THE GLOBAL OPIOID CRISIS: EFFECTIVE LAWS TO FIGHT RISING OVERDOSE FATALITIES THROUGH ACCESS TO NALOXONE

Molly Mahoney*

TABLE OF CONTENTS

I. Introduction	531
II. BACKGROUND	533
A. What are Opioids and What is Naloxone?	533
III. THE OPIOID EPIDEMIC IN THE UNITED STATES, THE UNITED KINGDOM	I, AND
AUSTRALIA	
A. The Opioid Epidemic in the United States	535
B. The Opioid Epidemic in the United Kingdom	
C. The Opioid Epidemic in Australia	
IV. LEGAL BACKGROUND OF NALOXONE ACCESS	540
A. Naloxone Drug Treatment Policies and Laws	
1. The United States' Prescription Drug Policy Regarding Naloxone A	
2. Prescription Drug Policy in the United Kingdom Regarding Nal	
Access	
3. Prescription Drug Policy in Australia Regarding Naloxone Access	
V. LEGAL ANALYSIS OF NALOXONE ACCESS	552
A. Legal Analysis of the United States' Naloxone Access Laws	
B. Legal Analysis of the United Kingdom's Naloxone Access Laws	
C. Legal Analysis of the Australia's Naloxone Access Laws	
VI. SUGGESTIONS FOR THE UNITED STATES FOR THE FUTURE	555
VII CONCLUCION	557

I. INTRODUCTION

"We're going to draw it up and we're going to make it a national emergency. It is a serious problem, the likes of which we have never had. You know, when I was growing up, they had the L.S.D. and they had certain generations of drugs. There's never been anything like what's happened to this country over

the last four or five years." - President Donald J. Trump on August 10, 2017, before a security briefing at his golf club in Bedminster, N.J. ¹

He is not wrong. There has not been anything quite like the current opioid epidemic in the United States before. The numbers are staggering. Upwards of 200,000 people have died in the United States from overdoses related to prescription opioids between 1999 and 2016.² To give this number some perspective, the interim report to President Trump from the Commission on Combating Drug Addiction and the Opioid Crisis stated that approximately 142 Americans die every day from this crisis, which means that the United States is enduring a death toll equal to the September 11th terrorist attacks every three weeks.³ This interim report to the President paints the morose picture of this crisis with disturbing facts such as that Americans consume more opioids than any other country in the world, and that in 2015, Americans were prescribed enough opioids so that every American could be medicated around the clock for three weeks.⁴

The United States accounts for 27% of global drug overdose deaths, but has only 4% of the world's population. This disparity is largely attributed to the rise in opioid addiction. While the United States is leading the world in overdoses, this epidemic is not unfamiliar to other countries. According to a 2018 factsheet on global health, of the roughly 450,000 people who died as a result of drug use in 2015, 118,000 of those deaths were associated with opioid use disorders. The United Nations Office on Drugs and Crime (UNODC) 2016 World Drug Report states that overdose deaths "contribute to between roughly a third and a half of all

- * J.D. Candidate, 2019, University of Arizona, James E. Rogers College of Law. To my father, Mark, and to the rest of my amazing family, thank you for your unconditional love and continuous support throughout my life. Special thanks to Professor Leila Barraza whose passion for public health law, direction, and feedback helped me immensely in the writing of this Note. Lastly, thank you to the members of the *Arizona Journal of International and Comparative Law* for their contributions to this publication.
- ¹ Michael D. Shear & Abby Goodnough, *Trump Plans to Declare Opioid Epidemic a National Emergency*, N.Y. TIMES, Aug. 10, 2017, https://www.nytimes.com/2017/08/10/us/politics/opioid-trump-emergency.html.
- ² Prescription Opioid Overdose Data, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 30, 2017), https://www.cdc.gov/drugoverdose/data/overdose.html.
- ³ COMM'N ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, COMMISSION INTERIM REPORT 1 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf.
 - COMM'N ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, *supra* note 3.
- ⁵ German Lopez, *America leads the world in drug overdose deaths by a lot*, Vox (June 28, 2017, 8:10 AM), https://www.vox.com/policy-and-politics/2017/6/28/15881246/drug-overdose-deaths-world.
- ⁶ See Ruth Dreifuss & Jorge Sampaio, Our International Perspective On America's Response To The Opioid Epidemic, HUFFINGTON POST (Nov. 2, 2017, 2:00 PM), https://www.huffingtonpost.com/entry/our-international-perspective-on-americas-response-to-the-opioid-epidemic_us_59fb5607e4b01b474048fde8.
- ⁷ Information sheet on opioid overdose, WORLD HEALTH ORG. (Aug. 2018), http://www.who.int/substance_abuse/information-sheet/en/.

drug-related deaths, which are attributable in most cases to opioids." According to reporting by the European Monitoring Centre for Drugs and Drug Addiction, in 2015, an estimated 8,441 overdose deaths occurred in Europe, mostly related to heroin and other opioids. This is 6% higher than the estimated 7,950 deaths in 2014 in Europe. Furthermore, opioid use may have grown in Africa, based on trend perceptions reported to the UNODC. In Australia, 68% of the 668 overdose deaths were related to pharmaceutical opioids in 2013. In Australia, 68% of the 668 overdose deaths were related to pharmaceutical opioids in 2013.

There are many different ways to prevent and treat drug overdose fatalities, such as needle and syringe exchange programs, opiate substitution therapy, and other evidence-based drug dependence treatments. However, the World Health Organization and the UNODC both highlight one treatment in particular—naloxone. It is an inexpensive medication that can completely reverse the effects of opioid overdose and prevent deaths due to opioid overdose.

This Note examines opioid overdose death rates in the United States, the United Kingdom, and Australia; the laws and policies related to naloxone put in place to curb these rates; and how effective these policies are in increasing access to this life-saving overdose treatment and in preventing overdose deaths. It will end with an outlook and suggestions for the United States moving forward.

II. BACKGROUND

A. What are Opioids and What is Naloxone?

Generally, opioids are a class of drugs that bind to opioid receptors in the brain, spinal cord, and elsewhere in the body, reducing pain signals to the brain. ¹⁶ Opioids get their name from opium, which is the brownish residue derived from the

 $^{^8}$ — Office on Drugs and Crime, World Drug Report 2016, at ix, U.N. Doc. E.16.XI.7 (June 2016).

⁹ European Drug Report 2017: The UK leads the sad statistic of drug overdose deaths in Europe, Eur. Comm'n (Aug. 6, 2017), https://ec.europa.eu/unitedkingdom/news/european-drug-report-2017-uk-leads-sad-statistic-drug-overdose-deaths-europe_en.

 $^{^{10}}$ Id

Office on Drugs and Crime, *supra* note 8, at xii.

Esther Han, *Prescription opioids are killing more Australians than heroin: Australian Bureau of Statistics*, THE SYDNEY MORNING HERALD, July 24, 2017, http://www.smh.com.au/national/health/prescription-opioids-are-killing-more-australians-than-heroin-australian-bureau-of-statistics-20170720-gxf5wa.html.

Office on Drugs and Crime, *supra* note 8, at xxi.

¹⁴ *Id.* at xxiv.

WORLD HEALTH ORG., *supra* note 7.

¹⁶ Opioid (Narcotic) Pain Medications, WEBMD, https://www.webmd.com/pain-management/guide/narcotic-pain-medications#1 (last visited Sept. 18, 2018).

juice of a poppy plant.¹⁷ The term opiate is an older term used to describe a class of drug that is derived from opium which includes morphine, heroin, and prescription painkillers such as OxyContin, Percocet, and Vicodin.¹⁸ The more modern term used today is opioid, which defines any natural or synthetic substance that binds to opioid receptors in the body such as the synthetic opioids methadone and fentanyl.¹⁹ Fentanyl, which began entering the drug supply in large amounts in 2014, can be fifty times more potent than heroin.²⁰ Opioids play an indispensable role in healthcare for their ability to help treat pain during surgery, critical care, and for certain types of long-term pain management—but the tradeoff is that they are extremely addictive.²¹ Research suggests that risks of long term opioid use increase significantly in the first days of opioid therapy—with strong correlation to long-term use (use of opioids one year later) after just five days of taking the drug.²² After a single day's supply on the drug, there is a 6% chance of patients being on an opioid a year later; long-term use jumps to 13% after just eight days on the drug.²³

Naloxone, sometimes referred to by its brand names Narcan or Evzio, is an opioid antagonist, or a drug that reverses the effects of an opioid drug overdose. ²⁴ It is also sometimes referred to as a "save" or "rescue" shot because it quickly reverses an overdose, effectively saving the life of the opioid user. ²⁵ When a user takes an opioid, the opioids bind to opioid receptors that mimic neurotransmitters, like endorphins, which numb the feeling of pain. ²⁶ In large doses, the drug then slows breathing—sometimes to the point of a life-threatening overdose—because the drug depresses the central nervous system and the respiratory system. ²⁷ A shot of naloxone into the muscle under the vein or skin, or a spray of naloxone into the user's nose, works by "kicking off" the opioids on the receptors in the body—totally reversing the overdose effects and helping the user to start breathing normally

HUGH C. HEMMINGS, JR. & TALMAGE D. EGAN, PHARMACOLOGY AND PHYSIOLOGY FOR ANESTHESIA: FOUNDATIONS AND CLINICAL APPLICATION 253 (2013).

¹⁸ Id.; Josh Katz, Short Answers to Hard Questions About the Opioid Crisis, N.Y. TIMES, Aug. 10, 2017, https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html.

¹⁹ HEMMINGS & EGAN, *supra* note 17; Katz, *supra* note 18.

²⁰ Katz, *supra* note 18.

HEMMINGS & EGAN, *supra* note 17; Katz, *supra* note 18.

Steven Reinberg, *Opioid dependence can start within just a few days*, CBS NEWS (Mar. 17, 2017, 12:23 PM), https://www.cbsnews.com/news/opioid-painkiller-addiction-dependence-can-start-in-days/.

 $^{^{23}}$ Ia

Nadia Kounang, What is naloxone?, CNN (Apr. 28, 2016, 4:37 PM), http://www.cnn.com/2016/04/28/health/what-is-naloxone-narcan-opioid-overdose/index.html.

²⁵ *Id*.

²⁶ Id

Understanding Naloxone, HARM REDUCTION COALITION, http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited Sept. 18, 2018).

again.²⁸ More powerful opioids, such as fentanyl, may necessitate several doses of naloxone to reverse the deadly effects of overdose because the higher the amount of opioids in the system, the more naloxone that is needed.²⁹ While generally administered by trained medical professionals, "injectable" naloxone also comes in forms that laypersons can administer at home—most commonly in the form of the "auto-injectable" Evzio or the prepackaged nasal spray Narcan.³⁰ Naloxone is a temporary drug that wears off in twenty to ninety minutes and has no potential for abuse because it is non-addictive.³¹

III. THE OPIOID EPIDEMIC IN THE UNITED STATES, THE UNITED KINGDOM, AND AUSTRALIA

A. The Opioid Epidemic in the United States

Drug overdose, mostly caused by opioids, is now the leading cause of death for Americans under fifty.³² Opioid overdose killed more than 33,000 people in 2015 alone.³³ The most recent provisional data from the Centers for Disease Control (CDC) as of August 2017 estimates that, of the roughly 64,000 drug overdose deaths in 2016 (21% increase from 2015), about 50,000 of those deaths are attributable to opioids.³⁴ This number of drug overdose deaths is higher than the "more than 38,000 who died in car crashes, the more than 36,000 who died from gun violence, and the more than 43,000 who died due to HIV/AIDS during that epidemic's peak in 1995."³⁵ Lately, social media and news in the United States have been inundated with these stories of opioid overdose rates.³⁶ Stories of heroin overdoses in the street—stories that the general public may have been used to

Kounang, *supra* note 24; HARM REDUCTION COALITION, *supra* note 27.

²⁹ Kounang, *supra* note 24; *Fentanyl*, Nat'l Inst. on Drug Abuse https://www.drugabuse.gov/publications/drugfacts/fentanyl (last updated June 2016).

³⁰ Opioid Overdose Reversal with Naloxone (Narcan, Evzio), NAT'L INST. ON DRUG ABUSE (Apr. 2018), https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio [hereinafter Opioid Overdose Reversal with Naloxone].

HARM REDUCTION COALITION, *supra* note 27.

³² Critical Public Health Law Leadership and Response to the Opioid Epidemic, THE NETWORK FOR PUB. HEALTH L., https://www.networkforphl.org/_email/_asset/t1bknj/ Network-Leadership-in-Legal-and-Policy-Interventions-Related-to-Opioid-Epidemic-Web.pdf?utm_source=Network+Report+8-31-17&utm_campaign=Network+Report+8-31-17&utm_medium=email&utm_content=324. (last visited Sept. 18, 2018).

³³ Opioid Overdose, CTR. FOR DISEASE CONTROL AND PREVENTION (Sept. 26, 2017), https://www.cdc.gov/drugoverdose/index.html [hereinafter Opioid Overdose, CDC].

Provisional Counts of Drug Overdose Deaths, as of 8/6/2017, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf. (last visited Sept. 18, 2018).

Lopez, supra note 5.

³⁶ See id. ("Another grim statistic in the opioid epidemic.").

hearing—have now morphed into stories of everyday citizens overdosing in other unexpected areas.³⁷ These horrific tales include the story of parents overdosing at children's softball practices,³⁸ and the viral photo on social media posted by the Ohio police depicting a couple passed out in the front seat of their parked car near a school bus with their four-year-old son in the back seat.³⁹ Other horrifying stories include a less common victim of the opioid epidemic—children.⁴⁰ These children are consuming their parent's opioids through ingestion or accidental contact with needles which has led to rising rates of children dying of opioid intoxication.⁴¹ In 2015, eighty-seven children died compared to just sixteen in 1999—a small fraction of the overall deaths from opioids, but a heartbreaking indication of how serious this problem has become.⁴²

To understand the current state of the opioid epidemic, it is important to examine how the United States got to this point. Interestingly, this is not the first time the United States has had a sizable epidemic of opioid addiction.⁴³ In the late 1800s, the spread of hypodermic medication made it very common for doctors to prescribe morphine, which led to iatrogenic (illness caused by medical treatment) morphine addiction.⁴⁴ To a lesser extent, other populations used opium during this time period, including mothers medicating their children, soldiers treating illnesses and injuries, and alcoholics treating hangovers.⁴⁵ Doctors tended to overprescribe morphine to their patients and themselves because it seemed to magically take care of painful symptoms.⁴⁶ However, with the emerging studies in bacteriology and the introduction to society of public health measures, many of the illnesses treated with morphine were prevented.⁴⁷ These revolutions mixed with the advent of aspirin and

³⁷ See Kelly Tatera, The Changing Face of an Opiate Addict, THE SCIENCE EXPLORER (Oct. 22, 2015), http://thescienceexplorer.com/humanity/changing-face-opiate-addict.

Margaret Talbot, *The Addicts Next Door*, The New Yorker, June 5 & 12, 2017, https://www.newyorker.com/magazine/2017/06/05/the-addicts-next-door.

³⁹ Snejana Farberov, Wasted: Horrifying photos of parents passed out by school bus after overdosing in their car with four-year-old boy in the backseat reveal the terrible toll of the opioid epidemic sweeping America, DAILYMAIL.COM (Sept. 9, 2016, 10:28 AM), http://www.dailymail.co.uk/news/article-3781814/Ohio-police-share-horrifying-photos-adults-passed-overdosing-car-toddler-backseat.html.

Julie Turkewitz, 'The Pills Are Everywhere': How the Opioid Crisis Claims Its Youngest Victims, N.Y. TIMES, Sept. 20, 2017, https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html.

⁴¹ *Id*.

⁴² Id

⁴³ Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 561 (2015).

⁴⁴ Id.

⁴⁵ *Id*.

⁴⁶ *Id*.

⁴⁷ *Id.* at 561–62.

stricter prescription laws made prescribing opioids a passé practice in the medical field. 48

For most of the 20th century, the opioid epidemic was largely attributed to the abuse of non-medical heroin in inner-city areas.⁴⁹ In the mid-1980s, a paper with low-quality evidence circulated among the medical community that supported the idea of expanding opioid prescriptions for chronic non-cancer pain, claiming that "opioid maintenance therapy can be a safe, salutary, and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."50 Then, in the mid-1990s, opioid use began to rise substantially due to the release of OxyContin, an extended release formulation of oxycodone, by the pharmaceutical company called Purdue Pharma.⁵¹ The introduction of this new wonder-drug was combined with a massive marketing campaign, largely produced by Purdue Pharma, that encompassed funding for more than 20,000 pain-related educational programs encouraging long-term use of opioids for chronic non-cancer pain. 52 Several medical organizations, including the Joint Commission,⁵³ bought into this idea of pain-centered treatment with the understanding that the risk of addiction was low, and in turn, started advocating aggressively for the treatment of pain with medications similar to OxyContin.⁵⁴

It turns out that this wide marketing and advocacy campaign for the "safe" prescription of opioids to treat long-term pain based on slim evidence may have been a reckless crusade for the medical community. While evidence still supports the use of opioids for short-term acute pain, recent studies show that the opposite may be true for many individuals with chronic pain. These reports indicate that there are higher rates of opioid misuse in the chronic pain group than previously thought, with prevalence rates as high as 50% among these patients. This is not to downplay the rise in opioid prescriptions for acute pain, which has also risen sharply. From 2009 to 2010, a study found that physicians prescribed opioids—often in high doses—to more than 50% of 1.14 million nonsurgical hospital admissions.

⁴⁸ Kolodny et al., *supra* note 43.

⁴⁹ *Id.* at 562.

⁵⁰ *Id.*; Russell Portenoy & Kathleen Foley, *Chronic Use of Opioid Analgesics in Non-Malignant pain: Report of 38 Cases*, 25 PAIN 171, 171 (1986).

Kolodny et al., *supra* note 43, at 562.

⁵² Id

The Joint Commission is a United States-based, independent, nonprofit organization that accredits more than 21,000 US health care organizations and programs. *About Us*, The Joint Comm'n, https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (last visited Sept. 18, 2018).

Kolodny et al., *supra* note 43, at 562.

⁵⁵ Anna Lembke et al., *Weighing the Risks and Benefits of Chronic Opioid Therapy*, 93 Am. FAMILY PHYSICIAN 982, 982, 986 (2016).

⁵⁶ *Id.* at 986.

Kolodny et al., *supra* note 43, at 563.

⁵⁸ Id.

The proliferation of these pills is not only spreading to more patients in recent years but also to friends of patients and to other family members in the home of the patient, including teens rummaging through medicine cabinets.⁵⁹ The higher rates of nonmedical use of opioids has raised concern about ties to the similarly increasing rates of heroin abuse.⁶⁰ According to a report by the Substance Abuse and Mental Health Services Administration (SAMHSA), four out of five recent heroin users report that they previously used nonmedical pain relievers; in contrast, only 1% of recent nonmedical pain-reliever-users have used heroin previously.⁶¹ Furthermore, according to provisional data for 2016 from the CDC, deaths resulting from synthetic opioids, mainly fentanyl, have doubled from 2015 to 2016.⁶² In fact, the rate of overdose deaths involving synthetic opioids has risen to more than 20,000 from just 3,000 in only three years.⁶³

This suggests that the opioid epidemic has strong correlations to the overprescription of painkillers. However, data suggest that overdoses from prescription opioids have leveled off since 2011, and the United States is now faced with higher death rates from heroin and fentanyl, which are rising alarmingly fast.⁶⁴ In Rhode Island, Pennsylvania, and Massachusetts, where the crisis is exceptionally severe, fentanyl is now involved in over half of all drug overdose deaths.⁶⁵ Between January and September of 2017, Maryland had 1,501 opioid-related deaths, with 1,173 of them tied to fentanyl.⁶⁶ More alarming is the emergence of carfentanil, an animal tranquilizer 100 times more potent than fentanyl, which was responsible for fifty-seven deaths in Maryland during the same time frame compared to zero the year before.⁶⁷

B. The Opioid Epidemic in the United Kingdom

According to the European Drug Report 2017, drug overdose deaths in Europe have increased for the third year in a row—most of them attributed to

⁵⁹ Lopez, *supra* note 5.

⁶⁰ Pradip K. Muhuri et al., Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, CBHSQ DATA REV., Aug. 2013, at 1, https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.pdf.

⁶¹ *Id*.

⁶² CTR. FOR DISEASE CONTROL AND PREVENTION, *supra* note 34, at 2.

Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES, Sept. 2, 2017, https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html?_r=0.

⁶⁴ Katz, *supra* note 18.

⁶⁵ *Id.*

Andrea K. McDaniels, Fentanyl continues to lead record opioid deaths in Maryland, BALT. SUN, Jan. 26, 2018, http://www.baltimoresun.com/health/bs-hs-opioid-deaths-20180126-story.html.

⁶⁷ *Id*.

opioids.⁶⁸ Two countries—the United Kingdom (31%) and Germany (15%)—comprise about half of these overdose deaths.⁶⁹ Five countries in the European Union, including the United Kingdom, have made up 76% of the estimated "high risk opioid users" with the United Kingdom having the most amount of users at 330,445.⁷⁰ Specifically, in 2015, England and Wales recorded a 26% increase in deaths caused by heroin overdose.⁷¹ Hospital inpatient data from the United Kingdom indicates that out of 41,628 inpatient discharges for drug poisoning in 2014, the majority were due to "other opioids including morphine and codeine," and that number has increased every year since 2008.⁷² Most concerning is that the number of opioid prescriptions in the United Kingdom has doubled from 2006 to 2016, an indication that there is a looming epidemic similar to the United States.⁷³ This may be evidenced by hospital admissions for opioid overdoses have more than doubled during that same time frame.⁷⁴

C. The Opioid Epidemic in Australia

Globally, Australia places eighth for the highest number of prescription opioid users. ⁷⁵ Use of these prescription painkillers in Australia is on the rise with increasing rates of opioid overdose deaths. ⁷⁶ However, the source of the opioid overdoses has changed in this country since the 1990s. ⁷⁷ In the late 1990s, most Australians dying from opioid overdose died from heroin. ⁷⁸ Following a steep decrease in the overdose deaths of heroin users at the turn of the century, there is now a steady increase in opioid overdose deaths from prescription opioids since

EUR. COMM'N, *supra* note 9.

⁶⁹ Id

⁷⁰ *Id*.

Damien Gayle, *Almost one in three drugs overdoses in Europe recorded in UK*, THE GUARDIAN, June 6, 2017, https://www.theguardian.com/society/2017/jun/06/almost-one-in-three-drugs-overdoses-in-europe-occur-in-the-uk.

⁷² EUR. MONITORING CTR. FOR DRUGS AND DRUG ADDICTION, UNITED KINGDOM COUNTRY DRUG REPORT 2017 8 (2017), http://www.emcdda.europa.eu/system/files/publications/4529/TD0116925ENN.pdf [hereinafter UK DRUG REPORT].

⁷³ Prescription opioid abuse rising in UK, Fox News (Oct. 17, 2017), http://www.foxnews.com/world/2017/10/17/prescription-opioid-abuse-rising-in-uk.html.

Sarah Marsh, *Overdoses on opioid painkillers more than double in a decade*, THE GUARDIAN, Sep. 13, 2017, https://www.theguardian.com/science/2017/sep/13/opioid-painkiller-overdoses-more-than-double-decade-england.

Julie Power, *Prescription opioid epidemic coming to Australia*, THE SYDNEY MORNING HERALD, Aug. 5, 2017, http://www.smh.com.au/national/prescription-opioid-epidemic-coming-to-australia-20170803-gxobvt.html.

Simon R. Lenton et al., *Australia reschedules naloxone for opioid overdose*, 204 MED. J. AUSTL. 146, 146 (2016), https://www.mja.com.au/system/files/issues/204_04/10.5694mja15.01181.pdf.

⁷⁷ See id.

⁷⁸ See id.

2007.⁷⁹ Last year, Australia reported that it has experienced the highest number of drug-induced deaths since the 1990s, most commonly associated with benzodiazepines and oxycodone (a prescription opioid).⁸⁰ Most alarmingly, Australia seems to be following the United States' patterns in this epidemic as Australia is seeing higher levels of use of opioids like fentanyl and oxycodone in rural areas, as opposed to in more urban locations.⁸¹

IV. LEGAL BACKGROUND OF NALOXONE ACCESS

A. Naloxone Drug Treatment Policies and Laws

1. The United States' Prescription Drug Policy Regarding Naloxone Access

In order to analyze what the United States is doing regarding the opioid epidemic, it is important to take a brief look at the country's history of drug legislation. Drug enforcement as we know it today did not come about until the middle of the 20th century. Reference as we know it today did not come about until the middle of the 20th century. In fact, the federal government only began to control drugs in the United States in the early 20th century after the Harrison Act of 1914 passed. The Harrison Act regulated and taxed drugs like cocaine and opium. Lecause this Act authorized enforcement agents to shut down places like city narcotic clinics, and to send drug violators to prison due to the discretionary nature of the law, users were forced to use illegal means to obtain their preferred drugs. Later came the passing of the Marihuana Tax Act of 1937, which led to all states making possession of marijuana illegal, and the Boggs Act in 1951, which established mandatory prison sentences for some drug offenses. After the Narcotic Control Act in 1956 passed, further punishment for drug offenses, such as the death penalty as punishment for selling heroin to youth, increased.

Simon R. Lenton et al., *supra* note 76; *see* Power, *supra* note 75.

Meredith Griffiths, *Drug-induced deaths at highest point since 1990s, heart disease in decline*, AUSTL. BROAD. CORP. (Sep. 27, 2017, 2:25 AM), http://www.abc.net.au/news/2017-09-27/drug-induced-deaths-at-highest-rate-since-1990s-abs-data-shows/8992986.

⁸¹ See Australian Associated Press, Opioid use rising in regional Australia, wastewater tests show, The GUARDIAN, Dec. 13, 2017, https://www.theguardian.com/australia-news/2017/dec/14/opioid-regional-australia-waste water-tests.

LISA N. SACCO, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS, CONG. RES. SERV., R43749, at 4 (2014).

⁸³ *Id.* at 2.

⁸⁴ *Id.* 2–3.

⁸⁵ *Id.* at 3.

⁸⁶ *Id.* at 3–4.

SACCO, supra note 82, at 4.

toward drug crimes began to shift toward a mixture of a medical approach to treating drug addiction, as well as a strong emphasis on increasing law enforcement on the issue. Reagan, most notably due to the advent of mandatory minimum penalties for drug trafficking offenses. From the training drug control with his infamous "War on Drugs" that began with the Controlled Substances Act in 1970. The Controlled Substances Act continues to serve as the statutory framework the Drug Enforcement Administration (DEA) uses to categorize controlled substances into five different schedules. The 1980s also saw rising rates of drug incarcerations under President Reagan, most notably due to the advent of mandatory minimum penalties for drug trafficking offenses.

As drug legislation and drug abuse trends continued to change in the last twenty to thirty years, Congress has responded in several different ways. In the 1990s, methamphetamine and other synthetic drugs gained popularity, alongside the rising rates of heroin and emerging prescription opioid abuse epidemic. 92 In response to the growing rate of pharmaceutical abuse, the DEA's Office of Diversion Control has been tasked with preventing, detecting, and investigating the "diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."93 This practice, known as "supply reduction," emphasizes domestic drug enforcement by having federal law enforcement agencies work with state and local agencies to generally target large drug trafficking organizations to make illicit drugs harder and more expensive to obtain.⁹⁴ In October 2017, President Trump said that to fight the opioid epidemic, the government would produce "really tough, really big, really great advertising" aimed at persuading Americans not to start using opioids in the first place, which is reminiscent of the "Just Say No" drug campaign coined by Nancy Reagan during her husband's continuation of the "War on Drugs" during the 1980s. 95

The federal government in the United States has the authority to control the use of prohibited controlled substances and controlled substances that are diverted from their intended medical purpose. The power to control these drugs mostly lies with the U.S. Attorney General. Furthermore, the Federal Drug Administration (FDA) is responsible for "protecting the public health by ensuring

⁸⁸ SACCO, *supra* note 82, at 3–5.

⁸⁹ *Id.* at 5.

⁹⁰ *Id.* at 6.

⁹¹ *Id.* at 8.

⁹² *Id.* at 11–14.

⁹³ Program Description, DRUG ENF'T ADMIN., OFF. OF DIVERSION CONTROL, http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html (last visited Sept. 18, 2018).

⁹⁴ SACCO, *supra* note 82, at 1.

Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, N.Y. TIMES, Oct. 26, 2017, https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html?_r=0.

⁹⁶ SACCO, *supra* note 82, at 1.

the safety, efficacy, and security" of human drugs. ⁹⁷ This brief history of the United States' strict enforcement of illicit drugs such as heroin, as well as the identification of the two entities that control drugs and their enforcement in this country (the Attorney General and the FDA), are all essential components in examining the opioid epidemic and how the federal government and states can help reduce overdose deaths by making naloxone easier to obtain.

Currently, the only way to obtain the life-saving opioid overdose reversal drug naloxone in the United States is through a personal prescription from a doctor or, as mentioned by the 21st Century Cures Act, a standing order that allows one to obtain the drug through a pharmacy or community-based hard reduction program. 98 Specifically, the FDA approved "user friendly versions" of naloxone—the first being Evzio, the auto-injector formulation of naloxone, in April 2014 and Narcan, the nasal spray, in November 2015—both only to be available through a prescription.⁹⁹ The standing orders that increase access to naloxone work two ways. The original definition of "standing order" in this context means that a physician can authorize the use of a drug to be carried out by other health care workers when certain conditions have been met. 100 An example of this is when a physician writes a prescription for naloxone, and then employees at a community-based program, such as a drug harm reduction program, who are trained to dispense naloxone, can administer the drug. 101 On a larger scale, almost all states have a statewide written standing order that is authorized by the state's Physician General that allows naloxone distribution by certain people, such as pharmacists, first responders, emergency medical personnel, or others who meet the criteria outlined in the order. 102

⁹⁷ What We Do, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated Mar. 28, 2018) [hereinafter What We Do].

⁹⁸ 42 U.S.C.A. § 290ee (Westlaw through Pub. L. No. 115–223); *see Drugs@FDA: FDA Approved Drug Products*, FED. DRUG ADMIN. (FDA), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=091422 (last visited Sept. 18, 2018).

Press Release, Fed. Drug Admin. (FDA), Evzio (naloxone auto-injector) Approved to Reverse Opioid Overdose (Apr. 23, 2018), https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm391449.htm; Press Release, Fed. Drug Admin. (FDA), Narcan (naloxone nasal spray) Approved to Reverse Opioid Overdose (Apr. 23, 2018), https://www.fda.gov/drugs/drugsafety/postmarketdrugsafety informationforpatientsandproviders/ucm472958.htm; Opioid Overdose Reversal with Naloxone, supra note 30.

¹⁰⁰ Case Studies: Standing Orders, NALOXONEINFO.ORG, http://naloxoneinfo.org/case-studies/standing-orders (last visited Sept. 18, 2018) [hereinafter Case Studies: Standing Orders].

¹⁰¹ *Id.*

¹⁰² Id.; THE NETWORK FOR PUB. HEALTH L., LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND OVERDOSE GOOD SAMARITAN LAWS 1 (2017), https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf.

Although naloxone has been administered by medical professionals for decades, these two forms of naloxone make administering the drug easier for those who are not medical professionals, such as addicts themselves or their family members. To make it easier for individuals to obtain naloxone, states have taken more substantial steps to increase laypersons' access to the drug since 2010. In fact, as of July 2017, all fifty states and the District of Columbia have passed legislation designed to improve layperson access to naloxone. These laws include civil, criminal, and disciplinary immunity for medical professionals who prescribe or dispense naloxone and similar immunity for laypeople who administer the drug (often called Good Samaritan laws). Also included are laws that permit organizations, such as harm reduction programs or needle exchange programs, to dispense the drug and permit laypeople to possess the drug without a prescription, such as a third party who is not at risk of an overdose (i.e. a family member of an addict) through a statewide standing order.

Interestingly, there has been apprehension from some members of the medical community who are fearful of co-prescribing opioids and naloxone due to legal concerns. However, the legal risk that a doctor takes when co-prescribing these drugs for a patient is no higher than that of any other medication they can prescribe and in fact, is lower than many, even without the legal protections that many states have passed in recent years. Below is a table outlining more specifically the different types of naloxone access laws that states have passed. 109

¹⁰³ COREY DAVIS, NALOXONE FOR COMMUNITY OPIOID OVERDOSE REVERSAL 1 (2015), http://prescribetoprevent.org/wp2015/wp-content/uploads/PHLRKnowledge
Asset_Naloxone_FINALfull_8June15.pdf.

¹⁰⁴ Id.

THE NETWORK FOR PUB. HEALTH L., *supra* note 102.

¹⁰⁶ Id. at 3–6 (providing a chart documenting every state's laws regarding improving naloxone access).

¹⁰⁷ Corey S. Davis et al., *Co-prescribing naloxone does not increase liability risk*, 37 SUBSTANCE ABUSE 498, 498 (2016).

Davis et al., *supra* note 107.

See Naloxone Overdose Prevention Laws, PRESCRIPTION DRUG ABUSE POL'Y SYS. (July 1, 2017), http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-150169 5139.

Table 1

Type of Naloxone Access Law	Number of states where it passed
Some sort of naloxone access law ¹¹⁰	51 (includes D.C.)
Law that gives prescribers immunity from criminal prosecution for prescribing, dispensing, or distributing naloxone to a layperson	37
Law where prescribers have immunity from civil liability for prescribing, dispensing, or distributing naloxone to a layperson	41
Law where prescribers have immunity from professional sanctions for prescribing, dispensing, or distributing naloxone to a layperson	35
Law that gives dispensers immunity from criminal prosecution for prescribing, dispensing, or distributing naloxone to a layperson	36
Law that give dispensers immunity from civil liability for prescribing, dispensing, or distributing naloxone to a layperson	41
Law that gives immunity from professional sanctions for dispensers	35
Law that says that prescriptions of naloxone are authorized for third parties	46
Law that says that pharmacists are allowed to dispense or distribute naloxone without a patient-specific prescription from another medical professional	50
Law where a layperson is immune from criminal liability when administering naloxone	38
Law where a layperson is immune from civil liability when administering naloxone	46
Law that removes criminal liability for possession of naloxone without a prescription	15

Scott Burris, Where Next for Opioids and the Law? Despair, Harm Reduction, Lawsuits, and Regulatory Reform, 131 Pub. Health Rep. 29, 29 (2017).

Further, many of these statutes have conditions on the immunity, such as requiring the person administering the drug to act with reasonable care, or requiring participation in a naloxone administration program.¹¹¹

As far as recent legislative action in the United States, President Obama signed into effect the 21st Century Cures Act in 2016 which, among other federal grants, allotted \$1 billion to help states manage opioid abuse concerns in their communities by improving access to treatment and strategies to prevent overdose deaths. 112 The Act allows the Secretary of Health and Human Services (HHS) to approve grants for each state, with preference going to states with higher incidence or prevalence rates of opioid use disorders, and provides for a maximum amount of \$200,000 per grant year. 113 These grants incentivize states to create action plans that can increase policies that many have already put into effect, like the statewide standing orders.¹¹⁴ Pursuant to these standing orders in the state, these grants authorized by the Secretary allow states to implement strategies for pharmacists to dispense drugs or devices for emergency treatment of opioid overdoses, such as naloxone, and to educate the public on how to use and obtain these life-saving drugs or devices. 115 These standing orders permit community-based organizations or other non-profit entities, such as substance abuse programs, to acquire, dispense, and/or administer drugs for the emergency treatment of an opioid overdose. 116 The grants also allow the standing orders in the applicable states to allow for police, fire, and other emergency medical services and first responders to acquire and administer naloxone to individuals who are overdosing on opioids. 117 HHS announced in April 2017 that the first of two rounds of funding of these grants provided for in the 21st Century Cures Act were awarded to all fifty states, the District of Columbia, four US territories, and the free associated states of Palau and Micronesia. 118 In addition, the former Secretary of HHS announced that \$485 million would be granted to the states based on their rates of overdose deaths and need for opioid addiction treatment 119

States have also taken matters into their own hands aside from accessing federal grant funding or passing their own legislation, such as Good Samaritan laws

See Prescription Drug Abuse Pol'y Sys., supra note 109.

SAMHSA to award nearly \$1 billion in new grants to address the nation's opioid crisis, Substance Abuse and Mental Health Serv. Admin. (SAMHSA) (Dec. 14, 2016), https://www.samhsa.gov/newsroom/press-announcements/201612141015.

¹¹³ 42 U.S.C.A. § 290dd–3 (Westlaw through Pub. L. No. 115–223); § 290ee (Westlaw); 21st Century Cures Act, H.R. 34, 114th Cong. § 1003 (2016).

THE NETWORK FOR PUB. HEALTH L., *supra* note 102, at 2.

¹¹⁵ § 290ee (Westlaw).

^{16 § 290}ee(c)(2) (Westlaw).

¹¹⁷ § 290ee(c)(3) (Westlaw); 42 U.S.C.A. § 290ee–1 (Westlaw through Pub. L. No. 115–223).

Press Release, Dep't of Health and Human Serv., Trump Administration awards grants to states to combat opioid crisis (Apr. 19, 2017), https://www.hhs.gov/about/news/2017/04/19/trump-administration-awards-grants-states-combat-opioid-crisis.html.

¹¹⁹ *Id*.

or statewide standing orders. Six states-Maryland, Massachusetts, Alaska, Arizona, Virginia, and Florida—have all declared some form of public health emergency that allows them to access emergency funding to implement strategies such as monitoring prescriptions of opioids and increasing access to naloxone. 120 For example, Arizona declared an emergency in June 2017 and used its declaration to set up real-time reports on numbers of overdoses and babies born addicted to opioids, and to train 1,000 law enforcement officers on how to use naloxone. 121 Furthermore, Mississippi, Ohio, Delaware, Oklahoma, New York, and many other jurisdictions have filed hundreds of lawsuits against pharmaceutical companies asserting they are responsible for purposely misleading doctors to overprescribe opioids to increase profits. 122

Additionally, retail pharmacy companies in the United States have voluntarily joined the fight for preventing opioid overdose deaths by making safer policies in their stores and increasing naloxone access. 123 CVS Pharmacy announced in September 2017 that it would limit opioid prescriptions to a sevenday supply to lower the chance of dependence, as well as requiring its pharmacists to discuss the risks of addiction with patients. 124 Walgreens announced in October 2017 that it would stock Narcan, the naloxone nasal spray, in all 8,000 locations of its stores and that it would educate patients on how to use the spray. 125 This announcement is in addition to the company's earlier commitment to having

Erin Mershon & Andrew Joseph, These states declared an emergency over the opioid crisis. Here's what happened, PBS NEWSHOUR (Aug. 10, 2017, 10:02 AM), https://www.pbs.org/newshour/health/states-declared-emergency-opioid-crisis-hereshappened.

¹²¹

Colin Dwyer, Ohio Sues 5 Major Drug Companies For 'Fueling Opioid Epidemic', NPR (May 31, 2017, 5:53 PM), http://www.npr.org/sections/thetwo-way/2017/05/31/ 530929307/ohio-sues-5-major-drug-companies-for-fueling-opioid-epidemic; Lopez, The growing number of lawsuits against opioid companies, explained, Vox (Feb. 27, 2018, 5:22 PM), https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-com panies-epidemic-lawsuits; Nate Raymond, Delaware sues opioid manufacturers, distributors over epidemic, REUTERS (Jan. 19, 2018, 1:54 PM), https://www.reuters.com/article/us-usaopioids-litigation/delaware-sues-opioid-manufacturers-distributors-over-epidemicidUSKBN1F82LI; Jonathan Stempel, New York sues OxyContin maker Purdue Pharma over opioids, REUTERS (Aug 14, 2018, 9:13 AM), https://www.reuters.com/article/us-usa-opioidspurduepharma/new-york-sues-oxycontin-maker-purdue-pharma-over-opioidsidUSKBN1KZ1WZ.

CVS to Limit Opioid Prescriptions to 7-Day Supply, NBC CHI. (Sept. 21, 2017, 6:27 PM), https://www.nbcchicago.com/news/national-international/CVS-to-Limit-Opioid-Prescriptions-to-7-Day-Supply-446592513.html?_osource=SocialFlowTwt_CHBrand &_osource=SocialFlowFB_CHBrand; Press Release, Walgreens, Walgreens Stocking Life Saving Narcan® Nasal Spray in All Pharmacies Nationwide (Oct. 24, 2017), http://news.walgreens.com/press-releases/general-news/walgreens-stocking-life-savingnarcan-nasal-spray-in-all-pharmacies-nationwide.htm.

NBC CHI., supra note 123.

Walgreens, supra note 123.

naloxone in all of the stores that had standing orders allowing pharmacists to dispense naloxone without a prescription. 126

Most recently, on October 26, 2017, President Trump declared the opioid crisis a national public health emergency and directed the executive government to "use every appropriate emergency authority" to fight the crisis. 127 This is a different designation than declaring a national emergency, which is what President Trump indicated he would declare in August 2017.¹²⁸ A declaration of a public health emergency allows the federal government to appoint new staff to address the emergency (pending any funding needed), to allow for new flexibilities with HIV/AIDS programs, to work with the DEA to expand the use of telemedicine services to treat people in rural areas ravaged by opioid use, and to allow for some grant money to be used to combat the opioid crisis. 129 A public health emergency, as opposed to a national emergency, does not make available funds from the Federal Emergency Management Agency, which are normally available after a major national disaster. 130 However, President Trump said that his administration would announce a new policy that would allow for federal Medicaid funding to treatment facilities that historically have been an exception to funding under the Social Security Act. 131 This would allow federal funding to treatment facilities with more than sixteen beds for those suffering from drug addiction. 132

President Trump's budget, passed in February 2018, includes \$3 billion in new funding in 2018 and \$10 billion in new funding in 2019 for the Department of Health and Human Services to combat the opioid epidemic. However, it is unclear if the new budget will be helpful in fighting the opioid crisis since it aims

Walgreens, *supra* note 123.

Miriam Valverde, *Donald Trump declares public health emergency over opioid crisis. Here's what that means*, POLITIFACT (Oct. 30, 2017, 8:55 AM), http://www.politifact.com/truth-o-meter/article/2017/oct/30/opioid-epidemic-united-states-and-trump-administra/.

See Shear & Goodnough, supra note 1.

Valverde, *supra* note 127; Davis, *supra* note 95.

Davis, *supra* note 95; Valverde, *supra* note 127.

¹³¹ 42 U.S.C.A. § 1396d(a)(29)(B) (Westlaw through Pub. L. No. 115–223); LEGAL ACTION CENTER, THE MEDICAID IMD EXCLUSION: AN OVERVIEW AND OPPORTUNITIES FOR REFORM 1 (2014), https://lac.org/wp-content/uploads/2014/07/IMD_exclusion_fact_sheet.pdf; Valverde, *supra* note 127.

Valverde, *supra* note 127.

Press Release, The White House, President Donald J. Trump is Combatting the Opioid Crisis (Mar. 1, 2018), https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-combatting-opioid-crisis/; Eli Watkins, *Conway touts new funding targeting opioid crisis*, CNN (Feb. 11, 2018, 10:18 AM), https://www.cnn.com/2018/02/11/politics/kellyanne-conway-opioid-cnntv/index.html.

to take away funding from services that also help people with drug addictions, such as Medicaid. 134

2. Prescription Drug Policy in the United Kingdom Regarding Naloxone Access

The United Kingdom's struggle with addiction to opioid prescriptions has been described as a "public health disaster." Addiction to heroin in England and Wales has increased significantly in recent years. 136 To understand how the United Kingdom is addressing overdose deaths that are attributed to opioid addictions, it is necessary to know the process by which its drug policies are established.

The laws that control drugs in the United Kingdom are organized into three statutes that regulate the use, possession, and distribution of drugs: The Medicines Act (1968), The Misuse of Drugs Act (1971), and The Psychoactive Substances Act (2016). The Medicines Act addresses the manufacture and supply of medicine and separates these medical drugs into: (1) prescription drug medicines, (2) pharmacy medicines, and (3) general sales list medicines. 138 Prescription drug medicines are only available to be administered by a pharmacist when instructed to by a doctor. Pharmacy medicines are only allowed to be administered by a pharmacist without a prescription. General sales list medicines are drugs that can be purchased anywhere, but have certain other restrictions. ¹³⁹ The Misuse of Drugs Act divides controlled substances into three classes in a descending scale of dangerousness (A, B, and C) that describe the penalties for certain drug offenses. 140 Similarly, in 2016, the Psychoactive Substances Act criminalized production, supply, or possession with intent to supply any psychoactive substance knowing that it is to be used for its psychoactive effects. ¹⁴¹ As far as opioids are concerned, under the Misuse of Drugs Act, heroin and many forms of morphine are scheduled under Class A Drugs, and are considered the most dangerous. 142

To treat the effects of overdose that these dangerous Class A drugs produce, amendments have been made to these drug laws to make access to naloxone easier. The Medicines Act allowed for the administration of naloxone "by

German Lopez, Trump's budget could help fight the opioid crisis — if it didn't try to repeal Obamacare, Vox (Feb. 13, 2018, 11:10 AM), https://www.vox.com/policy-andpolitics/2018/2/13/17004656/trump-budget-opioid-epidemic.

¹³⁵ Clare Wilson, Addiction to prescription drugs is UK 'public health disaster', NEWSCIENTIST (Oct. 24, 2016), https://www.newscientist.com/article/2110089-addiction-toprescription-drugs-is-uk-public-health-disaster/.

Gayle, supra note 71.

What are the UK drug laws?, DRUGWISE (Dec. 2016), http://www.drugwise.org.uk /what-are-the-uk-drug-laws/.

Id.

¹³⁹ Id.

¹⁴⁰ *Id.* at 4.

¹⁴¹

Misuse of Drugs Act 1971, c. 38, sch. 2 (Eng.); DRUGWISE, supra note 137.

an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner." In 2005, naloxone was added to Schedule 7 of the Medicines Act, which allows anyone to administer naloxone with the intent of saving a person's life in an emergency. Has action facilitated naloxone training programs and policies which encourage services like take-home naloxone kits. Has take-home naloxone programs provide an emergency supply of naloxone with instructions to drug users, their friends and family, and people likely to witness overdoses so that they can administer the drug to an overdose victim before the ambulance arrives. Has For example, in 2011, the Scottish Lord Advocate created guidelines to allow local services in contact with high-risk drug users to have emergency naloxone kits in stock. As of 2016, the United Kingdom and nine other European countries had enacted take-home naloxone programs.

Most recently in 2015, the United Kingdom passed amendments to regulations that make it easier for drug treatment centers to obtain naloxone without direct permission from a doctor or from under Patient Group Directions. ¹⁴⁹ Patient Group Directions (or directives) have worked similarly to standing orders, allowing medical professionals to administer drugs to larger groups of people without specific prescriptions for each individual and are still available after this change in 2015. ¹⁵⁰ The 2015 amendments expand access to naloxone by adding "drug workers" to the list of exempted professionals who can administer naloxone without

⁴³ Medicines Act 1968, c. 67, § 58(2)(b) (Eng.).

The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005, SI 2005/1507, art. 7, ¶ 4 (Eng.); The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005, SI 2005/1507, art. 7, Explanatory Memorandum ¶4.4 (Eng.); Eur. Monitoring Ctr. for Drugs and Drug Addiction, Preventing Opioid Overdose Deaths with Take-Home Naloxone 54 (John Strang & Rebecca McDonald eds., 2016), http://www.emcdda.europa.eu/system/files/publications/2089/TDXD15020ENN.pdf en [hereinafter Preventing Opioid Overdose Deaths].

PREVENTING OPIOID OVERDOSE DEATHS, *supra* note 144, at 69.

¹⁴⁶ *Id.* at 7.

¹⁴⁷ Id. at 54; Naloxone Training in Scotland Timeline, SCOTTISH DRUGS FORUM, http://www.sdf.org.uk/what-we-do/reducing-harm/take-home-naloxone/naloxone-training-scotland-timeline/ (last visited Sept. 1, 2018).

¹⁴⁸ UK Drug Report, *supra* note 72, at Figure 13; Preventing opioid overdose deaths, *supra* note 144.

¹⁴⁹ Widening the availability of naloxone, GOV.UK, https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/wide ning-the-availability-of-naloxone (last updated Aug. 1, 2018) [hereinafter Widening the availability of naloxone]; helena_6321, New Naloxone Regulations: Will Access To Vital Overdose Antidote Be Widened?, RELEASE: BLOG (Oct. 19, 2015, 10:19 AM), https://www.release.org.uk/blog/new-naloxone-regulations-will-access-vital-overdose-antidote-be-widened.

¹⁵⁰ Patient group directions: who can use them, GOV.UK (2017), https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them.

certain restrictions. 151 This broadened legislation is integral for the fight to reduce opioid overdose deaths.

3. Prescription Drug Policy in Australia Regarding Naloxone Access

While Australia is not experiencing "epidemic" levels of opioid addiction like the United States, 68% of its 668 overdose deaths in 2013 were linked to opioid pharmaceuticals. 152 Additionally, opioid-related hospitalizations of those aged thirty to fifty-nine years steadily rose for the last five years. 153 According to Keith Humphreys, a Stanford Professor of Psychiatry and Behavioral Sciences, Australia is among a group of countries that is "rapidly moving towards the same dangerous territory" as countries that are experiencing an opioid epidemic. ¹⁵⁴ In light of these statistics, Australia has made recent changes to how naloxone is accessed in the country. 155

However, it is important to explain how Australia has regulated drugs as a country. The first law restricting drugs was passed in 1857, which imposed an import duty on opium. 156 During the 1800s, Australia was one of the largest consumers of opiates due to several available patent medicines.¹⁵⁷ Australia also banned cannabis in 1926, while heroin was legally available by prescription until 1953, making Australia the world's largest per capita user of heroin at the time. 158 General drug abuse did not become widespread until the 1960s, which led to legislation passed by every state that made drug supply a separate offense from drug possession or use. 159 In 1985, federal and state governments passed a National Drug Strategy that was composed of prohibition and harm reduction strategies. 160 However, most resources to fight this issue in Australia are devoted to supply reduction attempts, such as border patrol strategies, and there are less resources for treatment and harm reduction. 161

In Australia, therapeutic goods, which include medicines, medical devices, and other biological products, are regulated by the Therapeutic Goods Administration (TGA), a division of the Australian Department of Health,

The Human Medicines (Amendment) (No. 3) Regulations 2015, SI 2015/1503, art. 10, ¶ 2 (UK); helena 6321, *supra* note 149.

Power, *supra* note 75.

¹⁵³

Power, supra note 75.

See Lenton et al., supra note 76.

Steve Bolt, Hot Topics: Drugs and the law, NEW S. WALES ST. LIBR. (2015), http://legalanswers.sl.nsw.gov.au/drugs-and-law-hot-topics/history-drug-laws-australia (citing Chapter Twelve: History of Drug Laws – Australia).

Id.

¹⁵⁸ Id.

¹⁵⁹ Id.

¹⁶⁰

Bolt, supra note 156.

established under the Therapeutic Drugs Act of 1989.¹⁶² This Act provides a "substantially uniform national system of controls over therapeutic goods." The TGA schedules medicines and chemicals that are made available to the public into ten scheduling categories. ¹⁶⁴

Naloxone has been scheduled in some capacity by the Australian government since 1973. In 1985, the National Health and Medical Research Council created a Schedule 4 entry for naloxone. Schedule 4 designates the drug as a prescription-only medicine. In December 2012, naloxone was added to the "Pharmaceutical Benefit Scheme" which allows the drug to be subsidized by the government. However, as a response to ninety-six individual submissions to down-schedule naloxone due to its life-saving properties, the TGA announced its final decision on November 24, 2015, to schedule naloxone as a Schedule 3 medicine "when used for the treatment of opioid overdose." This change designates naloxone as a pharmacist-only medicine so that it can be purchased overthe-counter. The decision still keeps the Schedule 4 designation in place so that if it is obtained with a doctor's prescription, the government still subsidizes the drug. This new designation under Schedule 3 removes the need for a prescription, but naloxone must still be dispensed by a doctor or pharmacist.

¹⁶² See generally Therapeutic Goods Act 1989 (Cth) (Austl.); About the Australian therapeutic goods legislation, Australian Gov't Dep't of Health Therapeutic Goods Admin., https://www.tga.gov.au/about-australian-therapeutic-goods-legislation#. Up2yD6r8nFA (last visited Sept. 1, 2018) [hereinafter About the Australian therapeutic goods legislation].

About the Australian therapeutic goods legislation, supra note 162.

¹⁶⁴ Scheduling basics, Austl. Gov't Dep't of Health Therapeutic Goods Admin., https://www.tga.gov.au/scheduling-basics (last visited Sept. 1, 2018) [hereinafter Scheduling basics].

THERAPEUTIC GOODS ADMIN., FINAL DECISIONS AND REASONS FOR DECISIONS BY A DELEGATE OF THE SECRETARY TO THE DEPARTMENT OF HEALTH 11 (2016), https://www.tga.gov.au/sites/default/files/final-decisions-and-reasons-decisions-delegate-medicines-secretary-department-health-november-2015.pdf.

¹⁶⁶ Id.

Scheduling basics, supra note 164.

¹⁶⁸ See About the PBS, Australian Government Department of Health, http://www.pbs.gov.au/info/about-the-pbs (last visited Sept. 1, 2018); Rebecca McDonald, et al., Twenty years of take-home naloxone for the prevention of overdose deaths from heroin and other opioids—Conception and maturation, 178 Drug & Alcohol Dependence 176, 178 (2017) (Table 1).

THERAPEUTIC GOODS ADMIN., *supra* note 165, at 13; Lenton et al., *supra* note 76.

Lenton et al., *supra* note 76.

¹⁷¹ *Id*.

¹⁷² *Id.* at 147.

V. LEGAL ANALYSIS OF NALOXONE ACCESS

A. Legal Analysis of the United States' Naloxone Access Laws

The United States has a system of federalism that uses dual sovereignty to allow individual states to pass laws, such as those related to drug enforcement, while federal laws already in place may compete. Additionally, the FDA has the authority to approve drugs such as naloxone to be available to the public, and to set how they are available—either through a prescription from a physician or over-the-counter.

While in the past there have been federal laws that have set draconian punishments for low-level drug offenses as outlined above, 175 there has been a shift in public opinion for sensible reforms, such as increased access to naloxone and immunity protections for medical professionals and others in cases of opioid overdose that are health-based, and which reduce drug enforcement's role in the drug epidemic. 176 So, even though the FDA regulates naloxone and has designated it as being available only under a prescription, every state has passed some sort of law that increases access to naloxone outside of this prescription-only boundary set by the FDA.¹⁷⁷ The purpose of the exhaustive table in Part III is to show how much the law regarding access to naloxone can vary in each jurisdiction within the United States. Most states have taken the initiative since 2010 to make these extensive, yet heterogeneous, statutory changes for increasing access to naloxone in the face of the FDA's restrictive policy of prescription-only availability. These changes have widened the availability of naloxone, providing many addicts who have overdosed a second chance at life. Studies have shown that increasing the availability of naloxone distribution programs and putting it the hands of laypeople reduces mortality.¹⁷⁹ In Colorado, for example, which has laws that allow prescriptions of naloxone to be authorized to third parties, the Harm Reduction

¹⁷³ See Robert A. Levy, Rights, Powers, Dual Sovereignty, and Federalism, CATO INSTITUTE (Sept./Oct. 2011), https://www.cato.org/policy-report/septemberoctober-2011/rights-powers-dual-sovereignty-federalism; see generally Laura Jarrett, Sessions nixes Obama-era rules leaving states alone that legalize pot, CNN (Jan. 4, 2018, 5:44 PM), http://www.cnn.com/2018/01/04/politics/jeff-sessions-cole-memo/index.html.

¹⁷⁴ See Information about Naloxone, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationfor patientsandproviders/ucm472923.htm (last updated Apr. 23, 2018).

See SACCO, supra note 82, at 9.

¹⁷⁶ See A Brief History of the Drug War, Drug Policy Alliance, http://www.drugpolicy.org/issues/brief-history-drug-war (last visited Sept. 1, 2018); Davis, supra note 103.

¹⁷⁷ Supra Part IV, "Table 1"; PRESCRIPTION DRUG ABUSE POLICY SYSTEM, supra note 109.

DAVIS, supra note 103, at 2.

¹⁷⁹ Rebecca E. Giglio, et al., *Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis*, 2 INJURY EPIDEMIOLOGY 1, 6 (2015).

Action Center in Denver has saved 553 lives with naloxone since 2012 when it started prescribing it to drug users. More broadly, a 2010 US survey of programs which trained administrators and distributed naloxone reported that since 1996, 53,032 people were given naloxone, which resulted in 10,171 overdose reversals. 181

It is possible that the FDA will be changing its policies and widening access. ¹⁸² According to the FDA's "Opioids Action Plan," the agency is currently reviewing the option of making naloxone available over-the-counter. ¹⁸³ Furthermore, the FDA held a competition for submissions of ideas for a "naloxone app" that could be developed to help improve access to those who need to obtain the overdose treatment in their immediate area by using their smartphone. ¹⁸⁴

B. Legal Analysis of the United Kingdom's Naloxone Access Laws

In comparison, the United Kingdom has a constitutional monarchy, led by a prime minister that selects heads of ministerial departments, one of them being the Department of Health.¹⁸⁵ This department contains the Medicines & Healthcare Products Regulatory Agency, which oversees the distribution of medicines like naloxone.¹⁸⁶ While naloxone is still a prescription-only medication under the Medicines Act, through amendment, it can now be supplied without a prescription by drug services and can be used by anyone to save a life in an emergency.¹⁸⁷ This amendment applies to all of the United Kingdom because of its national act

PRESCRIPTION DRUG ABUSE POL'Y SYS., *supra* note 109 (noting that Colorado has a naloxone access law); Jennifer Brown, *The opioid antidote: Naloxone has reversed hundreds of overdoses in Denver in the last year*, THE DENVER POST (May 1, 2017), https://www.denverpost.com/2017/04/28/opioid-overdoses-naloxone/.

¹⁸¹ Centers for Disease Control and Prevention, Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010, 61 MORBIDITY AND MORTALITY WEEKLY REPORT 101, 101 (2012).

¹⁸² Karen Mahoney, FDA Supports Greater Access to Naloxone to Help Reduce Opioid Overdose Deaths, U.S. FOOD & DRUG ADMIN.: FDA VOICE (Aug. 10, 2016), https://blogs.fda.gov/fdavoice/index.php/2016/08/fda-supports-greater-access-to-naloxone-to-help-reduce-opioid-overdose-deaths/.

¹⁸³ FDA Opioids Action Plan, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm484714.htm (last updated Apr. 26, 2018).

¹⁸⁴ Announcing the Winner of the 2016 FDA Naloxone App Competition, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm (last updated Dec. 16, 2016).

¹⁸⁵ See generally How government works, GOV.UK, https://www.gov.uk/government/how-government-works (last visited Sept. 1, 2018) [hereinafter How government works].

See Widening the availability of naloxone, supra note 149.

¹⁸⁷ *Id.*; The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005, SI 2005/1507, art. 7, ¶ 4 (UK); The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005, SI 2005/1507, Explanatory Note ¶ 6 (UK).

regarding medicines, and is similar to how the FDA operates in the United States. ¹⁸⁸ Essentially, the amendment that makes the United Kingdom's naloxone law system different from the United States is that there is no repercussion under the law for anyone who uses naloxone to save someone's life in an emergency. It operates similarly to states in the United States who have standing orders to provide drug treatment centers with naloxone for people who overdose. The difference between how states in the United States expanded naloxone access and what this recent 2015 amendment did in the United Kingdom, is that the new UK regulations "do not allow those individuals who have been supplied naloxone by a lawful drug treatment service to supply it to a third party at a later date." However, takehome naloxone provided by drug treatment services has proven to be successful due to these legal changes in the United Kingdom. ¹⁹⁰ Namely, Scotland, which created the first national naloxone program in November 2010, ¹⁹¹ saw a 36% reduction in the proportion of opioid-related deaths that occurred during the four weeks following a release from prison. ¹⁹²

C. Legal Analysis of the Australia's Naloxone Access Laws

In addition, Australia has a similar system of government to the United States because it is a federal system that divides its power between the commonwealth federal government and the six state governments. The difference when it comes to how naloxone can be accessed is that under the TGA, medical devices and drugs are regulated on a federal level (much like the FDA in the United States), so when the TGA in Australia approved naloxone as an overthe-counter drug, it applied to all six states in the country. States that have standing orders that allow pharmacists to distribute naloxone to anyone without a prescription. Australia has a number of take-home naloxone programs that have resulted in successful reports, including one program that recorded fifty-seven successful overdose reversals over two years.

What We Do, supra note 97.

GOV.UK, Widening the availability of naloxone, supra note 149.

¹⁹⁰ See Take Home Naloxone from October 2015, NALOXONE ACTION GRP. Eng. (Oct. 1, 2015), https://nagengland.wordpress.com/tag/facts/.

¹⁹¹ McDonald, et al., *supra* note 168.

¹⁹² Bird, et al., *Effectiveness of Scotland's National Naloxone Programme for reducing opioid-related deaths: a before (2006–10) versus after (2011–13) comparison*, 111 ADDICTION 883, 883 (2016).

¹⁹³ How Government Works, Australian Gov't, http://www.australiangov.au/aboutgovernment/how-government-works (last visited Sept. 7, 2018).

See id.; Lenton et al., supra note 76, at 147.

Anna Olsen, et al., Independent evaluation of the 'Implementing Expanded Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2014 6–7

VI. SUGGESTIONS FOR THE UNITED STATES FOR THE FUTURE

People can only enter recovery from an opioid addiction if they are living. For that reason, it is incredibly encouraging to see that many individual states in the United States are passing legislation to increase access to naloxone. Because naloxone gives an opioid addict a chance at rehabilitation, there should be as little barriers as possible for someone to obtain it. Some countries have extreme policies to help reduce overdose deaths. For example, Portugal has completely decriminalized drugs so that possession leads to a small fine and a referral to a treatment program. While this has proven to be successful in Portugal, it is unrealistic to think that the United States would follow suit. However, there are many things that each level of government can do to increase access to naloxone and prevent opioid overdose deaths.

The first suggestion for the future in the United States is for the FDA to approve naloxone as an over-the-counter medication. Even though most states have a standing order, this designation would streamline access across every state. This is similar to how Australia has enforced its nationwide policy through the TGA. Furthermore, using the United Kingdom as an example, it would be beneficial if there were sweeping federal legislation declaring immunity of every type (criminal, civil, professional) for those who administer naloxone while saving a person's life. This would give addicts, family members, friends, doctors, pharmacists, and all community workers peace of mind while administering naloxone to those who need it. The combination of the Australian over-the-counter approach and the United Kingdom's policy that allows anyone to administer naloxone while saving a life would be highly recommended to increase access. Since the FDA in the United States is currently considering making naloxone over-the-counter, there is a good chance at least one of these suggestions will take effect at some point. legislation aspect would need to be accomplished with major public support through constituents urging their congressmen for change and also through extensive lobbying of members of Congress.

Moreover, funding for naloxone is an issue due to rising costs and the extent of its demand. 197 For that reason, it may be advisable to implement one or more of the following suggestions. The first would be to garner widespread support for demanding pharmaceutical companies that manufacture naloxone to become more transparent with the reasons behind the changes in cost so that they are held

^{(2015),} http://www.atoda.org.au/wp-content/uploads/Naloxone-Evaluation-Report-FINAL August-2015 BI.pdf.

Chris Ingraham, *Portugal decriminalised drugs 14 years ago – and now hardly anyone dies from overdosing*, INDEPENDENT (June 7, 2015, 12:17 AM), http://www.independent.co.uk/news/world/europe/portugal-decriminalised-drugs-14-years-ago-and-now-hardly-anyone-dies-from-overdosing-10301780.html.

¹⁹⁷ See, e.g., Alison Kodjak, First Responders Spending More On Overdose Reversal Drug, NPR (Aug. 8, 2017, 4:09 PM), https://www.npr.org/sections/health-shots/2017/08/08/541626627/first-responders-spending-more-on-overdose-reversal-drug.

accountable.¹⁹⁸ Second, the federal or state governments could buy naloxone in bulk, helping to drive down costs.¹⁹⁹ Another suggestion would be to make coverage of naloxone under the Medicaid program a nationwide policy.²⁰⁰ Many states have covered naloxone under Medicaid because of its cost and its high demand in low-income populations. It would be extremely beneficial to have naloxone covered by every state's Medicaid system so that policies like coprescribing naloxone and opioids together would not be cost-prohibitive for many people.

Additionally, when President Trump declared a public health emergency, there was no allocation of federal funds to help combat this issue. ²⁰¹ The declaration of a public health emergency sends a message to the public that the Trump Administration is paying attention to the issue, but the lack of funds under this declaration leaves a lot to be desired by states hit the hardest by this epidemic. ²⁰² Therefore, it may also be advisable to declare a national emergency which unlocks funds not available under a public health emergency ²⁰³ and gives power to the Secretary of HHS to make changes to Medicaid and Medicare which could drastically change who gets access to things like naloxone. ²⁰⁴ Therefore, a mix between these two declarations would create a surplus of resources for the country to increase access to naloxone and to fight the opioid epidemic in other effective ways. Furthermore, state governments can also declare states of emergency that unlock funds to fight the opioid epidemic. ²⁰⁵

On a local level, it would be recommended to increase funding for naloxone access by creating more grants, such as the SAMHSA's grant to the

¹⁹⁸ Ravi Gupta, et al., The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths, 375 New Eng. J. Med. 2213, 2214 (2016).

¹⁹⁹ *Id.* at 2215; Several cities and towns have started buying in bulk, which have reduced costs. *See, e.g.*, Shira Schoenberg, *Communities save estimated \$186K through state bulk buying program for anti-overdose drug Narcan*, MASSLIVE (Nov. 30, 2016), http://www.masslive.com/politics/index.ssf/2016/11/state_bulk_buying_of_anti-over.html.

²⁰⁰ See Richard G. Frank & Carrie Fry, *Medicaid Expands Access to Lifesaving Naloxone*, THE COMMONWEALTH FUND (July 5, 2017), http://www.commonwealthfund.org/publications/blog/2017/jul/medicaid-helps-expand-lifesaving-naloxone.

Davis, *supra* note 95; Tamara Keith, *In Opioid Crisis, Public Health Emergency Vs. National Emergency*, NPR (Oct. 26, 2017, 1:43 PM), https://www.npr.org/2017/10/26/560229103/in-opioid-crisis-public-health-emergency-vs-national-emergency.

²⁰² See Brianna Ehley, *Trump declared an opioids emergency. Then nothing changed.*, POLITICO (Jan. 11, 2018, 5:01 AM), https://www.politico.com/story/2018/01/11/opioids-epidemic-trump-addiction-emergency-order-335848.

Davis, supra note 95.

^{204 1135} Waivers, CTRS FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Survey CertEmergPrep/1135-Waivers.html (last modified Dec. 12, 2017, 10:30 AM).

²⁰⁵ Several states have done this already, Arizona being one of them. *Governor Ducey Declares Statewide Health Emergency In Opioid Epidemic*, OFF. OF THE GOVERNOR DOUG DUCEY (June 5, 2017), https://azgovernor.gov/governor/news/2017/06/governor-ducey-declares-statewide-health-emergency-opioid-epidemic.

Arizona Department of Health Services, which facilitates a partnership with the University of Arizona for rural health that aims to train first responders. ²⁰⁶ Organizations armed with money from these grants can benefit their local opioid-affected community in ways that they are culturally educated to implement. Cities should also implement legislation that can make naloxone access easier. For example, Cambridge, Massachusetts is planning to place boxes filled with naloxone in areas of the city where rates of overdoses are high, so that anyone can easily administer the drug to someone who is overdosing. ²⁰⁷ These governments can also implement programs such as training members of the community on how to administer naloxone and implementing more take-home naloxone programs, which are proven to be very effective for opioid users. ²⁰⁸

VII. CONCLUSION

The opioid epidemic is a global threat to public health. Many thousands of people are overdosing and dying, and it is completely preventable. Currently, the United States is arguably seeing the worst of this public health problem. The United Kingdom, Australia, and several other countries are following in the United States' deadly footsteps of elevating rates of opioid overdose fatalities. However, the United Kingdom and Australia have proactively implemented legislation which affects the whole country and helps increase the access and use of naloxone, resulting in saving countless lives. It would be beneficial for the United States to implement these policies to help slow the rate of opioid overdose deaths. Furthermore, the United States, the United Kingdom, and Australia can and should learn from each other the different ways naloxone can be made more easily available. Thousands of lives are depending on these effective public health laws that increase naloxone access.

²⁰⁶ Gerri Kelly, *Center for Rural Health Gets* \$2.2*M Opioid Grant*, The U. of ARIZ. (Jan. 17, 2018), https://uanews.arizona.edu/story/center-rural-health-gets-22m-opioid-grant; The White House, *supra* note 133.

²⁰⁷ Katharine Q. Seelye, *A Public Overdose*. *An Antidote at Hand. Would Passers-By Use It?*, N.Y. Times, May 9, 2017, https://www.nytimes.com/2017/05/09/us/opioids-narcandrug-overdose-heroin-fentanyl.html? r=0.

McDonald et al., *supra* note 168, at 176.

