with a less-harmful, less-addictive one; has a complex history in the United States. Over the last several decades, the medical community has driven the effort to destigmatize medical maintenance treatment, citing its life-changing effectiveness.¹⁰²

Methadone is a synthetic opioid agonist classified as a Schedule II substance.¹⁰³ It is effective both in treating chronic pain and in treating opioid addiction.¹⁰⁴ Unlike heroin, morphine, and fentanyl, methadone is slow-acting and does not produce euphoric affects.¹⁰⁵ Methadone's slow-release property is the key to its success, allowing users to avoid withdrawal

¹⁰² Sarah E. Wakeman, et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, JAMA NETWORK OPEN (Feb. 5, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032>; *Study Highlights Effectiveness of Methadone and Buprenorphine*, NAT'L INSTITUTE ON DRUG ABUSE (Feb. 28, 2020), <https://www.drugabuse.gov/news-events/science-highlight/study-highlights-effectiveness-methadone-buprenorphine>; *Methadone and Buprenorphine Reduce Risk of Death After Opioid Overdose*, NAT'L INSTITUTE OF HEALTH (June 19, 2018), <https://www.nih.gov/news-events/news-releases/methadone-buprenorphine-reduce-risk-death-after-opioid-overdose>.

¹⁰³ 21 C.F.R. § 1308.12(c)(15).

¹⁰⁴ See Marisa Crane, *Side Effects and Long-Term Effects of Methadone*, AMERICAN ADDICTION CENTERS (last updated Nov. 25, 2019), <https://americanaddictioncenters.org/methadone-addiction/side-effects>.

¹⁰⁵ *Id.*

and reintegrate into society, leading relatively normal lives.¹⁰⁶ However, users can abuse or become dependent on methadone and a methadone overdose is lethal.¹⁰⁷ At the height of its distribution in the United States, methadone was responsible for 30% of all overdose deaths.¹⁰⁸

Buprenorphine is a Schedule III substance.¹⁰⁹ It is a partial opioid agonist, meaning that when it binds to mu opioid receptors, it causes a lesser conformational change and therefore a lesser depressive effect on the central nervous system.¹¹⁰ In full agonists, as dosage increases, the analgesic affect increases, but this is not the case for partial agonists. In partial agonists, as dosage increases, the analgesic effect of the drug begins to plateau.¹¹¹ For this reason, buprenorphine and other partial agonists are less lethal than other opioid substances.¹¹² A highly successful medication for opioid use disorder is Suboxone, which is a combination of

¹⁰⁶ *Pros and Cons of Methadone*, AMERICAN ADDICTION CENTERS (last updated Feb. 3, 2020), <https://americanaddictioncenters.org/methadone-addiction/pros-cons>.

¹⁰⁷ *Id.*

¹⁰⁸ Christopher M. Jones, et al., *Centers for Disease Control and Prevention, Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths*, 65 n. 26 MORBIDITY AND MORTALITY WEEKLY REPORT 667 (2016).

¹⁰⁹ 21 C.F.R. § 1308.13(e)(2)(i).

¹¹⁰ Fudin *supra* note 41.

¹¹¹ *Id.*

¹¹² Deborah Sontag, *Addiction Treatment with a Dark Side*, N.Y. TIMES (Nov. 17, 2013), <https://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html>.

buprenorphine and naloxone.¹¹³ Naloxone works as an opioid antagonist, so the common combination of the two substances, Suboxone, works as both a maintenance and detoxification drug.¹¹⁴ A study of MAT found that buprenorphine was significantly less lethal than methadone and that methadone patients remained in treatment for approximately twice as long as buprenorphine patients.¹¹⁵

A. Legislative History Surrounding Medically Assisted Treatments

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (CDAPCA), which included the CSA, was the first legislative attempt to address the opioid crisis from an administrative and regulatory perspective,¹¹⁶ but the Narcotic Addict Treatment Act of 1974 (NATA) created an annual registration process associated with opioid treatment programs and medically assisted treatment.¹¹⁷ The purpose of NATA was to “reach the common goal of making a modality of treatment available to those narcotic addicts for whom it is deemed

¹¹³ See Wakeman, et al., *supra* note 102.

¹¹⁴ *Compared to Methadone, Suboxone is Associated with Lower Mortality but Also Less Time in Treatment*, RECOVERY RESCH. INSTITUTE, <https://www.recoveryanswers.org/research-post/suboxone-mortality/>.

¹¹⁵ *Id.*

¹¹⁶ Pub. L. No. 91-513, 84 Stat. 1234.

¹¹⁷ Pub. L. No. 93-281, 88 Stat. 124-25. See also *Statutes, Regulations, and Guidelines*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN. (last updated June 24, 2021), <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines>.

appropriate while further limiting diversion of drugs to illicit channels.”¹¹⁸ NATA was born in response to growing concerns about rising rates of diversion from methadone programs as a result of both negligence and intentional exploitation, or “unscrupulous practitioners.”¹¹⁹ It established the Attorney General’s authority to grant and suspend registrations for opioid treatment programs.¹²⁰ SAMHSA is responsible for certifying opioid treatment programs and issuing standards for treatment.¹²¹

The Drug Addiction Treatment Act of 2000 (DATA Act) created the “DATA waiver,” an avenue through which physicians meeting certain criteria could treat OUD with Schedule III, IV, or V substances (buprenorphine) outside of an OTP.¹²² The purpose of the DATA Act was “to allow qualified physicians...to prescribe schedules IV and V antiaddiction medications in their

¹¹⁸ *Regulation of Methadone and Other Narcotic Drugs in Treatment Programs, Hearing before the H. Comm. on Interstate and Foreign Commerce, 93rd Cong. 14-15, (June 18, 27, 1973)* (statement of Jerome H. Jaffe, Director, Special Action Office for Drug Abuse Prevention).

¹¹⁹ *Id.* at 22 (statement of John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs). *See also id.* at 89 (statement of Mr. Rogers, expressing concern that methadone and heroin are one in the same).

¹²⁰ Pub. L. No. 93-281, 88 Stat. 124-25.

¹²¹ *See* 42 C.F.R. § 8.11-12.

¹²² Children’s Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000) (Title XXXV is known as the DATA Act).

offices without an additional drug enforcement registration if certain conditions [were] met,”¹²³ and Congress recognized that NATA had created a barrier to these treatments for patients without access to opioid treatment programs.¹²⁴ Congress noted the difference between buprenorphine and methadone with respect to abuse potential and buprenorphine’s promising treatment effectiveness.¹²⁵ The DATA Act limited waived physicians or practice groups to a small number of patients per year.¹²⁶ It granted the HHS Secretary authority to adjust the patient limit and add to the conditions for waiver.¹²⁷ In 2001, SAMHSA issued final regulations that created the regulatory system of accrediting opioid treatment programs.¹²⁸ In 2003, SAMSHA authorized OTPs to prescribe and dispense buprenorphine.¹²⁹ In 2008, the DEA changed the DATA waiver to apply to individual practitioners instead of practicing groups, meaning that individual qualified professionals could treat up to thirty patients in a year.¹³⁰

The Comprehensive Addiction and Recovery Act of 2016 (CARA) extended the scope of

¹²³ *The Drug Addiction Treatment Act of 1999, Hearing before the Subcomm. on Health and Environment of the H. Comm. on Commerce*, 106th Cong. 2 (1999) (statement of Sen. Orrin Hatch from Utah).

¹²⁴ *Id.* at 9 (prepared statement of Sen. Carl Levin from Michigan).

¹²⁵ *Id.* at 5-6 (statement of Sen. Carl Levin from Michigan).

¹²⁶ *Id.* at 9 (prepared statement of Sen. Carl Levin from Michigan).

¹²⁷ *Id.* at 3 (prepared statement of Sen. Orrin Hatch from Utah).

¹²⁸ 42 C.F.R. §§ 8.3-15.

¹²⁹ 77 Fed. Reg. 72752, 72753 (Dec. 6, 2012).

¹³⁰ 73 Fed. Reg. 29685 (May 22, 2008); 21 C.F.R. § 1301.

DATA waivers, temporarily increasing the types of practitioners authorized to administer or dispense maintenance and detoxification treatments in Schedule III, IV, or V under DATA 2000 to include nurse practitioners and physician assistants.¹³¹ CARA increased the maximum number of patients permitted per practitioner from 30 to 100 annually.¹³² HHS issued a final rule in 2016 creating a third tier maximum of 275 patients for practitioners under 42 CFR 8.610-8.655; practitioners previously eligible to treat 100 patients could now treat up to 275.¹³³ The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act) of 2018 expanded the scope of the DATA waiver even further.¹³⁴

¹³¹ Pub. L. 114-198, 133 Stat. 695 (2016); 42 C.F.R. § 8 (implementing the CARA). *See also* Karin E. Johnson, et al., *The Effects of the Comprehensive Addiction and Recovery Act of 2016 on Nurse Practitioner and Physician Assistant Buprenorphine Prescribing in Medicaid*, HEALTH AFFAIRS (Nov. 6, 2019) (describing the consequences of the CARA Act, noting that it resulted in increased prescription of buprenorphine among nurse practitioners and physician assistants), <https://www.healthaffairs.org/doi/10.1377/hblog20191105.242580/full/>.

¹³² Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 133 Stat. 695 (2016).

¹³³ Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 17639 (Mar. 30, 2016); *Summary: Major Components of the HHS Final Rule*, AM. SOC. ADDICTION MEDICINE (July 6, 2016), <https://www.asam.org/>.

¹³⁴ Pub. L. No. 115-271, 132 Stat. 3894 (2018). The SUPPORT Act made nurse specialists, certified registered nurse anesthetists, and clinical nurse midwives permanently eligible to obtain

B. Recent Developments

In the eleventh hour of the Trump administration and the dawn of the Biden administration, HHS issued guidelines to expand patient access to buprenorphine.¹³⁵ The guidelines *exempt* practitioners from X-waiver certification requirements outlined in 21 U.S.C. § 823(g)(2)(B)(i)-(ii) of the CSA, allowing them to treat up to thirty patients. The HHS Secretary determined that these training requirements served as barriers to OUD treatments.¹³⁶

For the first time, physicians and other qualified practitioners can obtain X-waivers without fulfilling the requirements originally intended to supplement the expertise and capabilities of opioid treatment programs. DEA registration requirements and patient limits

a “DATA-waiver” and treat up to 100 patients with MAT. *See* 21 U.S.C. §§ 823(g)(2)(B)(i)-(ii). The SUPPORT Act set forth additional conditions under which practitioners could obtain DATA waivers and expanded Medicaid coverage for MAT. Eligible physicians needed eight hours of training and other providers were required to complete 24 hours of “qualifying training.” All eligible providers had to prove capacity to provide counseling and ancillary services. It also removed the thirty-patient limit that would otherwise exist during a “waivered” practitioner’s first year of administering MAT. The SUPPORT Act allowed certain providers to treat 275 patients after one year of MAT.

¹³⁵ Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 Fed. Reg. 22439 (issued in January 2021, rolled back by the Biden administration, and reinstated in April 2021).

¹³⁶ *Id.* at 22440. *See also* Hugo Hanson, *Lisa’s Legacy: How the Buprenorphine X-Waiver Costs Lives*, FILTER (Aug. 20, 2019), <https://filtermag.org/buprenorphine-x-waiver-costs-lives>.

remain for practitioners treating thirty patients. The new guidelines also allow practitioners meeting the previous X-waiver criteria to treat up to 100 patients, as opposed to thirty, in their first year of administering MAT. The guidelines apply to X-waiver medications, like buprenorphine (Schedule III), but not methadone (Schedule II), which still must be dispensed by a SAMHSA certified narcotic treatment program with a valid DEA registration.¹³⁷

The DATA Waiver has evolved considerably since it came into existence in 2000. HHS's authority to determine practitioner eligibility for waiver in administering MAT for OUD is statutory allows the HHS Secretary to "issue regulations (through notice-and-comment rulemaking) or practice guidelines to address... additional exemptions from the requirements."¹³⁸ Where previous expansions of the DATA-waiver were made through notice-and-comment rulemaking or acts of Congress,¹³⁹ this recent expansion of the X-waiver occurred via issuance of agency guidance.¹⁴⁰

Furthermore, this expansion constitutes a de facto removal of the training requirement where it previously existed to provide an alternative means for non-DEA registered practitioners to administer potentially diversion and abuse-prone drugs. Removing the waiver requirement

¹³⁷ 42 C.F.R. § 8.11.

¹³⁸ 21 U.S.C. 823(g)(2)(H)(i).

¹³⁹ 70 Fed. Reg. 36338 (June 23, 2005); 73 Fed. Reg. 29685 (May 22, 2008); 77 Fed. Reg. 72752 (Dec. 6, 2012).

¹⁴⁰ See *supra* note 135. See also Richard A. Epstein, *The Role of Guidances in Modern Administrative Procedure: The Case for De Novo Review*, 8 J. OF LEGAL ANALYSIS 47, 61 (discussing the controversial nature of the administrative "interpretive rule").

essentially removes the OTP requirement for buprenorphine altogether. The guidelines still require non-physician qualified practitioners to administer the MAT under supervision of a DEA-registered physician in a treatment setting.¹⁴¹ The training and psychosocial services requirement exists based on the assumption that medical professionals outside of an OTP have lesser knowledge of OUD treatments and diversion prevention¹⁴² and the antiquated notion that MAT for OUD must be strictly regulated.¹⁴³ The recent guidelines directly oppose these premises, reasoning that because buprenorphine poses such a minimal risk of overdose and diversion, it can and should be prescribed or administered by any willing medical professional.

C. Predicted Outcomes of the Relaxed X-Waiver Requirements

These new practice guidelines will likely increase the number of dispensers and

¹⁴¹ This schedule III substance can now be dispensed by any qualifying professional that registers with the DEA *See supra* note 135 at 22440.

¹⁴² *See Medication Assisted Treatment for Opioid Use Disorders*, 81 Fed. Reg. 44711, 44713. Ironically, many practitioners do not prescribe buprenorphine and similar drugs due to lack of training. *See Erin J. Stringfellow, et al., Removing The X-Waiver Is One Small Step Toward Increasing Treatment of Opioid Use Disorder, But Great Leaps Are Needed*, HEALTH AFFAIRS (April 22, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210419.311749/full>.

¹⁴³ Jerome Jaffe & Charles O'Keefe, *From Morphine Clinics to Buprenorphine: Regulating Opioid Agonist Treatment of Addiction in the United States*, 70 Drug and Alcohol Dependence S3, S3-S5 (2003).

prescribers of buprenorphine.¹⁴⁴ Recent history demonstrates the impact of permitting physicians to prescribe buprenorphine without additional training;¹⁴⁵ this practice has been legal in France since 1995.¹⁴⁶ When France legalized physician prescription of buprenorphine in 1995, 1 in 5 primary care providers prescribed buprenorphine, almost 50% of heroin users were treated with buprenorphine, heroin use declined, and overdose mortality fell 79%.¹⁴⁷ However, abuse of buprenorphine and methadone increased dramatically and deaths from buprenorphine overdose, while rare, did occur.¹⁴⁸ Buprenorphine itself has abuse potential,¹⁴⁹ so expanding the scope of the DATA waiver (X-waiver) will likely contribute to the risk of diversion.¹⁵⁰ In France, overdose mortality declined despite the introduction of buprenorphine into the illicit

¹⁴⁴ Max Jordan Nguemeni Tiako, *Addressing Racial & Socioeconomic Disparities in Access to Medications for Opioid Use Disorder Amid COVID-19*, 122 J. OF SUBSTANCE ABUSE TREATMENT 108214.

¹⁴⁵ M. Fatseas & Marc Auriacrombe, *Why Buprenorphine is So Successful in Treating Opiate Addiction in France*, 9 CURRENT PSYCHIATRY REPORTS 358 (2007); DUFF *supra* note 20.

¹⁴⁶ Fatseas & Auriacrombe, *supra* note 145, at 358.

¹⁴⁷ *Id.* at 360.

¹⁴⁸ Fatseas & Auriacrombe, *supra* note 145, at 360-61 (noting that most deaths listing buprenorphine as a causal factor listed a comorbid substance in the toxicology report).

¹⁴⁹ See DUFF, *supra* note 145, at 6.

¹⁵⁰ See Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder, 83 Fed. Reg. 3071, 3073-74. See also Sontag *supra* note 112.

market because buprenorphine was, in essence, the lesser of two evils.¹⁵¹ The X-waiver requirements are not likely the greatest barrier to buprenorphine treatment,¹⁵² but their removal is a positive step in expanding access. Without any change in the OTP requirement, the X-waiver changes will not improve OUD patients' access to methadone.¹⁵³

III. Deregulation of Telemedicine and Telemedical Prescriptions Related to Opioid Use Disorder Medically Assisted Treatments

Within the first several months of the COVID-19 pandemic, government agencies recognized that patients' access to non-COVID-related medical care would be severely impacted. The DEA declared a public health emergency in response to the pandemic, triggering an emergency exception provision of the CSA.¹⁵⁴ SAMHSA and the DEA issued several publications temporarily expanding the scope of telemedical services for purposes of treating opioid use disorder.¹⁵⁵

¹⁵¹ Fatseas & Auriacrombe, *supra* note 145, at 361.

¹⁵² Stringfellow et al., *supra* note 142 (citing Jefferey R. DeFlavio, *Analysis of Barriers to Adoption of Buprenorphine Maintenance Therapy by Family Physicians*, 15 RURAL REMOTE HEALTH 3019 (2015), <https://pubmed.ncbi.nlm.nih.gov/25651434/>).

¹⁵³ See *Opioid Use Disorder: Challenges and Opportunities in Rural Communities*, The Pew Charitable Trusts (Feb. 7, 2019), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/02/opioid-use-disorder-challenges-and-opportunities-in-rural-communities>.

¹⁵⁴ Determination of Public Health Emergency, 85 Fed. Reg. 7316 (Feb. 4, 2020); 21 U.S.C. § 802(54)(D).

¹⁵⁵ See part III(B-C).

A. Legislative History of Controlled Substances and the Internet

The Ryan Haight Online Consumer Protection Act of 2008 (Ryan Haight Act) amended the CSA, narrowing the ability of practitioners to prescribe controlled substances via telecommunication.¹⁵⁶ This legislation developed in response to public concerns about pharmaceutical drug diversion on the internet after teenager Ryan Haight purchased prescription drugs from an online pharmacy and died from an overdose.¹⁵⁷ The purpose of the Ryan Haight Act is to prevent the illegal “delivery, distribution, or dispensing” of controlled substances via the internet.¹⁵⁸ In stating the need for this legislation, Congress explained that “‘rogue sites’ . . . engage in the illegal practices of distributing controlled substances without prescriptions or using a truncated prescription process so flawed that medical authorities reject it.”¹⁵⁹ The Act provides that to issue a valid prescription of a controlled substance, a practitioner must perform an in-

¹⁵⁶ 21 U.S.C. § 841(h)(1); 21 C.F.R. §§ 1301, 1306. *See* Ryan Haight Online Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (Oct. 15, 2008).

¹⁵⁷ *See* Dillon Vaughn, *Amending the Ryan Haight Act: Elevating Telemedicine Law to New Heights*, 7 Tex. A&M L. Rev. 475, 477 (emphasizing that Ryan Haight obtained the drugs without any contact with a physician).

¹⁵⁸ *See* Nathaniel M. Lacktman & Thomas B. Ferrante, *Congress Proposes Change to Ryan Haight Act to Allow Telemedicine Prescribing of Controlled Substances*, FOLEY & LARDNER LLP (March 5, 2018), <https://www.foley.com/en/insights/publications/2018/03/congress-proposes-change-to-ryan-haight-act-to-all>. *See also* H.R. REP. NO. 110-869 (2008).

¹⁵⁹ S. REP. NO. 110-521, 3 (2008).

person physical evaluation.¹⁶⁰ The Ryan Haight Act serves as a barrier to adequate access to healthcare for individuals seeking medically assisted treatment for opioid use disorder.¹⁶¹

The Ryan Haight Act includes some exceptions under which the DEA may authorize the prescription of controlled substances through telemedicine. The act allows the DEA to grant exceptions to the rule, at their discretion, by issuing special registrations to medical practitioners “[demonstrating] a legitimate need for the special registration” insofar as they are within the limits imposed by diversion prevention measures and overall “consistent with the public health and safety.”¹⁶² The DEA has not yet utilized this discretionary power.¹⁶³ The act also permits the DEA to grant these exceptions during a public health emergency.¹⁶⁴

When the HHS Secretary declared the COVID-19 pandemic a public health emergency in January 2020,¹⁶⁵ it gave the DEA the statutory authority to remove obstacles to practitioners in leveraging telemedicine to prescribe MATs.¹⁶⁶

B. New Flexibilities in Initiating Medically Assisted Treatment

Under the Ryan Haight Act, the Substance Abuse and Mental Health Services

¹⁶⁰ See Ryan Haight Online Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (Oct. 15, 2008); *see also* 42 C.F.R. § 8.12(f)(2).

¹⁶¹ See Vaughn, *supra* note 157, 482.

¹⁶² See DOOLING & STANLEY, *supra* 84 at 13 (citing 21 U.S.C. § 802(54)(G)).

¹⁶³ See Vaughn, *supra* note 157, 478.

¹⁶⁴ 21 U.S.C. § 802(54)(D).

¹⁶⁵ Determination of Public Health Emergency, 85 Fed. Reg. 7316 (Feb. 4, 2020).

¹⁶⁶ 21 U.S.C. § 802(54)(D).

Administration (SAMHSA) requires opioid treatment programs to evaluate patients in person before issuing buprenorphine, methadone, or directly dispensing the substances.¹⁶⁷ However, in January 2020, SAMHSA cited its statutory authority to remove the “in person” initiation requirement for buprenorphine due to the “extraordinary circumstances” presented by the COVID-19 pandemic.¹⁶⁸ Under SAMHSA’s guidelines, a practitioner, including DATA-waived practitioners, may initiate medically assisted treatments with buprenorphine following telemedicine evaluations, but these must include “two-way, interactive audio-visual communication” or communication via telephone.¹⁶⁹ Of course, all prescriptions issued under

¹⁶⁷ 42 C.F.R § 8.12(f)(2).

¹⁶⁸ 42 C.F.R. § 8.11(h); *See* SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency* (April 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>. In March, SAMSHA also published a notice relaxing penalties for HIPAA violations occurring through telehealth channels. *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>; *supra* note 135; 42 C.F.R. § 8.11(h) (stating, “An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and § 8.12).

¹⁶⁹ *See supra* note 33.

the new guidelines must be issued for “a legitimate medical purpose” under the CSA¹⁷⁰ and otherwise comply with all other laws surrounding the prescription of MATs. The DEA issued complimentary guidance supporting these changes.¹⁷¹ However, this change did not apply to medically assisted treatment with methadone, nor did it remove license and DEA requirements for practitioners.¹⁷²

C. New Flexibilities in Treating Existing Patients

“Take-home” medicine regulations, while important for preventing diversion and overdose of certain substances, limit the logistical benefits of telehealth care by forcing patients to pick up prescriptions at pharmacies or OTPs. Limitations on take-home medications for OUD patients became impractical given the pandemic environment.¹⁷³ The January 2020 emergency provisions from SAMHSA—and subsequently, the DEA—granted a temporary emergency exception to allow providers to continue administering controlled substances, including buprenorphine and methadone, to current OTP patients via telemedicine.¹⁷⁴ SAMHSA allowed

¹⁷⁰ 21 C.F.R. § 1306.04(a).

¹⁷¹ Letter from Thomas Prevoznik, Deputy Assistant Admin., Drug Enforcement Admin., to DEA Qualifying Practitioners (Mar. 31, 2020), <https://www.deadiversion.usdoj.gov/>.

¹⁷² 21 C.F.R. § 1306.07(a).

¹⁷³ 42 CFR § 8.12(h)(4)(i) (delineating eight factors that ought to be considered in determining whether a patient should be allowed to take more than one dose of medication home).

¹⁷⁴ *See supra* note 32. The issuance of this provision also means that doctors can prescribe opioid analgesics via telemedicine. *See also* Larry Beresford, *Docs Can Prescribe Opioids Via*

“stable patients” to take twenty-eight days of medicine home and “less stable patients” to take fourteen days of medicine home, essentially expanding the practitioner’s discretion to make these determinations.¹⁷⁵

D. Analysis of Legal Authorities

These public health emergency provisions are set to expire when the COVID-19 pandemic ends, but many healthcare professionals, politicians, and activists are pressuring the DEA to maintain these provisions for the benefit of OUD patients.¹⁷⁶ Several states are looking to pass legislation that would permanently remove regulatory barriers for medical professionals to treat patients via telemedicine and expand Medicaid coverage for telehealth services.¹⁷⁷

Telemedicine, For Now, MEDPAGE TODAY (Nov. 29, 2020),

<https://www.medpagetoday.com/practicemanagement/telehealth/89881>.

¹⁷⁵ SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Opioid Treatment Program (OTP) Guidance*, (last updated Mar. 19, 2020),

<https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. *See also* DRUG

ENFORCEMENT AGENCY, DEA075, HOW TO PRESCRIBE CONTROLLED SUBSTANCES TO PATIENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY.

¹⁷⁶ *See* Khatri et al., *supra* note 20.

¹⁷⁷ Marcia Augsburger, *Are States Making COVID-19 Telehealth Emergency Measures Permanent?*, JD SUPRA (June 9, 2021), <https://www.jdsupra.com/legalnews/are-states-making-covid-19-telehealth-6840706>; Matthew M. Shatzkes & Ehiguina L. Borha, *The State of Telehealth: Illinois Moves to Expand Telehealth Coverage*, NAT’L L. REV. (June 8, 2021), <https://www.natlawreview.com/article/state-telehealth-illinois-moves-to-expand-telehealth->

The pandemic effectively catalyzed the issuance of these emergency exemptions, but the DEA had the legal authority to implement the changes before the pandemic. The HHS Secretary under the Trump administration declared the opioid crisis a public health emergency in 2017.¹⁷⁸ The DEA could have implemented these emergency provisions under the public health emergency exception as it applies to the opioid crisis in general and the DEA can maintain the provisions now under the same exception, especially considering the recent uptick in fentanyl and other opioid overdoses.¹⁷⁹ If an administration makes a public health emergency declaration but refuses or simply fails to fulfill the obligations that underly the declaration, then the declaration is nothing more than an instrument of political posturing.

The Ryan Haight Act offers other exceptions that grant SAMHSA and the DEA authority to allow practitioners to use telemedicine to perform medical evaluations to prescribe controlled substances in special circumstances, regardless of whether a public health emergency exists.¹⁸⁰

coverage. *See also* Michael G. Lisitano & Nathaniel T. Arden, *Connecticut Governor Ned Lamont Signs Legislation Extending Expansion of COVID-19 Telehealth Services*, NAT'L L. REV. (May 19, 2021), <https://www.natlawreview.com/article/connecticut-governor-ned-lamont-signs-legislation-extending-expansion-covid-19>.

¹⁷⁸ Rebecca L. Haffajee & Richard G. Frank, *Making the Opioid Public Health Emergency Effective*, 75 n. 8 JAMA PSYCHIATRY 767 (2019).

¹⁷⁹ 21 U.S.C. § 802(54)(D). XAVIER BECERRA, RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (Apr. 15, 2021).

¹⁸⁰ *See* VICTORIA L. ELLIOTT, CONG. RSCH. SERV., R45240, THE SPECIAL REGISTRATION FOR TELEMEDICINE: IN BRIEF 3 (2018) (citing Letter from Senator Claire McCaskill, Senator Lisa

Specifically, law defines the “practice of telemedicine” to include remote treatment in accordance with “applicable Federal and State laws...which is being conducted under any other circumstances with the Attorney General and the [HHS] Secretary have jointly... determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.”¹⁸¹ Issuing joint regulations would make the current allowances for DATA-waived practitioners permanent.¹⁸² Telehealth providers who establish relationships with their patients over the telephone or via a videoconference, and can perform an adequate evaluation through this channel, deserve to exist in a separate category from “rogue sites.”¹⁸³

In addition, the DEA has the legal authority to create a special registration program for telemedicine practitioners wishing to prescribe buprenorphine.¹⁸⁴ Since the Special Registration for Telemedicine Act of 2018 (SRTA), a chapter of the SUPPORT Act, required the DEA to

Murkowski, and Senator Dan Sullivan to Robert W. Patterson, Acting Administrator, DEA, Jan. 30, 2018), <https://fas.org/sgp/crs/misc/R45240.pdf>.

¹⁸¹ 21 U.S.C. § 802(54)(G); BRIDGET C.E. DOOLING & LAURA STANLEY, GW REGULATORY STUDIES CENTER, EXTENDING PANDEMIC FLEXIBILITIES FOR OPIOID USE DISORDER TREATMENT: TELEMEDICINE & INITIATING BUPRENORPHINE TREATMENT 14 (2021), <https://regulatorystudies.columbian.gwu.edu/>.

¹⁸² *Id.* at 11-15. SAMHSA would need to exercise its authority under 42 C.F.R. § 8.11(h) to alter requirements for telemedical opioid treatment programs in order to provide for the same flexibility.

¹⁸³ See Vaughn, *supra* note 157; see also DOOLING & STANLEY, *supra* note 181.

¹⁸⁴ See 21 U.S.C. § 802(54)(E); DOOLING & STANLEY, *supra* note 181.

create specific rules to launch the special registration program, the DEA is legally obligated to do so.¹⁸⁵ The Act specified that the DEA was to generate the regulations within one year.¹⁸⁶ Through SRTA, Congress expressed intent to expand patients' access to telemedicine in response to a shortage in mental health care providers.¹⁸⁷ While the DEA has not yet issued these regulations, it still has an opportunity to design the regulations in a manner that responds adequately to the needs of patients relying on telehealth for maintenance or detoxification treatment.

IV. Recommendation

Our government agencies are responsible for implementing and enforcing the law. The DEA and HHS alone do not have the authority to permanently schedule an entire class of fentanyl analogues.¹⁸⁸ However, these agencies do have the authority to benefit the population of Americans affected by opioid use disorder by lessening regulatory obstacles to medically assisted treatment.

A. Fentanyl

History has proven that the government is ineffective in curbing rates of substance abuse. Substance abuse, like other behavioral disorders, is, in large part, a cultural symptom: sometimes

¹⁸⁵ ELLIOTT, *supra* note 180.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 1.

¹⁸⁸ *Supra* part I(B).

an act of nihilism and despair.¹⁸⁹ Substance abuse is also largely supply-driven. The United States government has succeeded in plateauing rates of abuse and overdose of certain substances by limiting their supply.¹⁹⁰ Despite many efforts to prevent synthetic opioids from falling into the hands of the American public, synthetic opioid-related deaths have continued to rise.¹⁹¹ Placing fentanyl-related substances in Schedule I and to create a threat of harsher punishment can only go so far in preventing drug traffickers from bringing fentanyl into the United States.

The FDA and HHS have incredible discretion in drug scheduling and their decisions have far reaching effects.¹⁹² However, the DEA does not have the authority to schedule an entire class of substances because the required administrative process entails testing and making determinations about individual substances.¹⁹³ It is not feasible for the DEA to continue in a struggle to predict which new modified of fentanyl analogue will enter the illicit market next.

¹⁸⁹ See Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. CHICAGO L. REV. ONLINE, <https://lawreviewblog.uchicago.edu/2020/11/16/covid-oliva/> (discussing the rise of “deaths of despair” over the last two decades).

¹⁹⁰ See *supra* note 12 (noting that rates of prescription opioid deaths declined when government implemented diversion-preventing measures).

¹⁹¹ *Supra* part I(A).

¹⁹² See Castillo, *supra* note 29. See also Naseem S. Miller, *Racial Disparities in Opioid Addiction Treatment: A Primer and Research Roundup*, THE JOURNALIST’S RESOURCE (May 17, 2021), <https://journalistsresource.org/home/systemic-racism-opioid-addiction-treatment>; Schwartzapfel, *supra* note 91.

¹⁹³ *Supra* part I(C).

The administrative process of scheduling is not designed for entire classes of substances.

If Congress believes, based on a reconciliation of the three major factors—potential for abuse or dependence, medical utility or benefit, lethality, and the cost of failing to schedule the substances—then as the representative body of the American people it should perform the bioethical analysis that may ultimately place fentanyl-related substances into Schedule I.

However, should Congress decide to schedule all fentanyl-related substances under Schedule I, it must consider the broad nature of this prospective legislation and attempt to address the “unintended consequences” of class-wide scheduling legislation.¹⁹⁴ If Congress does this, then the temporary scheduling order will end, and the decision will be subject to judicial review,¹⁹⁵ enabling courts to address the constitutionality of class-wide scheduling.

Expediting research of fentanyl analogues and rescheduling improperly scheduled substances is of the utmost importance in preserving the scientific legitimacy of drug scheduling. In order to prevent the legislation from restricting vital research,¹⁹⁶ Congress should task the DEA with expediting the process and lowering the transaction costs of obtaining the necessary registration to research fentanyl-related substances. For example, the DEA could increase the volume of schedule I substances that may be used for research purposes, especially those that have been proven to treat pain and addiction, including cannabis, ibogaine, and psychedelics.¹⁹⁷

¹⁹⁴ Comer et. al, *supra* note 94.

¹⁹⁵ LAMPE, *supra* note 63, at 2.

¹⁹⁶ See *supra* note 94, at 3-6 (discussing the potential of fentanyl analogs in treating OUD).

¹⁹⁷ Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV 649, 716 (2020).

Lethality, both short-term and long-term, ought to be the most heavily weighted factor in schedule determination if the intent of these regulations is to protect consumer health.

The fact that the DEA is overwhelmed by the volume of fentanyl-related substances should not prevent it from petitioning HHS to perform a scientific evaluation of these substances. There is no doubt fentanyl is here in the United States, and a single kilogram of it has the potential to cause 500,000 overdose deaths.¹⁹⁸ Even if class-wide scheduling prevents the rise of new fentanyl analogues, it will not likely prevent existing illicit channels from operating. Apart from preventing fentanyl from entering the United States, federal agencies must continue to address the other side of the fight by diminishing the demand for fentanyl and fentanyl-related substances by treating opioid addicts.

B. Buprenorphine

The DEA should initiate rulemaking procedures to permit all licensed, registered physicians to prescribe buprenorphine under the regular registration process for administering controlled substances. It is difficult, even without these barriers, to motivate addicts to seek treatment for their addiction and to identify practitioners willing and able to prescribe buprenorphine.¹⁹⁹ Doctors, pharmacists, and mid-level practitioners are required to obtain

¹⁹⁸ *See supra* note 40, at 10.

¹⁹⁹ A 2019 study determined that of all Americans struggling with a substance use disorder, 95.7% “did not feel that they needed treatment,” 1.2% “felt they needed treatment and made an effort to get treatment,” and 3.0% “felt they needed treatment and did not make an effort to get treatment.” The most common reason that someone with a substance use disorder did not receive treatment was “not being ready to stop using.” SUBSTANCE ABUSE AND MENTAL HEALTH

licenses to dispense controlled substances, including Schedule III substances like buprenorphine, regardless of whether they are being used for opioid use disorder treatment or not.²⁰⁰

Buprenorphine is not a substance with a high likelihood of abuse and diversion.²⁰¹ The inevitable diversion of some partial agonists is better than allowing addicts to fall victim to counterfeit pills laced with fentanyl. The French government has succeeded wildly in reducing rates of overdose by deregulating less lethal buprenorphine.

The Controlled Substance Act provides the authority for the DEA and SAMHSA to remove the OTP requirement and its related waiver requirement altogether.²⁰² While the intent of the DATA Act was not to eliminate the OTP requirement, but to supplement it under “very careful conditions,” Congress has made a clear effort over the last two decades to relax these conditions for the prescription of buprenorphine.²⁰³ The DATA Act explicitly permits the Attorney General and HHS Secretary to exempt practitioners from the conditions required to obtain the waiver.²⁰⁴

As previously noted, this change does not affect the administration of methadone.²⁰⁵ All

SERVS. ORG., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2019 NATIONAL SURVEY ON DRUG USE AND HEALTH 54 (Sep. 2020).

²⁰⁰ 21 C.F.R. § 1301.11

²⁰¹ *Supra* part I(A).

²⁰² *Supra* part II(B).

²⁰³ *Supra* note 125, at 6.

²⁰⁴ *See* 21 U.S.C. 823(g)(2)(H)(i)(II).

²⁰⁵ *See* part II(C).

evidence demonstrates that the existing OTP requirement for the provision of methadone is appropriate given its risk of diversion, abuse, and overdose.²⁰⁶ In France, it was the increase in buprenorphine prescriptions that rescued users from the high-risk alternative of methadone treatment.²⁰⁷ However, methadone is an essential tool for allowing OUD patients to reintegrate and participate socially and the OTP requirement limits patient access to methadone.²⁰⁸ Therefore, as the following section discusses, the DEA and SAMHSA must make an effort to broaden the definition of “qualified program” to account for advancements in technology and the increasing needs of marginalized communities.²⁰⁹

When the DEA and HHS regulate substances differently solely on the basis of whether they are used as painkillers or as maintenance and detoxification treatments, this stigmatizes the condition of substance dependence itself. Federal agencies must recognize opioid addiction as the life-threatening behavioral disorder that it is in order to shed the vestiges of historical stigma against opioid users.

C. Telehealth Expansions for Treating Opioid Use Disorder

Over the last decade, the American public has gained awareness of the disparate impact of the opioid crisis on low-income and rural communities and the cost of the opioid crisis in general. The DEA and HHS have failed to exercise their respective authorities under existing legislation to meet the evolving needs of these communities and the evolving threat that haunts

²⁰⁶ Crane, *supra* note 104.

²⁰⁷ Fatseas & Auriacrombe, *supra* note 145.

²⁰⁸ See Oliva, *supra* note 189.

²⁰⁹ *Infra* part IV(C).

them. The DEA and SAMHSA should not rescind the measures that they implemented to mitigate the “extraordinary circumstances” of the pandemic, the extraordinary circumstances of the opioid crisis are sufficiently dire.²¹⁰

The DEA should maintain its exemption for practitioners from the in-person requirement under 21 U.S.C. § 802(54)(D). Telehealth removes many transaction costs for patients, expanding the reach of the few healthcare providers willing and able to prescribe substances like buprenorphine. This would not mandate the prescription of buprenorphine over the internet or telephone, but it would give practitioners the option to do so, exercising their own professional judgment in how to best evaluate and treat their patients. One factor preventing doctors from abusing this flexibility is fear of liability for medical malpractice.²¹¹ The current exemption only applies to substances that a practitioner is registered to prescribe.²¹² Since X-waivered practitioners can prescribe buprenorphine and not methadone, for example, the exemption will not permit them to prescribe methadone via telemedicine. The DEA should also fulfill its legal obligation under SRTA to create a special registration program for telehealth providers.²¹³

SAMHSA should revisit its opioid treatment program requirements under 21 C.F.R § 8.12 to account for advancements in telemedicine in defining opioid treatment standards.

²¹⁰ See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION *supra* note 168.

²¹¹ Apart from following federal guidelines, physicians are required to follow state, medical board and manufacturer guidelines for prescribing opioids. See also Y. Tony Yang, *Managing Increasing Liability Risks Related to Opioid Prescribing*, AM. J. MEDICINE (Sep. 16, 2016).

²¹² DOOLING & STANLEY, *supra* note 181, at 11.

²¹³ See part III(D).

Because new telehealth technology is emerging, “take-home” use of controlled substances may not necessarily be unsupervised use; telemedicine can allow practitioners to adequately observe patients and has been proven to improve medicine adherence.²¹⁴ SAMHSA should also change its “take-home” guidelines to account for buprenorphine’s low lethality and diversion risk by raising the maximum number of buprenorphine doses that patients may possess for self-administration. SAMHSA and DEA should continue to explore other avenues of approach in expanding the physical reach of opioid use disorder treatment by reexamining its OTP and OTP registration requirements.²¹⁵

²¹⁴ See 21 C.F.R. § 8.12(h)(4)(i); see *Telemedicine and Patient Safety*, PATIENT SAFETY NETWORK (Sep. 1, 2016), <https://psnet.ahrq.gov/perspective/telemedicine-and-patient-safety> (demonstrating that telemedicine improves patient monitoring and care). See also Eric Wicklund, *Using Telehealth to Help Patients With Medication Adherence*, MHEALTHINTELLIGENCE (Mar. 9, 2018), <https://mhealthintelligence.com/news/using-telehealth-to-help-patients-with-medication-adherence>.

²¹⁵ Christine Vestal, *Federal Ban on Methadone Vans Seen as Barrier to Treatment*, THE PEW CHARITABLE TRUSTS (March 23, 2018), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/03/23/federal-ban-on-methadone-vans-seen-as-barrier-to-treatment>; *Opioid Use Disorder: Challenges and Opportunities in Rural Communities*, THE PEW CHARITABLE TRUSTS (Feb. 7, 2019), <https://www.pewtrusts.org/en/research-and-analysis/factsheets/2019/02/opioid-use-disorder-challenges-and-opportunities-in-rural-communities>. See 86 Fed. Reg. 33,861 (allowing mobile components of OTPs to dispense substances without a separate registration with DEA) (final rule effective July 28, 2021).

Conclusion

The battle against opioid use disorder in the United States is evolving. On one side, synthetic opioids are dominating the illicit market and increasing the lethality of the disorder. Maintaining the DEA's temporary class-wide scheduling order on fentanyl analogues is not a proper exercise of the agency's authority. The DEA can and should make an effort to expedite research of fentanyl analogues in order to schedule them properly, but ultimately Congress must balance the costs of class-wide scheduling against the benefit of disincentivizing illicit manufacturers from creating new synthetic opioids.

On the other side, modern medicine and advancing technology show promise in increasing patients' access to treatment when government gets out of the way. Use of buprenorphine produces positive results in curbing addiction and it poses only a very slight risk of overdose. The recent loosening of X-waiver requirements is an encouraging but insufficient step in expanding availability of buprenorphine; allowing all licensed physicians to prescribe the substance, as France did, would be more appropriate, especially given the low associated risk and the high associated reward. In addition, agencies must adapt their regulations to accommodate the technological strides in medicine that have arisen in response to the market that demands them. Upholding emergency provisions to deregulate telemedical opioid treatment is appropriate given the ongoing emergency of the opioid crisis; the DEA can further acknowledge the urgency of the situation by creating the new telemedicine regulations that Congress tasked it with creating years ago. In this way, government agencies can reflect our modern understanding of addiction and the cruciality of these health services.