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Do No Good: How Controlled Substance Regulations Prohibit the Use of Telemedicine to Provide Medication-Assisted Therapy for Opioid Use Disorder

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DO NO GOOD: HOW CONTROLLED SUBSTANCE REGULATIONS PROHIBIT THE USE OF TELEMEDICINE TO PROVIDE MEDICATION-ASSISTED THERAPY FOR OPIOID USE DISORDER

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I. INTRODUCTION

It started off innocently enough. As you walked around the corner you failed to see the forklift, and the driver failed to see you. You could feel the pain in your shoulder before you even hit the floor. The surgeon said it would be an easy recovery. For two months, you drove an hour to the city once a week, either to see the surgeon or for physical therapy. Those two months you used sick leave; actually, all of your sick leave and a few unpaid days since you had not been working long enough to qualify for the Family Medical Leave Act ("FMLA").[1] When you missed your second appointment, the surgeon dismissed you for failure to follow-up. After some pleading, you convinced your doctor, the only doctor in your town of fifteen hundred, to write prescriptions for your pain medicine.

That was eight months ago. Your doctor, a kindly, older man with a friendly bedside manner and a candy dish in the lobby, was not as strict as the surgeon; he did not have the time or training to monitor for the signs of addiction or misuse. He was not aware, and you did not volunteer, that you sometimes buy extra pills from friends because you sometimes need more than you did before. Once, he refused to write your prescription. You panicked and visited your mom. Seeing mom always helps. And you knew she still had your dad's pain medicine from when he had cancer. After stealing pills from a dead parent to treat pain from shoulder surgery, pain that should no longer be there, you realize you need to make a change. You talk to your doctor. You tell him about the extra pills. You tell him that you want to stop. He tells you about treatments available, about therapy and medications that are very effective when combined. Then the excitement turns to concern. Doctors need a special license to prescribe those medications and no one in town has it. He says that he can set up an appointment for you with a doctor in the city. You will have to take off more time from work.

Despite the current headlines, the Opioid Epidemic is a recurring theme in human history. And Opioid Use Disorder ("OUD"), while a relatively new diagnosis, is also an old problem.[2] Since humankind first discovered the opium poppy,[3] and especially since a

1. The Family Medical Leave Act provides employees with job-protected unpaid leave for qualified medical and family reasons. There are requirements to qualify, which include minimum hours worked and time employed. *See FMLA Frequently Asked Questions*, U.S. DEP'T. OF LABOR, https://www.dol.gov/agencies/whd/fmla (last visited Jan. 24, 2021).

2. Sankar Banyopadhyay, *An 8,000-year History of Use and Abuse of Opium and Opioids: How That Matters for a Successful Control of the Epidemic?*, NEUROLOGY (Apr. 16, 2019), https://n.neurology.org/content/92/15_Supplement/P4.9-055.

3. 21 U.S.C. § 802(19). Papaver somniferum, commonly called the opium poppy, is a flowering plant. It is the source of opium as well as poppy seeds for muffins. *Breadseed or Opium Poppy, Papaver somniferum,* WISCONSIN MASTER GARDENER (June 12, 2017), https://mastergardener.extension.wisc.edu/files/2017/06/Papaver_somniferum.pdf.

pharmacist discovered morphine,[4] humans have had a love-hate relationship with this drug. Human history, dating back to the dark ages, reveals attempts to alleviate pain and ease suffering.[5] Following the Civil War and the discovery of morphine,[6] it became very fashionable to treat even the mildest of pain with the strongest pain medicine ever discovered.[7] America's first opioid epidemic was in the late 1800s.[8] Primarily upper-middle-class white women, with the financial means to visit a physician, were overprescribed potent painkillers for everything from diarrhea to a toothache and from a cough to menstrual cramps.[9]

Telemedicine could provide another treatment option for the current opioid crisis. Though telehealth has been defined in broad terms encompassing almost any health-related activity combined with technology, telemedicine is the provision of typically in-person care via real-time videoconferencing equipment.[10] As technology has improved, telemedicine has advanced to include patient monitoring functions, diagnostic tests, and access to specialists located hundreds of miles from the patient.[11] The latter development, connecting patients with specialists that are otherwise out of reach, would be especially useful for the current opioid epidemic.

Medication-assisted therapy ("MAT") is the "use of medications, in combination with counseling and behavioral therapies, to provide a 'whole patient' approach to treatment of OUD."[12] However, due to regulations designed in part to help limit the illicit distribution of controlled substances and in part to punish those unfortunate enough to develop OUD, medication-assisted therapy has several artificial roadblocks. While the federal government has placed no limits on the number of patients a physician can treat

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4. Gillian R. Hamilton & Thomas F. Baskett, *In the Arms of Morpheus: the Development of Morphine for Postoperative Pain Relief*, 47 CAN. J. ANESTHESIA 367, 369 (2000).

5. Michael J. Brownstein, *A brief history of opiates, opioid peptides, and opioid receptors*, 90 PROC. NAT'L. ACAD. SCI. 5391 (1993).

6. Gillian R. Hamilton & Thomas F. Baskett, *supra* note 4, at 368.

7. Ramtin Arablouei & Rund Abdelfatah, *A History of Opioids in America*, NPR (Apr. 4, 2019), https://www.npr.org/2019/04/04/709767408/a-history-of-opioids-in-america.

8. *Id.*

9. Mark R. Jones, et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN & THERAPY 13, 15 (2018); *See* David Herzberg, *Entitled to Addiction? Pharmaceuticals, Race, and America's First Drug War,* 91 BULLETIN INST. HIST. MED. 586 (2017). Mr. Herzberg's article notes the preferential status federal drug law has created for white men and women, but especially upper-middle class white women, when accessing healthcare and obtaining controlled substances. This disparity was explored in recent research estimating that an additional 14,000 opioid-related deaths would have occurred if black Americans were prescribed opioids at a rate equal to white Americans. *See* Monica Alexander, et al., *Trends in Black and White Opioid Mortality in the United States, 1979-2015*, 29 EPIDEMIOLOGY 707, 707–08 (2018); Austin Frakt & Toni Monkovic, *A 'Rare Case Where Racial Biases' Protected African-Americans*, N.Y. TIMES (Nov. 25, 2019), https://www.nytimes.com/2019/11/25/upshot/opioid-epidemic-blacks.html; *see also* Arablouei & Abdelfatah, *supra* note 7.

10. Eric Wicklund, *Is There a Difference between Telemedicine and Telehealth?*, MHEALTH INTELLIGENCE (June 3, 2016), https://mhealthintelligence.com/features/is-there-a-difference-between-telemedicine-and-telehealth.

11. *Telehealth, Telemedicine and Telecare: What's What?*, FED. COMMC'NS COMM'N, https://www.fcc.gov/general/telehealth-telemedicine-and-telecare-whats-what [hereinafter FCC].

12. *Chapter 38 - Internet Eligible Controlled Substance Provider Designation*., INDIAN HEALTH SERV., https://www.ihs.gov/ihm/pc/part-3/chapter-38-internet-eligible-controlled-substance-provider-designation/.

with opioids,[13] there is a limit on the number of patients with OUD a physician can help.[14] Providers who wish to provide MAT must meet certain educational requirements and enroll in a special program with the Drug Enforcement Agency ("DEA").[15] Until recently, enrollment was limited to physicians, excluding nurse practitioners and physician assistants who make up the majority of providers in rural settings.[16] The use of telemedicine to deliver MAT therapy would greatly expand access to this effective OUD treatment. The combination of telemedicine and MAT would especially benefit rural patients, where opioid addiction is prevalent and access to addiction treatment practitioners is limited.[17]

This comment begins by explaining the history of opioid use and abuse, the development of telemedicine, and how current controlled substance legislation prevents the use of telemedicine to address the opioid crisis. Part II covers the history and development of opioids, briefly explaining the physiology of pain and opioids in the body; it explores the physiology and psychology of opioid addiction and the paradigm shift to opioid use disorder as a way of viewing addiction as a chronic disease state that can be treated.

Part III explores legislation designed to regulate the use and distribution of controlled substances. The Harrison Narcotics Act, passed in 1914, was the federal government's first attempt at controlled substance regulation. The Controlled Substance Act ("CSA"), passed in 1970, serves a broad purpose of regulating the manufacture, importation, and distribution of controlled substances.[18] It also regulates healthcare and medical practices involving controlled substances, including restrictions on where and how addiction treatment can be provided.[19] The Drug Addiction Treatment Act of 2000 amended the CSA to allow qualified physicians to prescribe narcotics for the purpose of treating OUD on an out-patient basis. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act"), an amendment to the CSA, places restrictions on prescribing controlled substances via the internet.

Part IV examines case law and other evidence to demonstrate that the Ryan Haight Act was unnecessary and ineffective legislation. Part IV then provides a prescription for legislative and regulatory solutions to allow the adoption of telemedicine to address the opioid crisis and shortage of substance abuse practitioners. Using telemedicine to provide medication-assisted therapy would provide a dramatic increase in treatment options for those diagnosed with OUD. Part IV advocates for an update to the definition of

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13. *See generally* Akshara Menon, et al., *Prescription Drug Time and Dosage Limit Laws,* PUB. HEALTH LAW (Mar. 5, 2015), http://www.cdc.gov/phlp/docs/menu_prescriptionlimits.pdf (summarizing and referencing laws regulating controlled substance prescriptions.).

14. 21 U.S.C. § 823(g)(2)(B)(iii)(I).

15. *Become a Buprenorphine Waivered Practitioner*, SAMHSA (last updated Sept. 1, 2020), https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner.

16. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 721–23 amended the Controlled Substances Act to allow qualified nurse practitioners and physician assistants to provide OUD treatment to patients in an office-based setting.

17. *Drug Overdose in Rural America*, CDC, https://www.cdc.gov/ruralhealth/drug-overdose/ (last visited Dec. 20, 2020).

18. 21 U.S.C. § 801

19. *See* 21 U.S.C. §§ 353(b), 802(21), and 829(b).

telemedicine to reflect advances in technology and changes in practice. It suggests that Congress remove the in-person medical examination requirement found in the Ryan Haight Act. Finally, it encourages Congress to update DATA 2000 to allow all physicians to prescribe medications for OUD treatment.

II. OPIOIDS AND TELEMEDICINE—THE PAST AND FUTURE OF MEDICINE

A. Opioids

i. Opium – The Pied Piper[20] of Medicine

"For such as cannot sleep, or are grievously pained, and upon whom being cut, or cauterized they wish to make a not-feeling pain." - Dioscorides[21]

Humans for millennia have sought out relief from pain and cures from illness from their surroundings.[22] Due to their abundance and ease of use, plants have been the dominant source of medicinal substances.[23] Early human writings evidence attempts at procuring relief using concoctions derived from plants.[24] Clay tablets found in Mesopotamia record the use of opium by the Sumerians almost 5400 years ago; they named it *Hul Gil*, the joy plant.[25] This record is one of the earliest documenting the cultivation and use of opium poppies.[26] From Mesopotamia, opium spread along historic trade routes to the rest of the ancient world.[27]

Originally, opium was only consumed in its natural form.[28] The patient would chew the poppy plant, or dissolve it in alcohol and drink the liquid, which limited the absorption and impact of the active ingredient.[29] Through advances in chemistry, the active component of opium—morphine—was identified and isolated.[30] Morphine, so named after the Greek god of dreams,[31] was discovered by a pharmacist in Germany in 1805.[32] Following the development of the hypodermic needle and syringe in the 1850s, morphine use in the medical field became widespread.[33]

Scientific researchers and the medical community hoped that morphine would be

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20. This Comment does not trivialize the enormous toll of OUD and the current opioid epidemic. However, the names that humanity has given opioids ("Hul Gil,," meaning plant of joy, and Heroin, after the "German term heros") illustrates our failure to appreciate the devastating consequences of misuse. *See* Andrew Rosenblum, et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXPERIMENTAL CLINICAL PSYCHOPHARMACOLOGY 405 (2008);Walter Sneader, *The Discovery of Heroin*, 352 LANCET 1697 (1998).

21. ROBERT T. GUNTHER, THE GREEK HERBAL OF DIOSCORIDES, BOOK IV 473 (1968).

22. Hamilton & Baskett, *supra* note 4, at 368.

23. *Id.*

24. *Id.*

25. Rosenblum, et al., *supra* note 20, at 405.

26. *Id.*

27. *Id.*

28. David F. Musto, *Opium, Cocaine and Marijuana in American History*, 265 SCI. AM. 40, 40 (1991).

29. *Id.*

30. *Id.*

31. *See* Hamilton & Baskett, *supra* note 4.

32. Hamilton & Baskett, *supra* note 4, at 369.

33. *Id.*

free from the abuse-potential seen with opium.[34] As the active component of opium, a smaller amount of drug could be used to produce the same effect.[35] However, morphine addiction grew quickly.[36] This led scientists to search for new compounds that were more potent or less addictive. In September 1898, Bayer Company introduced heroin and promoted it as "more effective and less addictive than morphine."[37] It was a short-lived marketing campaign.

ii. The Pharmacology, Physiology, and Psychology of Opioid Use Disorder Illustrates the Difficulty of Drafting Effective Drug Control Laws[38]

"Presently she cast a drug into the wine of which they drank to lull all pain and anger and bring forgetfulness of every sorrow."[39]

Opium is the precursor to modern day opioids,[40] with morphine as the primary active component of opium.[41] Opioid is a term which refers to all chemical compounds that bind to opioid receptors.[42] Several opioid medications have been developed in an attempt to improve upon morphine.[43] These include heroin, oxycodone, hydrocodone, codeine, and fentanyl.[44] Opioids bind to opioid receptors, initiating a cascade of chemical reactions in the brain, to produce pain relief.[45]

The degree to which an opioid "activates" an opioid receptor determines the magnitude of effect the drug produces. A full opioid agonist[46] is capable of fully activating an opioid receptor.[47] Higher doses of a full agonist results in full activation of a greater number of opioid receptors, giving a greater effect.[48] Partial opioid agonists have a limited ability to activate an opioid receptor and result in more limited effect.[49] A partial opioid agonist will result in lower levels of pain relief but also in lower levels of side effects, such as less respiratory depression and less euphoria.[50]

Endorphins are chemical molecules produced by the body involved in pain

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34. Brownstein, *supra* note 5, at 5391.
35. Musto, *supra* note 28, at 42.
36. Brownstein, *supra* note 5, at 5391.
37. Rosenblum, et al., *supra* note 20, at 406.
38. This section is provided as a brief overview of the biology of opioid use to aid in understanding the scope of the opioid epidemic.
39. Mark-Antoine Crocq, *Historical and cultural aspects of man's relationship with addictive drugs*, 9 DIALOGUES IN CLINICAL NEUROSCIENCE 355, 356 (2007).
40. Brownstein, *supra* note 5, at 5392.
41. George B. Stefano, *Reciprocal Evolution of Opiate Science from Medical and Cultural Perspectives*, 23 MED. SCI. MONITOR 2890, 2892 (2017).
42. Rosenblum, et al., *supra* note 20, at 406.
43. Stefano, *supra* note 41, at 2890.
44. Rosenblum, et al., *supra* note 20, at 406.
45. Stefano, *supra* note 41, at 2893.
46. An agonist is a drug that binds to a receptor and produces the same effect as the chemical naturally produced by the body. A partial agonist binds to the receptor but produces a smaller effect. This reduced effect cannot be overcome by higher doses. *See* Rosenblum, et al., *supra* note 20, at 407.
47. Rosenblum, et al., *supra* note 20, at 407.
48. *Id.*
49. *Id.*
50. *Id.*

management and the internal reward system.[51] Endorphins play an important role in positive reinforcement for behaviors such as sex, eating, and drinking.[52] Research has shown that morphine is chemically similar to endorphins.[53] The discovery that endorphins and morphine exhibit similar effects has aided research into opioid misuse and addiction.[54]

Opioid receptors are found in tissues throughout the bodies of all mammals as well as in various species from other phyla.[55] Studies have also shown that nervous system tissue from invertebrates contains multiple types of opioid receptor, indicating that opioid receptor expression is an evolutionarily conserved trait that predates the separation of vertebrates and invertebrates.[56]

While several subtypes of opioid receptors exist, most opioid pain medications exert their effect by activating the *mu* opioid receptor.[57] This activation is significant due to the role the mu receptor plays in the reward system of the brain.[58] Activity that results in activation of the reward system is positively reinforced, increasing the desire to repeat the activity.[59] In some individuals, this reward system activation leads to a dramatically increased desire to repeat the activity, which can result in OUD.[60] Repeated activation of the reward system by opioids is also associated with withdrawal symptoms, such as irritability and diarrhea.[61]

The problem of reward system activation is compounded when an individual misuses a short-acting opioid, such as heroin.[62] "Heroin has a short half-life"[63] and the euphoric feeling associated with use diminishes quickly.[64] An individual needs to take repeated doses to maintain the pleasurable feelings and avoid withdrawal symptoms.[65] Tolerance can also quickly develop, resulting in a need for increased amounts of drug to achieve the same effect.[66] This cycle of highs and lows can lead to a continuous need for ever increasing amounts of the drug.[67]

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51. Adam S. Sprouse-Blum, et al., *Understanding Endorphins and Their Importance in Pain Management*, 69 HAW. MED. J. 70 (2010).

52. *Id.*

53. Stefano, *supra* note 41, at 2890.

54. *Id.* at 2894.

55. *Id.* at 2893–94.

56. *Glossary*, MOUSE GENOME INFORMATICS, http://www.informatics.jax.org/glossary/evolutionary_conservation (last visited Nov. 27, 2019) (Evolutionary conservation is defined as "[t]he presence of similar genes, portions of genes, or chromosome segments in different species, reflecting both the common origin of species and an important functional property of the conserved element."); *see* Stefano, *supra* note 41, at 2893.

57. Rosenblum, et al., *supra* note 20, at 407.

58. *Id.*

59. *Id.*

60. *Id.*

61. American College of Obstetricians and Gynecologists, *ACOG Committee Opinion: Opioid Use and Opioid Use Disorder in Pregnancy*, 130 OBSTETRICS & GYNECOLOGY e81, e84 (2017) [hereinafter ACOG].

62. *Id.*

63. *Id.* In pharmacology, half-life refers to the amount of time for the amount of drug in the body to be reduced by one-half. If an individual takes 10mg of a drug with a two-hour half-life, after four hours only 25% of the drug will remain. The shorter the half-life the shorter the duration of effect.

64. *Id.*

65. *Id.*

66. Rosenblum, et al., *supra* note 20, at 408.

67. *Id.*

iii. Opioid Use Disorder and the Opioid Crisis—Physicians Pivot to Overusing Opioids as the Focus Shifts to Pain Control and Patient Satisfaction

OUD is characterized as a "problematic pattern of opioid use leading to clinically significant impairment or distress . . . ."[68] The diagnosis is based on several criteria, including unsuccessful efforts to cut down use and failure to fulfill obligations at work, school, or home.[69] Individuals who abuse or misuse opioids are now viewed as having a "chronic, treatable disease" and can "regain control of their health and their lives" with proper treatment.[70] The medical community, from psychiatrists and mental health practitioners[71] to obstetricians and gynecologists,[72] largely has adopted this view of opioid addiction.

The prior approach to opioids and opioid addiction started with the Harrison Narcotic Control Act of 1914, which sought to control widespread use and abuse of morphine, cocaine, and heroin.[73] The Act resulted in a general distrust of opioids by physicians and patients alike.[74] This belief persisted for decades.[75] Physicians were reluctant to prescribe opioids for long periods of time over concerns about addiction.[76] A seminal study was published in 1973.[77] This study noted that seventy-three percent of patients treated in a hospital setting experienced undertreated moderate-to-severe pain.[78] The study concluded that physicians had poor knowledge of pain control treatment options.[79] In 1990, the president of the American Pain Society wrote an editorial that asserted, without evidence, that the "[t]herapeutic use of opiate analgesics rarely results in addiction."[80] This assertion was a departure from the practice that persisted in the American medical community for decades.[81]

The federal government also played a role, perhaps unwittingly, in encouraging the current opioid epidemic. The Centers for Medicare and Medicaid Services ("CMS") publish standards that health care organizations must meet in order to receive federal funding. The Joint Commission is a nonprofit organization that accredits healthcare

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68. AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 541 (5th ed. 2013) (chapter discussing opioid use disorder diagnostic criteria) [hereinafter APA].

69. *Id.*

70. ACOG, *supra* note 61, at e82.

71. APA, *supra* note 68, at 543.

72. ACOG, *supra* note 61, at e82–e83.

73. Jones, et al., *supra* note 9, at 15.

74. *Id.*

75. Rosenblum, et al., *supra* note 20, at 406.

76. *Id.* at 405.

77. Richard Marks & Edward Sachar, *Undertreatment of Medical Inpatients with Narcotic Analgesics*, 78 ANNALS INTERNAL MED. 173 (1973).

78. *Id.* at 175.

79. *Id.* at 180–81.

80. Mitchell B. Max, *Improving Outcomes of Analgesic Treatment: Is Education Enough?*, 113 ANNALS INTERNAL MED. 885, 885 (1990); *see also* Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 303 N. ENGL. J. MED. 123 (1980) (An editor's note on the journal website includes a disclaimer for this letter); U.S. SENATE HOMELAND SEC. & GOV'T AFFAIRS COMM., FUELING AN EPIDEMIC: REPORT TWO 4 (2017) (A 2017 government report noting that the American Pain Society received over nearly a million dollars from opioid pharmaceutical manufacturers over a five year period.)

81. Jones, et al., *supra* note 9, at 15.

organizations.[82] The Joint Commission performs onsite investigations to determine whether healthcare systems are in compliance with the Commission's standards. These standards reflect CMS requirements, as well as new and emerging standards of care.[83] Joint Commission accreditation is extremely important to healthcare organizations: receiving accreditation provides eligibility to participate in Medicare and Medicaid, the largest purchasers of healthcare services in the country.[84]

In 2000, the Joint Commission[85] published new standards for pain management.[86] The updated standards from the Commission were largely consistent with the recommendations from the American Pain Society. In its recommendations, the APS argued for treating "pain as the fifth vital sign" and encouraged a more liberal approach to prescribing opioids.[87] New approaches to gauge pain were implemented, such as the numeric pain scale.[88] Joint Commission recommendations encouraged practitioners to screen all patients for pain, potentially increasing the likelihood that a patient would receive an opioid prescription.[89] Practitioners and nursing staff also mistakenly viewed "pain as the fifth vital sign" as a literal command to check pain levels each time vital signs were taken.[90] Physicians that did not adequately control a patient's pain risked legal action for substandard care.[91]

Perhaps not coincidentally, "overdoses related to opioid pills, started rising in the year 2000 . . . ."[92] As the focus changed to patient satisfaction, which placed a heavy emphasis on pain management, health care providers felt pressure to treat pain more

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82. *Joint Commission FAQs*, JOINT COMM'N, https://www.jointcommission.org/about-us/facts-about-the-joint-commission/joint-commission-faqs/ (last visited Jan. 12, 2020).

83. *Id.*

84. *See Why Achieve Accreditation?* JOINT COMM'N, https://www.jointcommission.org/accreditation-and-certification/become-accredited/why-achieve-accreditation/ (last visited Nov. 16, 2020); *see also What is the difference between Medicare and Medicaid?*, HHS, https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html (last visited Nov. 21, 2019). Medicare and Medicaid are the two largest federal health care programs. Both are administered by the Centers for Medicare and Medicaid, an agency within the Department of Health and Human Services. Medicare is an insurance program that primarily covers persons over 65 years-old and certain disabled younger persons. Medicaid is a federal assistance program that provides health care coverage for persons with very low incomes.

85. *Id.* The Joint Commission is a hospital accrediting body. Accreditation by the Joint Commission is vital for a hospital to receive federal funding, which constitutes the largest portion of the budget of many hospitals.

86. Jones, et al., *supra* note 9, at 15.

87. *See* Ill. Pub. Risk Fund v. Purdue Pharma L.P., 2019 WL 3080929 (N.D. Ill. July 15, 2019). (American Pain Society is listed as one of the "Front Group Defendants," essentially asserting that the society was a front group for opioid manufacturers, promoting their products while claiming to be an independent medical membership organization.); Jones, et al., *supra* note 9, at 15; s*ee also* Teresa Rummans, et al., *How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis*, 93 MAYO CLIN. PROC. 344–47 (2017).

88. David W. Baker, *The Joint Commission's Pain Standards: Origins and Evolution* (2017) https://www.jointcommission.org/-/media/tjc/documents/resources/pain-management/pain_std_history_web_version_05122017pdf.pdf?db=web&hash=E7D12A5C3BE9DF031F3D8FE0D8509580.

89. *Id.*

90. *Id.*

91. Kathryn L. Tucker, *Medico-Legal Case Report and Commentary: Inadequate Pain Management in the Context of Terminal Cancer. The Case of Lester Tomlinson*, 5 PAIN MED. 214, 214–15 (2004).

92. Daniel Ciccarone, *The Triple Wave Epidemic: Supply and Demand Drivers of the US Opioid Overdose Crisis*, 71 INT'L J. DRUG POL'Y 183–88, https://doi.org/10.1016/j.drugpo.2019.01.010 (last visited Sept. 21, 2019).

aggressively.[93] The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey collects information on patient satisfaction with hospital care.[94] Participation in the survey is another requirement for hospitals to receive full reimbursement from federal health care programs.[95] In the mid-2000s, when the survey was introduced, assessment of patients' satisfaction with pain control was heavily weighted.[96]

B. Telemedicine Has the Potential to Dramatically Impact the Future of Addiction Treatment by Connecting Providers with Patients Regardless of Location

i. Defining "Telemedicine"—More Than a Phone Call with the Doctor

The basic idea of telemedicine—delivering health care information across distances—reaches back in human history.[97] The ancient Greeks used smoke signals and reflected sunlight to communicate information about the outbreak of disease and the need for physicians.[98] Telemedicine is a "method of practicing medicine in which the physician is at one geographical location, the patient is at a different geographical location, and the two communicate through a secure electrical audio-visual connection."[99] The Federal Communications Commission definition includes "facilitating access to specialists that are not located in the same place as the patient."[100] That aspect of telemedicine—connecting patients with mental health practitioners and addiction specialists—is a pressing need nationally.[101]

Telemedicine is a subset of telehealth, a term that also includes services such as patient education and medication adherence counseling.[102] Telehealth also includes patient monitoring functions and patient education, such as a nurse instructing a patient on how to use a piece of medical equipment.[103] Telecare, a more general topic, encompasses items and services that patients can use on their own. It includes things such as fitness apps and sensors and digital medication reminder devices.[104]

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93. Rummans, et al., *supra* note 87, at 346–47 .
94. *Id.* at 346.
95. *Id.* at 347.
96. *Id.*
97. *History of Telemedicine,* MDPORTAL, http://mdportal.com/education/history-of-telemedicine.
98. *Id.*
99. Planned Parenthood of the Heartland, Inc. v. Iowa Bd. of Med., 865 N.W.2d 252, 255 (Iowa 2015).
100. FCC, *supra* note 11.
101. NAT'L COUNCIL FOR BEHAV. HEALTH, THE PSYCHIATRIC SHORTAGE: CAUSES AND SOLUTIONS 2 (Mar. 28, 2017), https://www.thenationalcouncil.org/wp-content/uploads/2017/03/Psychiatric-Shortage_National-Council-.pdf; *see also* Samantha Raphelson, *Severe Shortage of Psychiatrists Exacerbated by Lack of Federal Funding,* NPR (Mar. 9, 2018), https://www.npr.org/2018/03/09/592333771/severe-shortage-of-psychiatrists-exacerbated-by-lack-of-federal-funding.
102. FCC, *supra* note 11.
103. *Id.*
104. *Id.*

Telemedicine has shown great potential to cut costs[105] and improve care.[106] The functions listed above can allow a patient to avoid trips to a physician's office or hospital.[107] By allowing instant and convenient access to a physician, telemedicine can reduce the length of hospital stays or eliminate some hospital admissions altogether.[108] For example, the Veterans Health Administration experienced great success in treating patients when it introduced a telemedicine program in 2003.[109] The program enrolled veterans with chronic conditions aiming to avoid costly admission to long-term care facilities.[110] The program increased from two thousand patients in 2003 to over thirty thousand patients in 2007.[111] The program had a cost of one thousand six hundred dollars per year, compared to long-term care costs that averaged over seventy-seven thousand dollars per year.[112]

ii. Federal Regulation of Telemedicine Would Overcome Barriers Created by the State-by-State Approach of Medical Licensure

The practice of medicine, as well as telemedicine, is regulated on a state-by-state basis.[113] Some states have adopted policies that promote the use of telemedicine while others have imposed restrictions on the practice.[114] These mixed approaches have led to a patchwork of regulations that impose substantial burdens on practitioners and deprive patients of access to care.[115]

Some states impose limits on the practice of telemedicine by requiring practitioners to personally examine patients prior to making a diagnosis.[116] This restriction is similar to federal prohibitions on controlled substances prescriptions issued without an in-person exam.[117] There is also case law that demonstrates state medical boards, composed primarily of practicing physicians, promulgated rules to limit the use of telemedicine to

105. *See* Adam Darkins, et al., *Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions*, 14 TELEMEDICINE & E-HEALTH 1118, 1125 (2009); *see also* Steff Deschenes, *5 ways telemedicine is driving down healthcare costs*, HEALTHCARE IT NEWS (July 16, 2012), https://www.healthcareitnews.com/news/5-ways-telemedicine-driving-down-healthcare-costs; Susan Morse, *Telehealth eliminates time and distance to save money*, HEALTHCARE FIN. (Oct. 16, 2019), https://www.healthcarefinancenews.com/news/telehealth-eliminates-time-and-distance-save-money; Jack E. Russo, et al., *VA Telemedicine: An Analysis of Cost and Time Savings*, 22 TELEMEDICINE & E-HEALTH No. 3 (2016), http://online.liebertpub.com/doi/abs/10.1089/tmj.2015.0055#utm_source=ETOC&utm_medium=email&utm_campaign=tmj.

106. Jami L. Dellifraine & Kathryn H. Dansky, *Home-based telehealth: a review and meta-analysis*, 14 J. TELEMEDICINE & TELECARE 62 (2008).

107. Jay M. Zitter, *Regulation of and Liability Arising from Telemedicine*, 23 A.L.R. 7th Art. 5, 2 (2017).

108. *Id.*

109. Darkins, et al., *supra* note 105.

110. *Id.*

111. *Id.*

112. *Id.*

113. *See generally* FSMB, http:www.fsmb.org/.

114. U.S. DEP'T OF HEALTH & HUMAN SERVS. & THE HEALTH RES. & SERVS. ADMIN., HEALTH LICENSING BOARD REPORT TO CONGRESS 6 (2011).

115. FEDERAL COMMC'NS COMM'N, CONNECTING AMERICA: THE NATIONAL BROADBAND PLAN 206 (2010), https://transition.fcc.gov/national-broadband-plan/national-broadband-plan.pdf.

116. Zitter, *supra* note 107, at 2.

117. 21 U.S.C. § 829(e).

protect the interests of local physicians.[118]

Following the spread of telemedicine, there has been a push to regulate telemedicine at the federal level.[119] The licensure of pilots is an instructive analogy.[120] Pilots routinely and necessarily cross state boundaries. State-by-state regulation would lead to a fragmented and inefficient system that would greatly limit air travel. These same concerns are true for the regulation of telemedicine. Since telemedicine very likely to cross state lines, federal regulation would eliminate uncertainty for the urban physician with more specialized expertise treating a telemedicine patient who lives in a rural area in an adjacent state.

States are also historically protectionist when professional licensure issues are involved. In 2001, Oklahoma refused to join the Nurse Licensing Compact, which would allow for reciprocity of nursing licenses between states, because it would "authorize[] the legislatures of other states to determine . . . the qualifications of persons admitted to practicing nursing in Oklahoma."[121] Federal regulation would avoid this protectionism and allow for uniformity in standards and application.[122] This uniformity would increase access to physicians and, importantly, specialists for patients living in rural or otherwise underserved areas.

Another issue facing practitioners is reimbursement for services provided via telemedicine. As the largest purchaser of professional health care services, restrictions placed on telemedicine by Medicare have far reaching implications.[123] Medicare provides payment for telemedicine services in very limited circumstances.[124] Currently, patients must reside in federally designated rural areas in order to qualify for Medicare reimbursed telemedicine services.[125] This artificial limitation imposes unnecessary burdens on patients living in rural areas that fall outside a federally designated area, or rural areas that are near a large urban area.[126] Since one in three patients is covered by Medicare,[127] limits on reimbursement discourage practitioners from adopting telemedicine services into their practices.

One final consideration for telemedicine providers and policymakers is the impact

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118. *See* Teladoc, Inc. v. Tex. Med. Bd., 453 S.W.3d 606 (Tex. App. 2014).

119. Bill Marino, et al., *A Case for Federal Regulation of Telemedicine in the Wake of the Affordable Care Act*, 16 COLUM. SCI. & TECH. L. REV. 274 (May 17, 2015).

120. *Id.* at 284–85.

121. *Id.* at 286.

122. *Id.*

123. Centers for Medicare and Medicaid Services, *CMS Roadmaps Overview*, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/RoadmapOverview_OEA_1-16.pdf [hereinafter CMS Roadmap].

124. Mandy Bell, et al., *Geographic Restrictions for Medicare Telehealth Reimbursement* (May 2011), https://www.ruralhealthweb.org/getattachment/Advocate/Policy-Documents/GeographicRestrictionsforMedicareReimbursementPolicyPaper.pdf.aspx?lang=en-US; *see also* mHealthIntelligence, *CMS Finalizes Telehealth Expansion for Medicare Advantage Plans* (Apr. 8, 2019), https://mhealthintelligence.com/news/cms-finalizes-telehealth-expansion-for-medicare-advantage-plans (CMS has published rules effective in 2020 that will expand access to telehealth services for individuals enrolled in Medicare Advantage plans, which cover about thirty percent of Medicare beneficiaries.).

125. Bell, et al., *supra* note 124.

126. *Id.*

127. CMS Roadmap, *supra* note 123.

of the Health Insurance Portability and Accountability Act's ("HIPAA") Privacy and Security Rules. Providers should be aware that the methods used to communicate electronic protected health information ("ePHI") must remain secure.[128] HIPAA guidelines on telemedicine state "(1) only authorized users should have access to ePHI; (2) a system of secure communication should be implemented to protect the integrity of ePHI; and (3) a system of monitoring communications containing ePHI should be implemented to prevent accidental or malicious breaches."[129] HIPAA broadly governs the protection of personal health information, with restrictions on disclosures of information as well as standards for physician and electronic security.

iii. As an Activity That Will Necessarily Cross State Lines, Jurisdictional Issues for Telemedicine Abound

One of the most notable issues surrounding telemedicine is the ease with which it allows the practice of medicine to cross state lines. State laws permitting or restricting the practice of telemedicine are tasked with determining where the practice occurs. Does it occur where the physician is located, and likely licensed? Or does it occur wherever the patient happens to be, regardless of where the physician is licensed or located?

These questions do not have simple answers. Several laws have been proposed to increase access to telemedicine services that cross state lines.[130] States have historically argued that the regulation of health care professionals falls under the Police Power of the Tenth Amendment.[131] This argument has been weakened over several decades by the federal government's extensive involvement in health care.[132] The Controlled Substances Act ("CSA") greatly impacts the practice of medicine, as it limits what medications can be prescribed by state-licensed health professionals. The CSA also regulates the in-state production of controlled substances. In *Gonzales v. Raich*, the Supreme Court upheld part of the CSA that criminalizes the home production of marijuana, which California had legalized for medicinal purposes.[133] The majority in Gonzales found that the CSA was within Congress's authority to regulate interstate commerce.[134] Viewing telemedicine as an activity, like the manufacture and distribution of controlled substances, which will undoubtedly impact interstate commerce, federal regulation seems appropriate.

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128. HIPAA Guidelines on Telemedicine, HIPAA J., https://www.hipaajournal.com/hipaa-guidelines-on-telemedicine/.

129. *Id.*

130. *See generally* TELE-MED Act of 2013, H.R. 3077, 113th Cong. (2013); Telehealth Enhancement Act of 2014, S. 2662, 113th Cong (2014).

131. Marino, et al., *supra* note 119, at 297; *see also* Wendy Parmet, *Regulation and Federalism: Legal Impediments to State Health Care Reform*, 19 AM. J. L. & MED. 121, 123 (1993) (citing Mugler v. Kansas, 123 U.S. 623, 659 (1887)) (the Police Power derives from the "ancient power of sovereigns to regulate their internal affairs to ensure the health and safety of the citizenry," and is defined as the "right of the States of the Union . . . to protect the health, morals, and safety of their people by regulations . . . .").

132. *E.g.*, Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

133. *See generally* 545 U.S. 1 (2005).

134. *Id.* at 22.

III. CONGRESS ATTEMPTS TO CONTROL ACCESS TO THE MOST ADDICTIVE SUBSTANCES EVER DISCOVERED

A. The Federal Government's Many Approaches to Controlled Substances

i. The Harrison Narcotics Tax Act of 1914

In 1914, Congress passed the Harrison Narcotics Tax Act.[135] The Act passed in response to the "sudden emergence of street heroin" and widespread prescription morphine abuse.[136] The Act sought to control the widespread use and abuse of opioids, often obtained from a physician or pharmacist.[137] The Act restricted the prescribing and dispensing of "opium or cocoa leaves"[138] or any derivatives.[139] Physicians were allowed to prescribe opium or cocoa leaves, or derivatives, in the "course of his professional practice only."[140]

Through its Taxing Power, Congress imposed a small tax on each transfer of opioids.[141] In order to pay the tax, health care providers registered with and obtained a permit from the Treasury Department.[142] This registration requirement successfully compelled physicians and pharmacists to account for the quantities of opioids they were dispensing to patients.[143] The Act also required that dispensing records be maintained for inspection by government officials.[144]

In short order, negative consequences of the Act emerged. Physicians who provided OUD treatment were prosecuted for failing to "attempt to cure the morphine habit" and for dispensing or prescribing outside the scope of professional practice.[145] With physicians unwilling or unable to supply prescription opioids, most patients were forced to use underground opioid markets.[146] Until the passage of the Controlled Substances Act of 1970, this policy of limiting access to all opioids would continue.

ii. The Controlled Substances Act

The Controlled Substances Act ("CSA"), officially known as the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, became effective in

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135. Jones, et al., *supra* note 9, at 15.
136. *Id.*
137. Musto, *supra* note 28, at 40.
138. It is worth noting that derivatives of "opium and cocoa leaves" are pharmacologically distinct. One is a depressant, the other a stimulant. They were combined because of the assumption that both were addictive, associated with crime, and could get the user "high." Marijuana would also later be classified as a narcotic for similar reasons. *See* COMM. FOR THE SUBSTANCE COVERAGE STUDY DIV. OF HEALTH CARE SERVS., INST. OF MED., TREATING DRUG PROBLEMS VOL. 2 (Dean R. Gerstein & Henrick J. Harwood eds., 1992).
139. The Harrison Narcotic Act of 1914, Pub. L. No. 63-223, 785 (1914).
140. *Id.* at 786.
141. Musto, *supra* note 28, at 40.
142. *Id.*
143. *Id.*
144. The Harrison Narcotic Act of 1914, Pub. L. No. 63-223, 786 (1914).
145. Webb v. United States, 249 U.S. 96, 98 (1919).
146. Jeremy Lesser, *Today is the 100th Anniversary of the Harrison Narcotics Tax Act*, DRUG POL'Y ALLIANCE (Dec. 16, 2014), http://www.drugpolicy.org/blog/today-100th-anniversary-harrison-narcotics-tax-act.

1971.[147] It represents a broad attempt by Congress, through its Commerce Clause power,[148] to regulate the manufacture and distribution of controlled substances.[149] The CSA, codified at 21 U.S.C. § 801 contains three titles, each with a different focus.[150] Of importance to this comment, Title II addresses the registration, manufacture, and distribution of controlled substances.[151] The Drug Enforcement Agency is the federal agency charged with enforcing the provisions of the Act.[152]

The CSA categorizes medications into five schedules based on abuse potential and accepted medical use.[153] The Attorney General, in collaboration with the Secretary of the Department of Health and Human Services, determines a medication's schedule.[154] Medications determined to have a high abuse potential and no acceptable medical use are placed in the highest schedule, Schedule I.[155] This list includes drugs such as heroin, marijuana, ecstasy and LSD.[156] Medications listed in Schedule I may not be prescribed by physicians, and research using those medications is heavily restricted. Medications determined to have a lower abuse potential, such as oxycodone or Adderall, are placed in Schedule II.[157] Physicians are allowed to prescribe drugs in this schedule, although there are significant restrictions.[158] Drugs with lower abuse potential are placed in lower schedules with fewer restrictions.[159] Drugs with no abuse potential are excluded from regulation by the CSA.[160]

The CSA makes it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance.[161] It also bars the creation, possession, or distribution of counterfeit controlled substances.[162] Under 21 U.S.C. § 846, attempts and conspiracies to violate provisions of the CSA are punished with the same penalty as the attempted or conspired offense.[163] To add teeth to the regulations governing the manufacture and distribution of controlled substances, the CSA imposes severe penalties.[164] Violations of the CSA can incur substantial prison terms.[165] Violators may

147. Michael Gabay, *The Federal Controlled Substances Act: Schedules and Pharmacy Registration*, 48 HOSP. PHARM. 473 (2013).
148. 21 U.S.C. § 801(3)
149. Gabay, *supra* note 147, at 473.
150. *Id.*
151. *Id.*
152. OFFICE OF DIVERSION CONTROL, DRUG ENF'T AGENCY, PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 3 (2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.
153. 21 U.S.C. § 811(c).
154. Gabay, *supra* note 147, at 473.
155. *Id.* at 473–74.
156. 21 U.S.C. § 812(c).
157. *Id.* (Medications are listed by chemical name, which may differ greatly from the common brand or generic names).
158. *Id.* § 812(b).
159. *Id.* § 812(c).
160. *Id.* § 811(c)(1).
161. 21 U.S.C. § 841(a)(1).
162. *Id.* § 841(a)(2).
163. *Id.* § 846.
164. 21 U.S.C. § 841(b).
165. Brian T. Yeh, Cong. Research Serv., RL30722, Drug Offenses: Maximum Fines and Terms of

be charged with offenses ranging from drug trafficking[166] to environmental damage[167] and illegal manufacturing[168] to money laundering.[169] Penalties range from fines to imprisonment and even death.[170]

iii. The Narcotic Addict Treatment Act of 1974

The CSA was an acknowledgement by the federal government that some opioids serve a legitimate purpose and regulated access would be beneficial. However, the federal stance on OUD treatment remained unchanged. From the time of the Harrison Narcotics Act, physicians were barred from using legal opioids to treat patients with OUD.

The Narcotic Addict Treatment Act of 1974 ("NATA 1974") amended the CSA to place restrictions on physicians who prescribed narcotics for maintenance or detoxification treatment of opioid addiction.[171] The changes required physicians who dispense narcotic drugs to individuals for maintenance or detoxification treatment[172] to obtain a special registration from the DEA.[173] Physicians were also limited in the amount of methadone they could provide to patients for at-home use.[174] In the 1970s, medical treatment of opioid addiction was limited to "methadone clinics," where patients were administered a dose of medication.[175] This tight regulation and requirement of daily dosing limited the number of patients treated and contributed to the stigma of opioid addiction treatment.[176]

iv. Laws Expanding Access to OUD Treatment—The Drug Addiction Treatment Act of 2000 and The Comprehensive Addiction and Recovery Act of 2016

The Drug Addiction Treatment Act of 2000 ("DATA 2000") allowed physicians to seek a special registration to prescribe buprenorphine[177] as part of an in-office medication-

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Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws (2015).

166. *See generally* 21 U.S.C. § 841.

167. *Id.* § 841(b)(6).

168. 18 U.S.C. § 1956.

169. *Id*.

170. 21 U.S.C. § 841(b).

171. The Narcotic Addict Treatment Act of 1974 (P.L. 93-281).

172. 21 U.S.C. §§ 802(29)-(30). Maintenance treatment is "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. Detoxification treatment is "the dispensing, for a period not in excess of twenty-one days of a narcotic in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state." *Id.*

173. *Id.* § 823(g)(1).

174. FEDERAL REGULATION OF METHADONE TREATMENT 96 (Richard Rettig & Adam Yarmolinsky eds., 1995).

175. Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 54 (2010) (citing Michael Weinrich & Mary Stuart, *Provision of Methadone Treatment in Primary Care Medical Practices: Review of the Scottish Experience and Implications for US Policy*, 283 JAMA 1343, 1343–44 (2000)).

176. Kevin Fiscella, *Deregulating Buprenorphine Prescribing for Opioid Use Disorder Will Save Lives*, https://www.statnews.com/2019/03/12/deregulate-buprenophine-prescribing/.

177. Buprenorphine is an opioid that binds tightly to the opioid receptor. Since it binds tightly, it prevents use of other opioids. However, since it does not fully activate the mu receptor, it does not produce the euphoric "high" associated with other opioids. Hendree E. Jones, *Practical Considerations for the Clinical Use of Buprenorphine,* 2 SCI. & PRAC. PERSP. 4, 5 (2004).

assisted treatment (MAT) program. DATA 2000 greatly expanded access to MAT therapy. Patients were no longer required to seek treatment from a federal drug treatment program. Physicians are required to undergo additional training in order to register.[178] The statute also limits the number of patients a physician may treat with MAT.[179] Registration was also limited to physicians. Nurse practitioners and physician assistants were excluded.[180] This limitation disproportionally impacted patients living in rural areas who often lack access to physicians and are increasingly served by mid-level practitioners.[181]

While DATA 2000 increased the availability of office-based MAT therapy, access was still negatively impacted by the limits on the types of practitioners and the number of patients. The Comprehensive Addiction and Recovery Act of 2016 ("CARA 2016") sought to improve access to the in-office MAT therapy allowed by DATA 2000.[182] CARA 2016 amended the CSA to include qualified nurse practitioners and physician assistants among those practitioners able to prescribe buprenorphine for office-based MAT therapy.[183] The increase in available practitioners expanded access for patients seeking treatment.

B. A Tragic Event and a Well-Intentioned Reaction

In the late 1990's, the internet boom allowed for the development and proliferation of internet pharmacies.[184] These pharmacies set up websites to promote their services and to interact with potential patients.[185] The websites used metatags such as "hydrocodone no prescription"[186] and search engine optimization services from companies like Google to make their services easier to find.[187] Internet pharmacies used these websites to collect patient data, such as mailing address and payment information, and to host an online questionnaire: the online questionnaire served as the basis for the prescription order.[188]

The basic operation of these pharmacies followed a similar formula. A patient visited the website and completed the online questionnaire.[189] The patient indicated his desired medication and submitted the completed questionnaire.[190] Those answers were forwarded to a contracted physician who, after a cursory review, issued a prescription for the desired medications.[191] That prescription was sent to the pharmacy's physical location to be filled

178. 21 U.S.C. § 823(g)(2)(G).
179. *Id.* § 823(g)(2)(B)(iii).
180. Originally, the definitions used at 21 U.S.C. § 823(g)(2)(G) only included "physicians."
181. Hilary Barnes, Michael R. Richards, Matthew D. McHugh & Grant Martsolf, *Rural And Nonrural Primary Care Physician Practices Increasingly Rely On Nurse Practitioners,* 37 HEALTH AFFAIRS 6 (2018).
182. 21 U.S.C. § 823(g)(2)(G).
183. *Id.*
184. Camille Guerra & Timothy Mackey, *USA Criminal and Civil Prosecutions Associated with Illicit Online Pharmacies: Legal Analysis and Global Implications*, 1 MA@POC 104 (2017).
185. *See* United States v. Darji, 609 Fed. Appx. 320 (6th Cir. 2015) (offering a full description of the typical "internet" pharmacy operation).
186. *Id*. at 323.
187. Guerra, *supra* note 184, at e115.
188. *Darji*, 609 Fed. Appx. at 323.
189. *Id.*
190. *Id.*
191. *Id.* at 323–24.

and mailed to the patient.[192]

Ryan Haight was a high school senior who purchased hydrocodone from an online pharmacy.[193] He died of an overdose of that drug when he was seventeen years old.[194] The pharmacy, owned and operated by Clayton Fuchs, maintained a website that provided customers an online questionnaire.[195] Ryan completed the questionnaire and submitted it to the pharmacy's contracted physician who prescribed the requested medications.[196] The prescription was forwarded to Fuchs' pharmacy for dispensing and mailing.[197] Ryan and the physician never directly interacted.[198]

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008, commonly referred to as the Ryan Haight Act, was passed in response to the tragedy of Ryan's death.[199] The Ryan Haight Act sought to ban the online questionnaire and minimal medical evaluation format used by illegitimate online pharmacies.[200] However, given the imprecise language of the statute, along with its narrow and outdated definition of telemedicine,[201] the Ryan Haight Act has stood in the way of the meaningful adoption and use of telemedicine to treat opioid addiction. In a sad bit of irony, an act which was designed to decrease opioid misuse operates, in effect, to hinder one method to addressing the opioid crisis.

The Ryan Haight Act amended the CSA to create restrictions on the practice of prescribing controlled substances using the internet.[202] The Act provides that "[n]o controlled substance . . . may be . . . dispensed by means of the Internet without a valid prescription."[203] The Act defines a valid prescription for a controlled substance as one "issued for a legitimate medical purpose in the usual course of professional practice" by a practitioner who has conducted at least one in-person medical evaluation.[204] This prohibition was specifically aimed at the business model of illicit online pharmacies.[205]

The Ryan Haight Act also created a state cause of action.[206] Under this amendment to the CSA, States have the ability to file in federal district court a civil action to seek a nationwide injunction against conduct found to violate internet pharmacy regulations.[207] States can also claim damages and seek restitution.[208] Under the statute, the state must

192. *Id.* at 324.
193. Bethany Lipman, Note, *Prescribing Medicine for Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets*, 50 AM. L. REV. 545, 545 (2013)
194. S. Rep. No. 110-521, at 8 (2008).
195. Jeff Karberg, Progress in the Challenge to Regulate Online Pharmacies, 23 J. L. & Health 113, 130 (2010).
196. S. Rep. No. 110-521, at 8–9 (2008).
197. *Id*.
198. *Id.*
199. *Id*. at 7.
200. *Id.* at 19.
201. 21 U.S.C. § 802(54).
202. *Id.* § 829(e).
203. *Id.* § 829(e)(1).
204. *Id.* § 829(e)(2)(A).
205. Jeff Karberg, *Progress in the Challenge to Regulate Online Pharmacies*, 23 J. L. & HEALTH 113, 122 (2010).
206. 21 U.S. C. § 882(c)(1).
207. *Id.* § 882(c)(1)(a).
208. *Id.* § 882(c)(1).

provide advanced notice to the federal government, which has the right to intervene and be heard on all matters relating to the case.[209]

The legislative history of the Ryan Haight Act shows the overarching purpose of the act was to reduce the incidence of adolescent prescription drug abuse.[210] Joseph Califano, Chief Executive Officer of the National Center on Addiction and Substance Abuse ("CASA"), testified that "the fastest growing drug abuse among our Nation's children involves prescription drugs."[211] During a hearing before the Senate Committee on the Judiciary, Francine Haight, Ryan's mother, testified that "[t]ighter controls on the sale of controlled substances on the internet . . . will help."[212]

Further testimony addressed the government's concerns with combating prescription drug abuse and the proliferation of illicit online pharmacies. Alberto Gonzales, then Attorney General, testified that it was difficult for law enforcement "to track any of the individuals behind the websites" because the websites "either posted no information or simply gave false information."[213] The Senate report also noted the voluntary nature of the method of certifying internet pharmacies.[214]

IV. A PRESCRIPTION FOR CHANGE

A. Unnecessary Legislation—In an Age of "Internet-based drug trafficking organization[s]," "[O]utside the usual course of professional practice" Is Still the Standard.

In *Gonzales v. Oregon*, the Supreme Court stated that the CSA "bars doctors from using their prescription writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood."[215] Several cases illustrate that the prohibitions found in the CSA and the *Gonzales* court admonition were undoubtedly meant to apply to the distribution of controlled substances via the internet by online pharmacies.[216] Case law contains numerous examples of defendants charged with violations of the CSA prior to the passage of the Ryan Haight Act. Under the Ryan Haight Act, the scope of the CSA was broadened to include regulations regarding the practice of telemedicine and the use of the internet in the distribution of controlled substances.[217]

In *United States v. Darji* and *United States v. Hazelwood*, the defendants were charged with violations of the CSA[218] related to their operation of an illicit online

209. *Id.* § 882(c)(2).
210. S. Rep. No. 110-521, at 1 (2008).
211. *Id.* at 2.
212. *Id.* at 9.
213. *Id.* at 7; *see also* State v. Sowell, 213 N.J. 89, 105 (N.J. 2013) ("Nearly all criminal activity involves some effort at concealment.").
214. S. Rep. No. 110-521, at 4 (2008); *see also Digital Pharmacy Accreditation*, NABP, https://nabp.pharmacy/programs/vipps/ (last visited Jan. 24, 2021). This program was started as a way for consumers to verify the legitimacy of an online pharmacy. If a consumer is looking to make illegitimate drug purchases online, this voluntary program seems wholly ineffective.
215. 546 U.S. 243, 269–70 (2006).
216. Cases explored *infra*.
217. S. Rep. No. 110-521, at 12–13 (2008).
218. United States v. Darji, 609 Fed. App'x. 320, 323 (6th Cir. 2015); United States v. Hazelwood, 2011 WL

pharmacy.[219] This case highlights the difference between the in-person encounter requirement[220] found in the Ryan Haight Act and the "legitimate medical purpose" language found in the Controlled Substances Act. The defendants were indicted prior to the passage of the Ryan Haight Act on charges involving an internet pharmacy distributing controlled substances based on a submitted questionnaire. Since the CSA contains language that prohibits the distribution of controlled substances outside the normal scope of professional practice, internet "pill mill"[221] pharmacy operators were routinely charged and convicted prior to the passage of the Ryan Haight Act.

The *Darji* defendants were charged, along with several others, with numerous offenses based on their involvement in the illicit online pharmacy.[222] The court characterized the operation as an "Internet-based drug trafficking organization"[223] and an "internet pill mill."[224] Undercover agents were able to demonstrate the illegitimate nature of the medical review used to evaluate the online questionnaire responses. One agent submitted responses describing pain from "heartworms, and excessive barking" and listed current medications as Kyltix and Nylabone.[225] He was prescribed hydrocodone on three separate occasions.[226] Another agent was able to obtain hydrocodone using medical records "submitted by a pregnant man."[227]

The defendants filed several motions to contest the charges against them.[228] The defendants argued that the charges against them should be dismissed because their conduct was not a violation of the CSA at the time.[229] The defendants relied on the in-person encounter requirement created by the Ryan Haight Act to argue that their actions were not *per se* illegal prior to the passage of the act.[230] In response to that argument, the court

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2565294. (Both cases stem from the same underlying facts.)

219. Internet pharmacies are generally grouped into one of three categories. First are those that fill prescriptions pursuant to a legitimate prescription. These are generally associated with a traditional brick and mortar pharmacy and largely exist to service existing customers. In the second category are pharmacies that provide prescriptions after a physician reviews an online questionnaire completed by a consumer. These pharmacies have an air of legitimacy because of their association with licensed physicians. In the third category are the rogue internet pharmacies not connected to any licensed physician or pharmacist and that sell drugs directly to consumers. The focus of the Ryan Haight Act was on category two pharmacies. For a complete discussion on the different categories of online pharmacies, see Bethany Lipman, Note, *Prescribing Medicine for Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets*, 50 AM. L. REV. 545, 549 (2013); *see also* Ludmila Bussiki Silva Clifton, Comment, *Internet Drug Sales: Is It Time to Welcome "Big Brother" into Your Medicine Cabinet?*, 20 J. CONTEMP. HEALTH L. & POL'Y 541, 546 (2004).

220. 21 U.S.C. § 829(e)(2)(A).

221. United States v. Hazelwood, Case No.: 1:10 CR 150, 2011 WL 2565294, at *23–24 (N.D. Ohio Nov. 22, 2011). "Pill mill" is a slang term to refer to pharmacies that fill inordinate amounts of controlled substance prescriptions. The judge held in this case that the term was a "factually supported and proper" way to refer to the operations of the defendants.

222. *Hazelwood*, 2011 WL 2565294, at *1.

223. *Id.* at *1.

224. *Id.* at *2.

225. *Darji*, 609 F. App'x. at 324.

226. *Id.*

227. *Id.*

228. *Hazelwood*, 2011 WL 2565294, at *1.

229. *Id.* at *3.

230. *Id.* at *3.

conducted a thorough examination of the CSA and the Ryan Haight Act. [231]

The court noted that the CSA provides that "it shall be unlawful for any person knowingly or intentionally - (1) to manufacture, distribute, or dispense a controlled substance."[232] An exception to this broad prohibition is provided for the practice of medicine. A controlled substance may be dispensed or prescribed "for a legitimate medical purpose by an individual practitioner acting the usual course of his professional practice."[233]

There are no statutory definitions of legitimate medical purpose and the CSA "does not specifically define the range of acceptable medical practices."[234] In several online pharmacy cases, defendants argued that the CSA was unconstitutionally vague because of the lack of definition for legitimate medical purpose.[235] In *United States v. Orta-Rosario*, the 4th Circuit rejected a claim that the CSA was impermissibly vague.[236] The *Orta-Rosario* court concluded that since "there are no specific guidelines concerning what is . . . outside the usual course of professional practice," courts "must engage in a case-by-case analysis" to determine if defendants have violated the CSA.[237] Courts have generally held that "[t]he term professional practice refers to generally accepted medical practice."[238]

The *Darji* court contrasted the language of the CSA with that found in the Ryan Haight Act. The Ryan Haight Act narrows the exception available for dispensing controlled substances by prescription. The Act created the requirement of a valid prescription, which requires the practitioner to conduct at least one in-person medical evaluation of the patient. This language is in addition to the "legitimate medical purpose" requirement.

The Government conceded that the Ryan Haight Act was not applicable to the *Darji* defendants but maintained that their conduct was a violation of the CSA. The defendants were being charged for distributing controlled substances "outside the usual scope of professional practice."[239] The fact that their activity involved the internet was irrelevant.[240]

The *Birbragher* case demonstrates the wide array of statutory penalties possible for violations of the CSA by an individual who is not a physician or pharmacy.[241] The defendant was involved in an elaborate plan to distribute controlled substances via the internet. The defendant operated Pharmacom, a company that "used the internet to

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231. *Hazelwood*, 2011 WL 2565294.
232. *Id.* at *3; 21 U.S.C. § 841(a)(1).
233. 21 C.F.R §1306.04(a).
234. United States v. Orta-Rosario, 469 F. App'x 140, 143 (2012).
235. *See* United States v. Birbragher, 603 F.3d 478 (8th Cir. 2010); United States v. Lovern, 590 F.3d 1095, 1103 (10th Cir. 2009); United States v. Quinones, 536 F. Supp. 2d 267, 273 (E.D.N.Y. 2008).
236. 469 F. App'x. 140, 143.
237. *Id.* (quoting United States v. Singh, 54 F.3d 1182, 1187 (4th Cir. 1995)).
238. United States v. Vamos, 797 F.2d 1146, 1151 (2d Cir. 1986) (internal quotations omitted).
239. *Hazelwood*, 2011 WL 2565294, at *4.
240. *See Quinones*, 536 F. Supp. 2d at 271 (finding the fact that the defendants allegedly carried out their activities through the internet to be irrelevant to the charges).
241. *See Birbragher*, 603 F.3d 478 (8th Cir. 2010); *see also* 21 U.S.C. § 822(a)–(b) (The distinction between individual physicians and a pharmacy as an entity is found in the statute. The DEA registers individual prescribers and pharmacies, as opposed to individual pharmacists.).

distribute prescription drugs."[242] Pharmacom operated the typical website where patients filled out a questionnaire that would be submitted to a physician. However, Pharmacom did not operate a pharmacy but rather contracted with one to dispense the "approved 'prescription' orders."[243] During the course of its operation, from January 2003 to May 2004, Pharmacom spent $3.14 million on internet advertising and marketing.[244] Physicians were employed from around the country. Some were not even licensed to practice medicine in the U.S.[245]

In a 2007 indictment, Birbragher and his codefendants were charged with multiple drug and money laundering violations.[246] Birbragher was charged with conspiracy to violate provisions of the CSA related to dispensing controlled substances outside the usual course of professional practice.[247] He was also charged with leasing space to maintain a pharmacy "for the purpose of distributing Schedule III and Schedule IV controlled substances" outside the usual course of practice.[248] Further, he was charged with conspiring to violate 21 U.S.C. § 861(a)(1) for "knowingly and intentionally employ[ing] minors, to violate the drug laws."[249]

In addition to the drug related charges, Birbragher was indicted for conspiring to "conduct . . . financial transactions involving the proceeds of the . . . drug conspiracy."[250] Each of the conspiracy charges related back to the "unlawful activity" of the "illegal dispensing of Schedule III and IV controlled substances."[251]

Similar to other online pharmacy defendants, Birbragher asserted in his defense that the CSA was unconstitutionally vague in violation of the Fifth Amendment right to due process.[252] However, unlike the Darji defendants, Birbragher argued that the CSA was vague as applied to himself as a non-physician or non-pharmacist. The court noted that 21 U.S.C. § 841(a)(1) bars "any person [from] knowingly or intentionally . . . manufactur[ing], distribut[ing], or dispens[ing] . . . a controlled substance."[253] The exception for medical practice, rather than the general bar, unsurprisingly applies to physicians and pharmacies acting in the usual course of professional practice.

B. Ineffective Legislation—The Ryan Haight Act Has Failed to Curtail Illicit Online Pharmacies

The cases listed *supra* illustrate the types of activity—the illicit distribution of large amounts of controlled substances, clearly outside the bounds of professional medical practice—that the Ryan Haight Act sought to prohibit. However, as demonstrated by the

242. *Birbragher*, 603 F.3d at 481.
243. *Id.* (internal quotations omitted).
244. *Id.* at 482.
245. *Id.* at 481
246. *Id.* at 482.
247. *Birbragher*, 603 F.3d at 482.
248. *Id.* at 483.
249. *Id.* at 482.
250. *Id.* at 483.
251. *Id.*
252. *Birbragher*, 603 F.3d at 484.
253. *Id.* at 486; *see also* 21 U.S.C. § 841(a)(1).

cases, statutory and regulatory tools to combat this type of behavior existed prior to the passage of the Act. These "pill mill" cases did not involve a valid patient-prescriber relationship, nor was one contemplated. These operations were clearly outside the bounds of professional conduct and were designed to distribute as many controlled substances prescriptions as possible to maximize profits.

The legislative history of the Ryan Haight Act reveals that some of the underlying justifications of the act were fundamentally flawed. Joseph Rannazzisi, then a deputy assistant administrator at the DEA, testified that the "DEA believes a majority of the rogue [pharmacy] sites operating today are based in the United States . . . ."[254] However, a 2016 report estimated 30,000 to 35,000 illicit online pharmacies were in operation, with most located outside of the U.S.[255]

Mr. Rannazzisi also testified to the effect that the DEA thought the online questionnaire format was "in many cases . . . a ruse created to identify exactly what type of prescription controlled substance the customer wants to purchase."[256] The remedy to this was to define a valid prescription as requiring at least one face-to-face meeting. However, a 2008 study from the National Center on Addiction and Substance Abuse (CASA) estimated that "nearly 85% of Web sites offering controlled prescription medications for sale do not require a legitimate prescription."[257]

Another issue is the narrow definition of telemedicine found in the CSA. Congress should amend the CSA to include the commonly accepted and practiced definition of telemedicine. This would yield a more effective and patient-centered approach to treatment of OUD. Expanding the statutory definition of telemedicine to allow for interactions between a physician and a patient who is at home would dramatically increase the access to clinically effective substance abuse treatment.

The statutory definitions of telemedicine are far too restrictive and simply fail to accommodate the current practice of telemedicine.[258] Telemedicine is broken down into seven subtypes. One subtype includes a situation where the patient is being treated by a remote physician while in the physical presence of another physician. While this definition would be useful in connecting a patient with a distantly located specialist, such as a consultation with a gastroenterologist, it does not account for the current realities of health care. This definition requires the presence of two licensed physicians. Given the current physician shortage,[259] it is unlikely that a patient would timely be able to arrange such an appointment.

In November 2018, the Indian Health Service ("IHS") announced a new policy to

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254. *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (written statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.).

255. *Internet Pharmacies: Most Rogue Sites Operate from Abroad, and Many Sell Counterfeit Drugs: Testimony Before the H. Subcomm. on Oversight and Investigations*, 113th Cong. (2014) (statement of Marcia Crosse, Director, Health Care, U.S. Government Accountability Office).

256. S. Rep. No. 110-521, at 10 (2008).

257. Anupam B. Jena, et al., *Prescription Medication Abuse and Illegitimate Internet-Based Pharmacies*, 155 ANN. INTERN. MED. 848 (2011).

258. 21 U.S.C. § 802(54)(E).

259. *New Findings Confirm Predictions on Physician Shortage*, AM. ASS'N. MED. COL. (Apr. 23, 2019), https://www.aamc.org/news-insights/press-releases/new-findings-confirm-predictions-physician-shortage.

expand access to MAT in remote locations.[260] One of the definitions of telemedicine includes certain providers who are employed by IHS.[261] This definition dispenses with the need for a licensed practitioner to be physically located with the patient. Acknowledging the difficulty of accessing care in rural or remote areas, combined with the limited number of DATA 2000-waived providers, IHS said that the new policy will allow patients to access care more conveniently while reducing the time to start treatment.[262] This potentially lowers the risk of relapse and overdose death.[263]

Included in the CSA's list of exceptions to the in-person examination requirement is the Special Registration Process.[264] This exception waives the in-person exam requirement for practitioners specially registered with the DEA. To date, the procedure for applying for the special registration has not been announced. In late 2019, the DEA announced a proposed rule that would activate the special registration exception and establish the situations where special registration would apply. While this would increase the number of substance abuse treatment providers available, especially in rural areas, it still serves as an unnecessary limit on access to treatment.

For these reasons Congress should remove the in-person medical examination requirement from the CSA or update the definition of telemedicine to include the reality of current medical practice. Increasing access, through another exception that requires practitioners to meet several requirements, is not a solution. While the original intentions of the Ryan Haight Act were noble, the unintended consequences of the in-person exam requirement work in opposition to the goal of the act. With advances in high-speed internet and high-definition video, a practitioner can conduct a thorough medical encounter without the necessity of an in-person visit.

C. Symptoms of Overregulation—U.S. Drug Policy Adds Regulations to Solve Problems Caused by Regulations

Iatrogenic illness is a disease state or symptom caused by a medical treatment. A typical situation involves prescribing an additional medicine to treat the side effects of the first medicine. This presents a striking analogy to the restrictions placed on MAT-therapy for OUD. Controlled substance regulations, designed to control access to dangerous, addictive drugs, also makes it more difficult to obtain treatment for addiction to dangerous, addictive drugs.

One theme that is readily apparent in U.S. drug policy is the reliance on regulations to solve problems caused by regulations. In 1919, the U.S. Supreme Court held that the Harrison Narcotic Act prohibited the prescribing and dispensing of morphine to a habitual user in order to "keep him comfortable by maintaining his customary use."[265] This federal stance on addiction, and on medicine's role in the treatment of addiction, would affect

260. *IHS Announces a New Policy to Expand Access to Medication Assisted Treatment in Remote Locations*, IHS, https://www.ihs.gov/newsroom/ihs-blog/november2018/ihs-announces-a-new-policy-to-expand-access-to-medication-assisted-treatment-in-remote-locations/ (last visited Jan. 24, 2021).

261. 21 U.S.C. § 802(54)(C).

262. *See* IHS, *supra* note 260.

263. *Id.*

264. 21 U.S.C. § 831(h).

265. Webb v. United States, 249 U.S. 96, 99 (1919).

addiction treatment for fifty-six years until the passage of the CSA.

The CSA, as amended by NATA 1974, allowed physicians to dispense medications for maintenance and detoxification treatment. Finally, individuals with OUD could seek medical intervention for their condition. However, the restrictions imposed upon addiction treatment, such as stringent controls on the amount of medicine a physician could give a patient, created the typical "methadone clinic"[266] experience. Patients were required to make daily trips to the clinic to receive daily doses because Congress feared that patients would abuse methadone if given more than a few pills at a time.

With DATA 2000, Congress expanded access to MAT by allowing physicians to treat OUD in an office-based setting like any other chronic condition. A patient was able to see a physician in the privacy of a clinic office. Prescriptions for medication, typically buprenorphine, could be written and filled at the patient's local pharmacy. With a month supply of medication, the patient can focus on recovery rather than planning for another trip to the methadone clinic.

However, with the increase came another set of regulations. To obtain a DATA 2000 waiver, a physician is required to meet one of several onerous requirements. A physician must have a board certification in addiction medicine, complete additional training in addiction medicine, or have participated as an investigator in a clinical trial that lead "to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment."[267] After meeting one of these requirements, a physician is then limited to the number of patients she may treat. While the ability to prescribe buprenorphine in this setting has been expanded to include nurse practitioners and physician assistants, the unnecessary barriers of additional registration still prevent access to treatment by those most in need.

DATA 2000 also fails to recognize the safety and success of widespread access to buprenorphine treatment. Several addiction medicine organizations and physician groups have called on Congress to remove the restrictions on prescribing buprenorphine for OUD treatment. Proponents cite buprenorphine's partial agonist status and its relative safety compared to commonly prescribed and less regulated full agonists such as oxycodone.[268] The scope of the limitation created by the intersection of DATA 2000 and Ryan Haight Act restrictions becomes clearer when numbers are added to the analysis. Just 464 deaths related to buprenorphine were reported between 2002 and 2013, compared to the half a million overdose deaths between 2000 and 2014 involving mostly full opioid agonists, like oxycodone, fentanyl, or heroin.[269]

Another common reaction to the increase in opioid misuse and overdose deaths is to introduce or strengthen regulations for state-level prescription monitoring programs.[270]

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266. Methadone is a Schedule II opioid medication. It is used for both pain management and addiction treatment. Since it is in Schedule II, it is considered to have a high abuse potential and high likelihood of physical dependence if abused. This view lead to tight restrictions on its use, especially when treating OUD.

267. 21 U.S.C. § 823(g)(2)(G)(ii)

268. Kevin Fiscella, *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder*, 76 JAMA PSYCHIATRY 229 (2019).

269. *Id.*

270. Prescription Monitoring Programs (PMPs) are state-run databases for collecting information on the dispensing of controlled substance prescription medications. Dispensers, such as pharmacies or prescribers, are

However, while some evidence suggests that this leads to decreases in prescription drug misuse, a concomitant rise in heroin use occurs.[271] Other studies have found that when regulations increase the restrictions on Schedule II medications, physicians shift to less-regulated Schedule III medications instead of decreasing overall opioid prescribing.[272]

Congress should adopt a policy of decreasing regulations in order to increase access to treatment for OUD. All of these instances and situations listed above indicate that more regulations do not provide meaningful reductions in opioid abuse and misuse. Rather than continuing to focus on approaches that limit access to opioids, both licit and illicit, Congress should take steps to increase access to treatment for OUD. Removing the restrictions on prescribing buprenorphine in an office-based setting would be a productive step toward decreasing opioid abuse and misuse.

V. CONCLUSION

Due to the unique pharmacology of opioids and pathophysiology of OUD, increased and improved access to treatment and experienced practitioners is necessary. Efforts by IHS and VHA to increase access to MAT using telemedicine have proven effective. In the time it takes to read this comment, five people will have died from an opioid overdose. Press conferences announcing good intentions followed by inaction have cost thousands of lives. Half-steps to improve access continue to take time that would more effectively be used to treat patients with OUD.

Given the disparate impact of the opioid epidemic on rural areas, combined with the lack of access to mental health professionals and addiction specialists, legislative and regulatory action to improve and expand access to telemedicine services is needed. Access to treatment for OUD from the privacy and convenience of your home would dramatically increase the number of patients that receive this effective therapy.

The combined effect of the DATA 2000 and Ryan Haight Act amendments to the CSA work to artificially and unnecessarily limit the number and availability of substance use treatment providers. Congress has shown the ability to focus on the problem of the opioid epidemic, but not the willingness to make substantial changes. Increasing access to treatment, rather than limiting access to opioids, will have a greater impact on patients with OUD and should be the approach adopted by Congress.

- Joshua D. McCann[*]

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required to report to the database information such as the patient name, drug name and strength, and quantity. The information is then available for other healthcare providers to review prior to prescribing or dispensing a controlled substance prescription. *See* Anca M. Grecu, *Mandatory Access Prescription Drug Monitoring Programs and Prescription Drug Abuse*, 38 J. POL'Y ANALYSIS & MGMT. 181 (2019).

271. Grecu, *supra* note 270, at 181.

272. Stephanie Tran, *The Effect of a Federal Controlled Substance Act Schedule Change on Hydrocodone Combination Products Claims in a Medicaid Population*, 23 J. MANAG. CARE SPEC. PHARM. 532, 533 (2017).

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