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THE PERFECT STORM? OPIOID EPIDEMIC MEETS COVID-19 PANDEMIC: REEVALUATING THE ROLE THE RYAN HAIGHT ACT AND THE DEA PLAY IN THE FUTURE OF SAFE ACCESS TO VIRTUAL HEALTHCARE

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The COVID-19 pandemic facilitated a dramatic shift to a reliance upon virtual means for communication, education, and work-from-home careers. In addition, there was a surge in telehealth appointments as an alternative to the traditional in-person provision-of-care model. However, COVID-19 was not operating in isolation but rather in conjunction with the worsening opioid epidemic. Unfortunately, the two public health emergencies coinciding with the rapid development and dependency upon telemedicine created the perfect breeding grounds for illicit online pharmacies to take root and grow into massive criminal organizations that illegally distribute controlled substances, such as opioids. Limited federal legislation and the patchwork of state legislation is insufficient to manage the serious risk these illicit online pharmacies pose to the public's safety. Thus, it is necessary to enact further legislation that maximizes the protections against illicit online pharmacies while minimizing collateral burdens and barriers to care, especially for vulnerable populations that need telehealth the most. While it is desirable that Congress enact further legislation to this end, given the immediate need presented by illicit online pharmacies, it is best to divert resources towards the Drug Enforcement Agency, specifically the Diversion Control Division, to increase enforcement and produce additional guidance, as well as educational materials.

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I. INTRODUCTION

The emergence of the highly infectious coronavirus disease ("COVID-19") and the resulting pandemic drastically altered the landscape and trajectory of advancements in the healthcare industry.[1] Although Americans watched COVID-19 slowly travel

[1] *See* Asim Kichloo et al., *Telemedicine, the Current COVID-19 Pandemic and the Future: a Narrative Review and Perspectives Moving Forward in the USA*, NAT'L CTR. FOR BIOTECH. INFO. (Aug. 18, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7437610/#R3 [https://perma.cc/JKP3-QJSY] (discussing the rise in

from continent to continent, anticipating its continued spread, there was still an aura of disbelief when the virus arrived on U.S. soil in February of 2020.[2] Identifying the virus as an impending danger, the Centers for Disease Control and Prevention ("CDC") advised Americans across the country, including healthcare providers, to implement social distancing guidelines to slow the spread of the virus and protect the country's most vulnerable populations.[3] One crucially important aspect of these guidelines was the CDC's recommendation that healthcare facilities offer clinical services virtually, which sparked an ensuing surge in the use of telemedicine.[4]

Telemedicine is a specific subset of telehealth, defined as "a service that seeks to improve a patient's health by permitting two-way, real-time interactive communication between the patient and the physician at a distant site."[5] Telehealth, on the other hand, is a broader concept that encompasses telemedicine, as well as any "technology used to collect and transmit patient data such as telephones, email and remote patient monitoring (RPM) devices to provide health education or ancillary healthcare services."[6] Somewhat surprisingly, the concept of telemedicine originates from the "use of ancient hieroglyphs and scrolls to share information

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the importance of telemedicine in response to COVID-19, as well as future implications of the increase in usage of telemedicine for the future of medicine).

[2] *See* Andrew Selsky, *Wash. State Sees 1st Virus Death*, NBC DFW (Feb. 24, 2020), https://www.nbcdfw.com/news/coronavirus/person-in-washington-state-first-in-us-to-die-from-new-virus/2321864/ [https://perma.cc/X5W3-QLR8] (reporting that panic did not really ensue until after the first death in the United States as a result of the COVID-19 virus, which was immediately followed by the declaration of a state of emergency by Washington state, causing immense anxiety and compelling people to suddenly clear the shelves of stores of important necessities).

[3] *See* Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 30, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6943a3.htm [https://perma.cc/5GF3-VRZP].

[4] *See id.*

[5] Kichloo et al., *supra* note 1, at 1 (quoting *Telehealth*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/benefits/telemedicine/index.html [https://perma.cc/B6ZB-Z2E5]).

[6] *Id.*

about health-related events such as outbreaks or epidemics."[7] In more modern times, the concept of telemedicine stems from astronauts and advancements in space exploration. Specifically, the National Aeronautics and Space Administration ("NASA") was instrumental in delegating resources for the development of telemedicine in order to provide medical care to astronauts by monitoring their vitals, determining diagnoses, and providing treatment while in space.[8] Today, within the context of COVID-19, telemedicine is a vital solution to medical care accessibility barriers caused by the combination of a highly infectious disease and a healthcare system built on an in-person provision-of-care model.[9]

With the emergence of COVID-19, the reliance upon telemedicine grew exponentially. One study revealed that in April of 2020, "overall telehealth utilization for office visits and outpatient care was 78-times higher than in February 2020."[10] Although experts acknowledge the shift from in-person appointments to telemedicine was "borne out of necessity," they also believe several factors contributed to telemedicine's ability to take root in today's medical system and grow to unprecedented levels as an option for the provision of medical care.[11] These factors include: (1) "increased consumer willingness to use telehealth"; (2) "increased provider willingness to use telehealth"; and, (3) "regulatory changes enabling

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[7] *See id.* at 2 (detailing the origins of telemedicine beginning with hieroglyphs, then the use of telegraphs during the Civil War, and then the use of videoconferencing for telepsychiatry in 1959).

[8] *See id.*

[9] Sirina Keesara et al., *Covid-19 and Health Care's Digital Revolution*, NEW ENG. J. MED. (2020), https://www.nejm.org/doi/full/10.1056/NEJMp2005835 [https://perma.cc/W9Q5-724G] ("This [in-person] care structure contributes to the spread of the virus to uninfected patients who are seeking evaluation. Vulnerable populations such as patients with multiple chronic conditions or immunosuppression will face the difficult choice between risking iatrogenic Covid-19 exposure during a clinician visit and postponing needed care.").

[10] Oleg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?*, MCKINSEY & CO. (July 9, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality [https://perma.cc/9VBG-NXE2].

[11] *See id.*

greater access and reimbursement."[12] In effect, these factors enabled telehealth to build a "bridge to care."[13]

Today, the use of telemedicine is still significantly higher than before the COVID-19 pandemic, although its prevalence has decreased since the initial spike that occurred soon after the pandemic began.[14] In July of 2021, medical professionals observed a plateau in telehealth appointment demand; however, the subsequent surge in cases due to the even more infectious Delta variant correlated with another surge in telehealth appointment requests.[15]

Just as the prevalence of infections from the Delta variant was decreasing, a new variant called Omicron[16] reinforced the newfound reliance on telehealth. Despite the more widespread availability of COVID-19 vaccinations, breakthrough infections persisted, although serious hospitalizations and deaths were reduced by vaccinations and booster shots.[17] As a result of the everchanging conditions with the mutating virus, the pandemic has created a world where virtual interactions, such as those between a patient and doctor, are considered normal.

With no end to the COVID-19 pandemic in sight, there has been a substantial increased investment[18] in telehealth, solidifying telemedicine as a fixture in healthcare systems' offered services. The Mayo Clinic expects telemedicine to eventually be fully integrated into the healthcare system and has indicated that "telemedicine will become a force multiplier, given its ability to

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[12] *Id.*

[13] *Id.*

[14] *See* Bestsennyy, *supra* note 10 ("As of July 2021 . . . [t]elehealth utilization has stabilized at levels 38X higher than before the pandemic.").

[15] *See* Emily Anthes, *The Delta Variant: What Scientists Know*, N.Y. TIMES (June 22, 2021), https://www.nytimes.com/2021/06/22/health/delta-variant-covid.html [https://perma.cc/64N7-DGSU].

[16] *Omicron Variant: What You Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 2, 2022), https://www.cdc.gov/media/releases/2021/s1201-omicron-variant.html [https://perma.cc/UZU3-EUBF].

[17] *See id.*

[18] Bestsennyy, *supra* note 10 ("Investment in virtual care and digital health more broadly has skyrocketed, fueling further innovation, with 3X the level of venture capitalist digital health investment in 2020 than it had in 2017.").

scale care, improve the efficiency of workflows, and expand provider reach to underserved areas, including rural or geographically isolated populations globally."[19] Additionally, the Mayo Clinic has explained that telemedicine will improve in-home care by making sure patients follow their individualized care plans administered remotely, thereby reducing hospitalizations.[20] Not only can virtual visits be used to monitor providers' patients at home, but "text, email and mobile phone applications as well as data from wearable devices can be used to share information between patients and clinicians."[21]

The COVID-19 pandemic has facilitated the expansion of medical care accessibility by utilizing existing technologies but revolutionizing them with a new purpose, evidenced by the newfound ability to obtain prescriptions from online pharmacies. Despite telemedicine's increased uses going forward, the advancements of telehealth are still shackled to legislation of the past. In 2008, Congress passed the Ryan Haight Act ("RHA") as an attempt to directly target online pharmacies.[22] Amending the Controlled Substances Act ("CSA"), the most notable addition included in the RHA is the requirement that a patient must have at least one in-person meeting with a doctor before receiving a prescription for a controlled substance.[23] Amidst the COVID-19 pandemic, this in-person requirement proved to be a significant obstacle to individuals obtaining their medications in a safe, socially distanced manner.

When COVID-19 prompted the U.S. Department of Health and Human Services ("HHS") to issue a public health emergency

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[19] Zelalem Temesgen et al., *Health Care After the COVID-19 Pandemic and the Influence of Telemedicine*, MAYO CLINIC (Sept. 1, 2020), https://www.mayoclinicproceedings.org/article/S0025-6196(20)30789-8/fulltext [https://perma.cc/EA4Q-Y4MV]; *see also* Kichloo et al., *supra* note 1 ("Virtual appointments may provide specialty care to populations where it otherwise may not be available, such as those living in rural areas, deployed on military assignments or in prisons.").

[20] *See* Temesgen et al., *supra* note 19.

[21] Kichloo et al., *supra* note 1, at 1.

[22] 21 U.S.C. § 829(e)(1).

[23] *Id.*

declaration,[24] the declaration triggered an exception to the CSA so that the provision requiring an in-person medical evaluation to receive controlled substances would no longer be enforced by the U.S. Drug Enforcement Administration ("DEA").[25] Although it will take years to know the effectiveness of this pandemic-related policy change orchestrated by the DEA,[26] the in-person requirement has likely both protected some patients from illicit online pharmacies, while simultaneously creating an obstacle to medical care access for others. The rollback of the in-person provision of the RHA provides the unique opportunity to reassess its inclusion in the future regulation of illicit online pharmacies.

While this Article explains the patchwork of state law and the barriers to successful compliance for online pharmacies, this Article focuses on the reevaluation of the in-person requirement included in the RHA, as well as the role the DEA is playing and can play in stymieing the opioid crisis that has been exacerbated due to the combination of COVID-19 and the rise of telemedicine. While the in-person medical evaluation was implemented with good intentions, the unintended result of preventing medical care access for certain individuals provides an illustrative example to help guide the future mindset when regulating online pharmacies. Specifically, future regulations of illicit online pharmacies must focus on providing the most protection against illicit online pharmacies while minimizing collateral burdens and barriers to care, especially for vulnerable populations that need telehealth the most.

Although there are benefits to online pharmacies, the extreme dangers presented by the distribution of opioids by illicit online pharmacies requires careful consideration of the future of the RHA

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[24] *Public Health Emergency Declarations*, DIVERSION CONTROL DIV., https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx [https://perma.cc/RGR3-XXUV] (last visited Sept. 30, 2021).

[25] *COVID-19 Information Page*, DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/coronavirus.html [https://perma.cc/ZB7L-8X4T] (last visited Sept. 30, 2021).

[26] Libby Baney et al., *The Future of Telehealth and the Ryan Haight Act Post-Pandemic*, NAT'L ASS'N BDS. PHARMACY (Apr. 22, 2021) https://nabp.pharmacy/news/blog/the-future-of-telehealth-and-the-ryan-haight-act-post-pandemic/ [https://perma.cc/VU6J-5E2D].

and the continued role the DEA can play in stymieing the crisis. While Congressional action would be desirable to remedy the patchwork of statutes enacted by individual states regulating online pharmacies, such action cannot be taken fast enough to address the immediate need presented by illicit online pharmacies. Therefore, the DEA is best-situated to strike the balance of providing protections against these pharmacies, while minimizing the burdens to the populations that rely on virtual medical care. Consequently, the DEA should utilize its broad grant of authority to enhance regulation of illicit online pharmacies. To effectively combat these illegal operations and their contributions to the opioid endemic, the DEA may require increased funding directed to the Diversion Control Division ("DCD"), circulating additional guidance requiring more robust relationships between prescribing physicians and patients, and prioritizing the development of effective enforcement strategies.

This Article proceeds in five parts. Part II explores both the significant benefits, as well as the serious risks of telemedicine. Part III summarizes the tragic history of the opioid epidemic to contextualize how illicit online pharmacies contributed to that crisis. Part IV analyzes the statutory and regulatory structure related to online pharmacies, past and present, and at both the federal and state levels, and illuminates the inconsistencies in online pharmacy regulations amongst the states. Part V utilizes a study analyzing illicit online pharmacy prosecutions to focus on specific charges and imposed penalties. Finally, Part VI addresses the cracks in current U.S. law and regulatory schemes exposed and exacerbated by the COVID-19 pandemic and explores solutions, such as the adoption of a universalized Model State Legislation for the regulation of online pharmacies at the state level. However, this Article suggests that the best option to ensure safe access to telemedicine is ultimately for Congress to pass a statute standardizing the regulation of illicit online pharmacies amongst the states. But in the meantime, increased efforts and initiatives from the DEA are necessary.

II. THE SIGNIFICANT BENEFITS AND SERIOUS RISKS OF TELEMEDICINE

The advancements in telemedicine have provided a plethora of benefits by delivering medical care virtually. Despite these benefits, the rapid growth of telemedicine has also created a suitable environment for illicit online pharmacies to flourish. Thus, it is important to identify the benefits of telemedicine to balance them against the severity of risk presented by illicit online pharmacies. This balancing can be utilized to inform future regulations by providing maximum protections against such illegal operations while minimizing the obstacles preventing access to virtual care. In this way, regulations can work to ensure that the benefits successfully outweigh the risks.

A. Significant Benefits of Telemedicine

The inherent characteristics of telemedicine, including convenience and efficiency, certainly make it an attractive model for delivering healthcare services. The ease with which patients can receive care in the comfort of their home encourages individuals to seek medical care as soon as they suspect care is needed, rather than procrastinating due to the inconvenience of traveling to a doctor's office.[27] Seeking medical care sooner can lead to earlier diagnoses and more timely treatment.[28] Further, telemedicine "can bring care to patients who may have difficulty traveling to their appointments, such as the elderly, the disabled, or those lacking sufficient transportation."[29]

In addition to the convenience, there is a significant efficiency aspect associated with telemedicine; it makes the provision of medical care more expedient. "Between travel time to healthcare facilities, waiting room time, and time actually obtaining medical care, Americans spend an average of 123 [minutes] per visit, with an average face-to-face time with a physician of 20.5 [minutes]."[30]

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[27] *See* Temesgen et al., *supra* note 19.
[28] *See id.*
[29] Kichloo et al., *supra* note 1, at 6.
[30] *Id.*

Finally, telemedicine can also add an additional revenue stream for providers,[31] as well as reduce the healthcare industry's carbon footprint.[32] While all of these benefits certainly make telemedicine attractive, the Mayo Clinic has warned "careful planning" and "continued scrutiny" will be required as telemedicine is implemented[33]—and for good reason, considering the associated risks telemedicine presents.

B. Serious Risks of Telemedicine

Although telemedicine has substantial and important benefits, there is concern that the disadvantages may outweigh the benefits. One current challenge to telemedicine is the "lack of consumer awareness regarding . . . access to it, its services and its cost."[34] According to a study conducted in 2019, "74.3% of consumers are unaware or believe their health system does not offer telemedicine services,"[35] which is especially true in rural areas.[36]

Even more persuasive is the fact that telemedicine is viewed with skepticism by those who need healthcare services the most. In fact, the same 2019 study revealed "0% of customers who indicated their health as 'poor' reported using telemedicine in the past year," highlighting a major concern that the community members who really should be reaping the benefits of telemedicine are not utilizing the service at all.[37] For those who do use telemedicine, many have voiced serious concerns about the security of their personal health information.[38] But the biggest threat of all might be one that patients

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[31] *See id.* ("[E]xpanding a practice's reach into new communities without the need to move locations. In addition, the option of telemedicine services within a practice may attract new consumers who would otherwise be unwilling to seek medical care.").

[32] *See id.* ("Replacing in-person visits with telemedicine appointments has the potential to decrease carbon emissions via reducing travel to and from appointments.").

[33] *See* Temesgen et al., *supra* note 19.

[34] Kichloo et al., *supra* note 1, at 6.

[35] *Id.*

[36] *See id.*

[37] *See id.*

[38] *See id.*; *see also* Keesara et al., *supra* note 9 ("Department of Health and Human Services (HHS) has announced that it is using its enforcement discretion

have yet to fully realize: the collateral rise of illicit online pharmacies.

C. Arguably the Biggest Telemedicine Threat: Illicit Online Pharmacies

The growth of telemedicine has created a suitable environment for illicit online pharmacies to flourish. Although the first online pharmacy was established in 1999,[39] the recent increased reliance on virtually-delivered health care has heightened the demand for online pharmacies—but not all of these pharmacies are law-abiding operations. A study conducted in 2016 by the Center for Safe Internet Pharmacies found:

> Illicit online pharmacies are a far more common occurrence in the digital sphere than legitimate ones, with internet security firms estimating that 96% of all global online pharmacies actually operate illegally by failing to adhere to regulatory and safety requirements and are ergo in violation of professional, legal and ethical principles.[40]

This statistic demonstrates the imminent danger most of these illicit online pharmacies pose to the public's safety. Specifically related to the possibility of illicit pharmacies distributing controlled substances illegally is the threat that such actions are bound to be exacerbated by governments easing restrictions and oversight associated with virtual medical care to increase access to health care in response to the COVID-19 pandemic. The response by the DEA and the determination of the RHA's future applicability are two key considerations moving forward when thinking about how to provide the appropriate safeguards to neutralize the threat posed by illicit online pharmacies, especially in the midst of the opioid epidemic.

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and will not impose penalties for using HIPAA-noncompliant private communications technologies to provide telehealth services during this public health emergency.").

[39] *See* Tim K. Mackey & Gaurvika Nayyar*, Digital Danger: A Review of the Global Public Health, Patient Safety and Cybersecurity Threats Posed By Illicit Online Pharmacies,* 118 BRITISH MED. BULL. 115, 116 (2016).

[40] *See id.* (citing *The Internet Pharmacy Market in 2016: Trends, Challenges and Opportunities*, LEGALSCRIPT.COM, (Jan. 2016), http://safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf [https://perma.cc/AFB3-88AS].)

III. BACKGROUND ON THE OPIOID EPIDEMIC

Around 3400 B.C. the Sumerians in Mesopotamia cultivated the poppy plant, naming the plant *Hul Fil*, or the "joy plant," after observing its effect on individuals who consumed it.[41] Over time, the poppy plant rapidly spread across all major civilizations but eventually transformed into a form commonly known in modern times as opioids. Derived from the poppy plant as a treatment for pain, opioids became the "magic wand"[42] for pain treatment in the nineteenth century, leading to overprescribing of the pain medication and eventually sparking concerns about its abuse and potential to be addictive.[43] The worries of the addictive qualities of opioids during the twentieth century led to the "widely held perception among professionals in the United States that the long-term use of opioid therapy to treat chronic pain was contraindicated by the risk of addiction, increased disability and lack of efficacy over time."[44] Although medical professionals were the ones prescribing opioids, seemingly with no restrictions, doctors were not the primary facilitator of the resulting opioid crisis.

Surprisingly, however, steps taken by the federal government is what sparked increased opioid usage in the United States.[45] In 1935, Congress passed the Social Security Act, which, among other things, created the Centers for Medicare and Medicaid Services ("CMS"), a federal agency, and mandated that the CMS establish "minimum health and safety and standards that must be met by providers and

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[41] Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, NAT'L CTR. FOR BIOTECH. INFO. (July 16, 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ [https://perma.cc/CZA3-CRM6].

[42] Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAG. (Jan. 4, 2018), https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/ [https://perma.cc/UJ3R-KMY6].

[43] *See* Rosenblum et al., *supra* note 41.

[44] *Id.*

[45] *See Quality, Safety & Oversight - Certification & Compliance*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 12, 2022), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc [https://perma.cc/L4AN-UGZU].

suppliers participating in the Medicare and Medicaid programs."[46] The Joint Commission, a nonprofit that accredits hospitals to receive funding from Medicare and Medicaid, worked with CMS to create a set of standards to receive funding.[47]

Then, in 1996, Purdue Pharma aggressively marketed OxyContin, claiming that "[o]ne dose relieves pain for 12 hours, more than twice as long as generic medications."[48] In 1980, in support of the safety of OxyContin, a group of doctors wrote a letter to the New England Journal of Medicine, which has been erroneously cited for the assertion that "the risk of addiction [to OxyContin] was less than one percent."[49] With "dubious or misinterpreted research" widely publicized,[50] Purdue Pharma encouraged doctors to prescribe higher doses—as opposed to more frequent doses—when the pain relief did not last twelve hours.[51] This suggestion contradicted research "show[ing] that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death."[52]

In 2001, the Joint Commission implemented new pain assessment and management standards for hospitals.[53] The revised standards encouraged that more attention be delegated to pain management,[54] and doctors and nurses started implementing

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[46] *Id.*

[47] *Standards Development Process*, JOINT COMM'N https://www.jointcommission.org/standards/about-our-standards/ [https://perma.cc/TB7G-CDRF] (last visited Feb. 5, 2022).

[48] Harriet Ryan et al., *"You Want a Description of Hell?" Oxycontin's 12-Hour Problem*, L.A. TIMES, (May 5, 2016), https://www.latimes.com/projects/oxycontin-part1/ [https://perma.cc/9Y6G-NCNB].

[49] The Editorial Board, *An Opioid Crisis Foretold*, N.Y. TIMES (Apr. 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html [https://perma.cc/FK2G-NXD7].

[50] *Id.*

[51] Ryan et. al., *supra* note 48.

[52] *Id.*

[53] *The Joint Commission: Over a Century of Quality and Safety*, JOINT COMM'N (2022), https://www.jointcommission.org/-/media/tjc/documents/about-us/tjc-history-timeline-through-2021.pdf [https://perma.cc/ZW4Q-N8VC].

[54] David W. Baker, *Clarification of April 13, 2016, Statement on Pain Management,* JOINT COMM'N (Apr. 18, 2016), https://jointcommission.new-media-release.com/2016_statement/downloads/April_2016_Pain_Statement.pdf

numerical rating scales to assess pain in an effort to satisfy the standards to continue to receive funding.[55] Drug companies capitalized on the need for better pain treatment methods and began promoting opioid painkillers as the solution.[56] The combination of the Joint Commission's standards for pain assessment and treatment, as well as doctors more loosely prescribing opioids in reliance upon drug companies' manipulative marketing practices, resulted in a massive spike in drug overdoses and deaths.[57] Specifically, the CDC reported that "since 2000, the rate of deaths from drug overdoses ha[d] increased 137% including a 200% increase in the rate of overdose deaths involving opioids."[58] In 2016, an "estimated 40% of opioid overdose deaths involved a prescription opioid."[59]

Today, the opioid epidemic rages on; the increase of opioid prescriptions to treat pain has led to systemic misuse.[60] The CDC's National Center for Health Statistics estimated that 100,306 drug overdoses were attributed to opioids in the United States in the mere

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[https://perma.cc/AZK3-QB2P] ("The Joint Commission first established standards for pain assessment and treatment in 2001 in response to the national outcry about the widespread problem of undertreatment of pain."); *see also* David W. Baker, *The Joint Commission's Pain Standards: Origins and Evolution*, THE JOINT COMM'N (May 5, 2017), https://www.jointcommission.org/-/media/tjc/documents/resources/pain-management/pain_std_history_web_version_05122017pdf.pdf?db=web&hash=E7D12A5C3BE9DF031F3D8FE0D8509580&hash=E7D12A5C3BE9DF031F3D8FE0D8509580 [https://perma.cc/6P9H-NMVX].

[55] *See* Baker, *The Joint Commission's Pain Standards: Origins and Evolution*, *supra* note 54.

[56] German Lopez, *A Rising Death Toll*, N.Y. TIMES (Feb. 14, 2022), https://www.nytimes.com/2022/02/13/briefing/opioids-drug-overdose-death-toll.html?searchResultPosition=1 [https://perma.cc/FJ3H-QKGG].

[57] *Id.*

[58] *Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 1, 2016), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm#:~:text=During%202014%2C%2047%2C055%20drug%20overdose,in%202014%20(Figure%201). [https://perma.cc/3DAN-35U5].

[59] *What Is the U.S. Opioid Epidemic?*, U.S. DEP'T OF HEALTH & HUM. SERVS. https://www.hhs.gov/opioids/about-the-epidemic/index.html [https://perma.cc/X36D-WVJZ] (last visited Feb 5, 2022).

[60] *Id.*

span of a year (from April 2020 to April 2021).[61] To put that astonishing number into perspective, that number is an increase of 28.5% from the 78,056 drug overdose deaths during 2020[62] and is also "more than vehicle crash and gun deaths combined."[63] In addition to concerns about drug users overdosing on opioids, there is also a concern for newborns experiencing withdrawal symptoms from opioids as a result of their mothers' use while pregnant.[64]

In the past two years alone, the drug epidemic has worsened. Overdose deaths spiked 50% as fentanyl, a synthetic opioid, "spread in illegal markets . . . [and] more people turned to drugs during the pandemic, and treatment facilities and other services shut down."[65] Recognizing the severity of the opioid epidemic, the HHS declared the opioid crisis an official "public health emergency" in October of 2017.[66] In January of 2022, the HHS renewed its determination as a result of the ongoing, tragic consequences of the opioid crisis.[67] Despite widespread misuse of opioids since the early 2000s, the drug epidemic was finally recognized as a public health emergency in 2017 and has been exacerbated by the COVID-19 pandemic. With an increased likelihood of death resulting from drug overdose and the rising death toll, the current regulatory framework does not reflect the severity of the opioid epidemic and telemedicine's contribution to the problem.

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[61] *Drug Overdose Deaths in the U.S. Top 100,000 Annually*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 17, 2021), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm [https://perma.cc/75PM-RT8R].

[62] *Id.*

[63] Lopez, *supra* note 56.

[64] *What is the U.S. Opioid Epidemic?*, *supra* note 59.

[65] Lopez, *supra* note 56.

[66] *Public Health Emergency Declarations*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx [https://perma.cc/ZL5T-VXCW] (last visited Feb. 5, 2022).

[67] *Renewal of Determination That a Public Health Emergency Exists*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Jan. 3, 2022), https://aspr.hhs.gov/legal/PHE/Pages/Opioid-3Jan22.aspx [https://perma.cc/N8UM-N8ZK].

IV. THE CURRENT ONLINE PHARMACY REGULATORY SCHEME

Telemedicine is regulated at both the federal and state level.[68] There are only two primary pieces of legislation at the federal level: the CSA and the RHA.[69] Additionally, "all 50 states' and Washington DC's laws, policies and regulations on telemedicine differ significantly."[70] Finally, there is the DEA, a federal agency, that has been delegated enforcement power of the federal legislation.[71]

A. Federal Regulations of Online Pharmacies

The first major relevant federal legislation, the CSA,[72] was enacted in 1970 to "improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances."[73] The CSA requires manufacturers, distributors, and dispensers of controlled substances to register with the DEA, the agency with enforcement authority under the Act.[74] Ideally, this legislation creates a "closed system" where controlled substances can be adequately tracked throughout their cycle—from when they were manufactured to when they reach a patient's hand.[75] Additionally, the CSA imposes potential criminal liability "for any person to knowingly or intentionally . . . manufacture, distribute, or dispense . . . a controlled substance."[76]

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[68] *See, e.g.*, 21 U.S.C. § 829; *see also* Kichloo et al., *supra* note 1, at 2.
[69] 21 U.S.C. § 801 *et. seq.*; 21 U.S.C. § 829(e).
[70] Kichloo et al., *supra* note 1, at 2.
[71] 21 C.F.R. § 1300.01.
[72] 21 U.S.C. § 802(6).
[73] Michael Gabay, *The Federal Controlled Substances Act: Schedules and Pharmacy Registration*, NAT'L CTR. FOR BIOTECH. INFO. (May 29, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3839489/ [https://perma.cc/8VT3-SEF3]. 21 U.S.C. § 802(6) ("The term 'controlled substance' means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.").
[74] *See id.*
[75] *See id.*
[76] 21 U.S.C. § 841(a)(1).

In 1970, when the CSA was passed, the existence of online pharmacies was obviously not considered. Modern telehealth technology has exposed the insufficiency of the CSA as a comprehensive regulatory mechanism. Congress became aware of the CSA's inadequacy to handle the byproducts of the technology revolution in healthcare.[77] One boy's story in particular grabbed Congress's attention.

Ryan Haight was at the top of his class and loved to "attempt[] all sports with great enthusiasm," according to his mother, Francene, who testified to the Judiciary Committee on May 16, 2007.[78] When Ryan was seventeen, he became involved in online chat rooms where individuals encouraged him to get drugs for "experimental purposes, fun, and to make him feel better."[79] Ryan navigated to one of the websites, filled out a questionnaire, and a doctor, who had never evaluated Ryan or performed an examination, prescribed him Valium and Morphine.[80] An internet pharmacy then delivered the controlled substances right to his home.[81] On February 12, 2001, when Ryan was eighteen years old, his mother found him lifeless in bed; he had overdosed on the prescribed drugs he easily obtained, delivered right to his front door.[82]

At the plea of his mother and others, Congress passed the RHA (formally, the Ryan Haight Online Pharmacy Consumer Protection Act) in October 2008. The RHA amended the CSA by adding an additional section on "Controlled substances dispensed by means of the Internet."[83] This section provides that "[n]o controlled substance . . . may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."[84] Under the RHA, a "valid prescription" is "a prescription that is issued for a legitimate medical

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[77] *Id.* § 829(e)(1).

[78] *Ryan Haight Online Pharmacy Consumer Protection Act of 2008: Hearing on H.R. 6353 Before the S. Comm. on the Judiciary*, 110th Congress (2007) (statement of Francene Haight), https://www.judiciary.senate.gov/imo/media/doc/haight_testimony_05_16_07.pdf [https://perma.cc/M22S-9UJ7].

[79] *Id.*

[80] *See id.*

[81] *See id.*

[82] *See id.*

[83] 21 U.S.C. § 829(e)(1).

[84] *Id.*

purpose in the usual course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient . . . ."[85] Courts have interpreted the language "legitimate medical purpose" to mean "generally accepted medical practice."[86] Thus, one of the RHA's most notable changes to the CSA is that the prescription for a controlled substance cannot be made without a doctor meeting with a patient in person at least once.

The RHA also added stricter requirements for online pharmacies, to be enforced by the DEA. Specifically, section 831, titled, "Additional requirements relating to online pharmacies and telemedicine," specifies a list of disclosures online pharmacies must clearly make on their internet site's homepage.[87] Included in this list are disclosures of "[t]he name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration" and "[t]he pharmacy's telephone number and email address."[88] The Statute also mandates online pharmacies to clearly display on their website's homepage a statement indicating their compliance with section 831.[89] The RHA also leaves some regulatory power to the states:

> Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.[90]

In addition to directly affording states the power to regulate pharmacies, the RHA requires the state licensure of the pharmacist-in-charge to be disclosed on a pharmacy's website, as well as a list of every state where the pharmacy is "licensed to dispense controlled substances."[91] Finally, the RHA also requires disclosure of who the online pharmacy has a "contractual relationship [with] to

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[85] *Id.* § 829(e)(2)(A)(i).
[86] United States v. Vamos, 797 F.2d 1146, 1151 (2d Cir. 1986).
[87] 21 U.S.C. § 831(c).
[88] *Id.* § 831 (c)(1)–(2).
[89] *Id.* § 831(a).
[90] *Id.* § 831(b).
[91] *Id.* § 831(c)(3)–(4).

provide medical evaluations or issue prescriptions for controlled substances . . . ." on the internet site's homepage.[92] The command for online pharmacies to comply with the requirements of state law is echoed in the Code of Federal Regulations ("CFR") concerning "Special Requirements for Online Pharmacies."[93]

As enabled by section 821, the CFR addresses the regulation of online pharmacies with respect to registration as part of the Uniform Controlled Substances Act stating:

> [I]t is unlawful for any person to knowingly or intentionally fill a prescription for a controlled substance that was issued in a manner that constitutes dispensing by means of the Internet unless such person is a pharmacist who is acting in the usual course of his professional practice and is acting on behalf of a pharmacy whose registration has been modified under sections 1301.13 and 1301.19 of this chapter to authorize it to operate as an online pharmacy.[94]

Additionally, under section 821, the U.S. Attorney General is "authorized to promulgate rules and regulations"[95] and empowered to delegate any of their designated functions to other government officials.[96] The Attorney General has delegated broad authority to the DEA[97] to regulate the distribution of controlled substances by online pharmacies. The DEA exercised its enforcement power in response to the HHS declaring a public health emergency determination by announcing that some of the provisions of the RHA would no longer be enforced.[98]

B. Public Health Emergency Limits Effect of the RHA

In March of 2020, HHS Secretary Alex Azar determined the COVID-19 outbreak was a public health emergency, triggering an

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[92] *Id.* § 831(c).
[93] 21 C.F.R. § 1301.19.
[94] *Id.* § 1306.09.
[95] 21 U.S.C. § 821.
[96] *Id.* § 871(a).
[97] 21 C.F.R. § 1300.01.
[98] *COVID-19 Information Page*, DEA DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/coronavirus.html [https://perma.cc/ZB7L-8X4T] (last visited Sept. 30, 2021).

exception to the CSA.[99] In announcing the exception, the DCD stated that:

> For as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all . . . controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met: [(1)] The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice; [(2)] The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and [(3)] The practitioner is acting in accordance with applicable Federal and State laws.[100]

On January 14, 2022, the DEA renewed its determination due to the "continued consequences" of the COVID-19 pandemic.[101] This renewal meant some provisions of the RHA were and continue to be ineffective, such that controlled substances can be prescribed without the in-person medical evaluation typically required. Therefore, COVID-19 has removed what has been considered one of the most prominent safeguards against illicit online pharmacies, which is the in-person medical evaluation requirement of the RHA.

There has been much debate, however, over the efficacy and desirability of the RHA in-person medical evaluation requirement.[102] This debate necessitates the reconsideration of the desirability of an in-person medical evaluation within the overall framework of legislating in a way that allows for the maximization of protections against illicit online pharmacies while minimizing the burdens it places on those that are at risk of being denied needed virtual medical care.

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[99] *See id.*

[100] *See id.*

[101] *Public Health Emergency Declarations*, DEA DIVERSION CONTROL DIV., https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx [https://perma.cc/RGR3-XXUV] (last visited Sept. 30, 2021).

[102] Nisha Basu & Jonathan Bush, *Archaic In-person Exam for Digital Prescribing Is Holding Back Health Care Innovation*, STAT (Dec. 8, 2021), https://www.statnews.com/2021/12/08/archaic-in-person-exam-law-barrier-digital-prescribing-health-care-innovation/ [https://perma.cc/4TLL-ARTF].

C. State Regulations of Online Pharmacies

As briefly described above, the CSA and the RHA both specifically delegate power to regulate online pharmacies to the states. This delegation has resulted in inconsistent regulatory frameworks amongst the states. As an example, North Carolina has a rather robust set of Pharmacy Laws.[103] In those Pharmacy Laws, despite "COVID-19" appearing forty-five times, online pharmacies are never directly addressed or even mentioned.[104] But online pharmacies are operations that are unique and distinct from traditional pharmacies. Consequently, superimposing laws that were passed to regulate brick-and-mortar pharmacies has been and likely will continue to be insufficient to effectively abate the grave danger posed by illicit online pharmacies.

Included in North Carolina's Pharmacy Laws is the requirement that "[e]very person who manufactures, distributes, dispenses, or conducts research with any controlled substance within this State or who proposes to engage in any of these activities shall annually register with the North Carolina Department of Health and Human Services" and pay a registration fee.[105] In response to COVID-19, Governor Roy Cooper sought to make access to controlled substances easier with Executive Order No. 116, allowing customers to receive their controlled substances using an expired driver's license or identification card.[106]

There are, however, some states that mention online pharmacies explicitly in their Pharmacy Laws. For example, Indiana identifies which state's laws apply by asserting that online pharmacies shall comply with "the licensure laws of the state in which the mail order or internet based pharmacy is domiciled."[107] Relatedly, Illinois also requires that any online pharmacy that provides any kind of pharmaceutical services in Illinois abide by Illinois law on the

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[103] For a compilation of some of the Pharmacy Laws of North Carolina, see *Pharmacy Laws of North Carolina*, N.C. BD. OF PHARM., (Sept. 2021), http://www.ncbop.org/LawsRules/Statutes.pdf [https://perma.cc/7B2C-NPUD].

[104] *Id.*

[105] N.C. Gen. Stat. § 90-101.

[106] *Pharmacy Laws of North Carolina*, *supra* note 103 at 80.

[107] IND. CODE ANN. § 25-26-18-2(1).

matter.[108] Arkansas has a robust subsection on online pharmacies and painstakingly discusses extensive requirements for both the internet sales and the internet sites for the online pharmacies themselves.[109] Arkansas even includes a provision stating:

> A pharmacist practicing within or outside Arkansas may not fill a prescription order to dispense a prescription-only drug to a patient if the pharmacist knows or reasonably should have known under the circumstances that the prescription order was issued: (1) On the basis of: (A) An internet questionnaire; (B) An internet consultation; or (C) A telephonic consultation; and (2) Without a valid prior patient-practitioner relationship.[110]

The deference to state regulation within the federal regulatory scheme, in conjunction with erratic regulation at the state level, demonstrates the difficulty of effective regulation of online pharmacies in this new era of burgeoning telehealth services. These deficiencies suggest that a universalized approach to the regulation of online pharmacies would more effectively prevent the illegal distribution of controlled substances. In addition, the inconsistencies in protections provided against illicit online pharmacies requires standardization to achieve the goal of maximizing the safeguards against these pharmacies while avoiding unnecessary obstacles preventing access to virtual medical care. Through the analysis of prosecutions based on the present regulatory and enforcement scheme under the CSA, it becomes clear that the criminal penalties are not high enough and are underenforced, both in terms of the number of prosecutions and the penalties imposed.

V. AN ANALYSIS OF CRIMINAL PROSECUTIONS OF ILLICIT ONLINE PHARMACIES

Several criminal cases provide insight into how these illicit online pharmacies function. In *U.S. v. Darji*,[111] the government charged James Hazelwood and USMeds with conspiracy to distribute controlled substances and several counts of unlawful drug

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[108] 225 ILL. COMP. STAT. ANN. 85/16a.
[109] *See* ARK. CODE ANN. § 17-92-1002.
[110] *Id.* § 17-92-1004.
[111] U.S. v. Darji, 609 F. App'x 320 (6th Cir. 2015).

distribution due to their operation of an "internet pill mill."[112] Hazelwood created websites targeting potential customers seeking to order prescription pain pills online and directed them to his website by pushing his own websites when people searched phrases such as "hydrocodone no prescription."[113] Once on his websites, customers would "select the type of drug, the strength, and the quantity desired."[114] In effect, his online business operations functioned just like the website used by Ryan Haight.

This input from the customer could not be changed by any doctor participating in the conspiracy.[115] After a customer had nearly completed the process by entering a payment method and delivery address, the customer would fill out a short questionnaire.[116] The customer would then have an extremely brief telephone "consult" with a doctor, which proved to be a mere formality.[117] An overwhelming majority of customers were approved with one doctor authorizing "between 700 and 900 hydrocodone prescriptions a week," including prescriptions based on questionnaires providing inadequate information to form the basis of such a prescription.[118] Finally, the information would be sent to a pharmacy working with the conspiracy that filled the order and shipped the medication to the customer directly.[119]

When federal agents began investigating, they uncovered that "the operation's review of medical records was a sham."[120] One undercover agent filled out a questionnaire, naming himself "Park Rover" and described his medical complaints as "involv[ing] pain resulting from running into a fence while chasing a ball, heartworms and excessive barking."[121] Park Rover lived at "1523 Bark Street," was under the care of "Dr. Zachary Shihtzu," and "listed his current

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[112] *See id.* at 323.
[113] *Id.*
[114] *Id.*
[115] *See id.*
[116] *Id.*
[117] *Id.* at 324.
[118] *Id.*
[119] *See id.*
[120] *Id.*
[121] *Id.*

medications as Kyltix (a substance used on dogs to repel or kill ticks) and Nyla bone (a canine chew toy)."[122]

Park Rover successfully ordered hydrocodone on three separate occasions.[123] The organization transitioned to a "direct script" model where they had co-conspirator doctors write prescriptions for hydrocodone that they would ship directly to the customer so that the customer could fill the prescription themselves.[124] The parties involved were ultimately convicted of drug-conspiracy, unlawful drug distribution, and conspiracy to commit money laundering.[125]

Another case, *U.S. v. Birbragher*,[126] highlights the international component of these schemes, as well as the marketing and advertising that these illicit online pharmacies employ. In *Birbragher*, the company "Pharmacom" operated a website, www.buymeds.com, where customers placed orders for controlled substances requiring prescriptions by answering a short health history questionnaire and providing a payment method.[127] Then, a doctor that was not even licensed to practice medicine anywhere in the United States would review the order.[128] The doctor never conducted an in-person exam of any kind, and had often never even glanced at the patient-customer's medical records before the doctor "digitally affixed" their signature to the prescription generated by Pharmacon.[129] In addition to the fact that international doctors not licensed in the United States were signing these prescriptions, Pharmacon spent $3.14 million for marketing and advertising to target individuals trying to obtain controlled substances.[130]

In 2017, an in-depth study analyzed prosecutions of those involved with illicit online pharmacies.[131] Three striking discoveries

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[122] *Id.*
[123] *See id.*
[124] *Id.*
[125] *See id.* at 336, 339.
[126] 603 F.3d 478 (8th Cir. 2010).
[127] *Id.* at 481.
[128] *See id.*
[129] *Id.*
[130] *See id.* at 482.
[131] Camille Guerra & Timothy K. Mackey, *USA Criminal and Civil Prosecutions Associated with Illicit Online Pharmacies: Legal Analysis and*

were revealed. First, the charges of conspiracy to distribute controlled substances and conspiracy to launder money were among the most common charges in the United States.[132]

Second, the study also found: "Alarmingly, none of the cases reviewed involved charges associated with serious bodily injury or manslaughter for the negligent distribution or dispensing of pharmaceuticals by physicians to patients with whom the physicians never had contact," despite the number of deaths associated with those negligent distributions.[133] The author of this study argued that the absence of charges associated with serious bodily injury or manslaughter was due to the "inability to prove intent to harm."[134] The study mentioned that doctors prescribing drugs that resulted in deaths could be seen as negligent or reckless; however, the likelihood of these charges resulting in convictions, as well as prosecutors' preference to avoid long trials with difficult burdens of proof, have deterred bringing these cases.[135]

Third, and perhaps most surprising, was the revelation that legitimate business entities actually paid the highest fines as a result of their connection with the criminal operations of distributing illicit drugs.[136] The U.S. Department of Justice ("DOJ") reported that "Google Forfeit[ed] $500 Million Generated by Online Ads & Prescription Drug Sales by Canadian Online Pharmacies."[137] The DOJ held Google accountable for "allowing online Canadian

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Global Implications, J. MED. ACCESS e104 (Dec. 14, 2017), https://journals.sagepub.com/doi/full/10.5301/maapoc.0000020 [https://perma.cc/34TZ-N7L8]. The study was conducted by first locating prosecutions within the narrow subject matter of illicit online pharmacies and then cross referencing all of the defendants identified in those cases through the Public Access to Court Electronic Records (PACER). *Id.* After compiling the court documents from all of the cases found from 2000-2016, the data was analyzed. *See id.*

[132] *See id.* at e109.

[133] *Id.*

[134] *Id.*

[135] *See id.*

[136] *See id.*

[137] *See Google Forfeits $500 Million Generated by Online Ads & Prescription Drug Sales by Canadian Online Pharmacies*, U.S. DEP'T JUST. (Aug. 24, 2011), https://www.justice.gov/opa/pr/google-forfeits-500-million-generated-online-ads-prescription-drug-sales-canadian-online [https://perma.cc/6TJJ-5VJH].

pharmacies to place advertisements through its AdWords program targeting consumers in the United States, resulting in the unlawful importation of controlled and non-controlled prescriptions into the United States."[138] Given the amount of resources these criminal enterprises delegate to marketing and advertisements,[139] holding search engines such as Google accountable could be an important piece of the puzzle in enforcing regulations of illicit online pharmacies, especially considering the current, state-focused regulatory framework.

The study concluded that, "given the clear patient risk associated with the operation of illicit online pharmacies (including the sale of controlled substances), penalties imposed by federal prosecutors do not appear to have parity"[140] in that the penalties are not harsh enough to deter the dangerous distribution of highly-addictive prescription drugs.[141] Their profits are produced by inflating the "fill fees" to as much as $20 to $25 , which is "more than ten times the national average" of prescriptions given by pharmacies with physical locations.[142] One criminal enterprise was able to generate approximately $160 million in sales and $126 million in revenue in the span of two years.[143]

One of the major concerns with the inadequacy of the penalties is the wide variety of punishments.[144] The study revealed that the maximum sentence in the data collection was thirty years of imprisonment, while the lightest punishment included no imprisonment or probation.[145] Likewise, the study reflected a similar variance in restitution ranging from $0 to more than $24 million.[146] As a helpful illustration, Dr. Ogle, the doctor who authorized Ryan Haight's deadly prescription drugs,[147] was sentenced to a mere

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[138] *Id.*
[139] United States v. Birbragher, 603 F.3d 478, 482 (8th Cir. 2010).
[140] Guerra & Mackey, *supra* note 131.
[141] *See id.*
[142] U.S. v. Darji, 609 F. App'x 320, 324 (6th Cir. 2015).
[143] *See* Guerra & Mackey, *supra* note 131.
[144] *See id.*
[145] *Id.*
[146] *Id.*
[147] *See infra* Part III.A

twenty-four months in prison and ordered to pay approximately $8,000 in restitution to Ryan's parents.[148]

The inconsistency in application, as well as the markedly low punishments associated with overdose deaths, is concerning. For example, in one case involving a patient's death due to overdose, two doctors were charged with: (1) distribution of controlled substances, (2) conspiracy to distribute controlled substances, (3) distributing of misbranded drugs, (4) aiding & abetting, (5) wire fraud, (6) money laundering, and (7) criminal forfeiture.[149] Yet, one doctor only received three years' probation and eight-hundred hours of community service. Another received a two-year prison sentence and three years' supervised release with ninety-six hours of community service. Significantly, these penalties appear inconsequential when these doctors' actions led to the loss of life of an individual. The grave danger these illicit online pharmacies pose to the general public should be reflected in the severity and consistency of sentencing included in the forthcoming regulation of illicit online pharmacies.

VI. PROPOSED SOLUTIONS

The combination of relatively minor penalties with a weak regulatory framework is an extremely dangerous threat to the public's safety in a time when telemedicine is rapidly growing. The DCD has made its decision to temporarily render the in-person medical evaluation requirement ineffective based on a fear that those needing controlled substances would be prevented from access in the midst of the COVID-19 public health emergency. This choice creates the opportunity to reconsider the need for the in-person evaluations and reconceptualize the goals of further regulations of illicit online pharmacies.

While access to needed medications is a legitimate interest of the federal government, the DCD's attempt to limit the danger created by the removal of important amendments to the CSA in enumerating a list of conditions is not a satisfactory substitution to prevent mass distribution of controlled substances. Further, the

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[148] *See* Guerra & Mackey, *supra* note 131.
[149] *Id.*

regulatory framework is not sufficient to effectively manage the risk that illicit online pharmacies pose to the general public, necessitating an alternative approach. In the future, regardless of the form of the regulation, the emphasis should be placed on maximizing the protections afforded against illicit online pharmacies circumventing regulations to distribute controlled substances illegally, while minimizing the obstacles that prevent safe, affordable access to medical care.

A. Model State Legislation for States to Regulate Online Pharmacies

One viable remedy to fill the cracks in the present regulatory scheme would be to utilize the Uniform Law Commission to draft a model statutory framework to be adopted by the individual states in an effort to standardize the regulation of online pharmacies. This framework would provide a potential solution to one of the most serious current regulatory problems: inconsistencies amongst regulatory frameworks in various states. Consistency is especially important given that the distribution of controlled substances now transcends borders through telehealth and online pharmacies. With some state pharmacy laws designating the proper choice-of-law and others remaining silent on this issue, this variance poses yet another burden to prosecuting those involved with illicit online pharmacies distributing controlled substances.

However, this suggestion will likely prove to be ineffective as it cannot adequately address one of the largest concerns with the current regulatory framework that is a patchwork of legislation from state to state. Proposing a Model State Legislation will give the states the option to consider passing it; however, the Model Legislation is nothing more than a choice. States can choose to adopt the Model Legislation in its entirety, make changes, or not adopt it at all.

Significantly, controlled substances dispensed via online pharmacies cross state lines, even international borders, quite frequently. Model State Legislation cannot provide the necessary regulation given the prevalent problem of determining which jurisdiction's law applies in a given case. As demonstrated by

Birbragher,[150] the head of an illicit pharmacy operation can be located in one state, the doctor making the bogus prescriptions in another, the pharmacy filling the prescriptions in yet another, and the website reaching and serving customers in all fifty states.

In addition to the persistent patchwork problem, adoption of Model State Legislation would be a slow solution, as there is no mandated time frame for adopting the legislation through enactment or even a mandate that the legislation ever be adopted or enacted. This volition is a pressing problem; there is not enough time to wait for state after state to hopefully adopt the Model State Legislation. By perpetuating inconsistencies in the protections afforded against illicit online pharmacies, this solution fails to maximize protections across all fifty states. For this reason, amongst others, a comprehensive federal regulatory approach is preferable.

B. The Preferable, Long-term Solution: Congressional Action

To address the pressing needs produced by dangers posed by online pharmacies in light of the opioid epidemic in the midst of the COVID-19 pandemic, Congress should step in and pass a statute that standardizes the regulation of online pharmacies. Congress has the ability and the resources to carefully weigh the benefits and costs of future legislation to strike a balance between placing adequate safeguards against illicit online pharmacies while being cognizant to avoid unnecessarily impeding access to medical care. Significantly, many of the concerns that motivated the passage of the RHA still ring true today.

First, concern over the alarming rise in the abuse of prescription controlled substances[151] is still highly prevalent, even more prevalent than it was in 2008 when the RHA was passed. As mentioned in Part II, the opioid epidemic has raged on. The epidemic prompted the

[150] *See* United States v. Birbragher, 603 F.3d 478, 478 (8th Cir. 2010).
[151] S. REP. NO. 110-521, at 8–9 (2008).

declaration of a public health emergency in 2017,[152] and that public health emergency is still in full effect.[153]

The second concern included in the Senate Report conducted prior to the passage of the RHA, namely the "lack of effective controls over prescribed controlled substances distributed by rogue internet pharmacies,"[154] has also not been resolved post-RHA. The concern that the internet provides the perfect marketplace for drug traffickers remains true today.[155] The rapid shift to telemedicine has allowed illicit online pharmacies to flourish as individuals take to the Internet to find prescription drugs. The RHA has failed to provide "effective controls over prescribed controlled substances," as evidenced by the increase in overdose deaths during the pandemic.[156] Thus, the "demonstrated need for a federal legislative solution" remains true.[157]

Given the nature of the online pharmacy industry, these activities related to manufacturing, prescribing, and ultimately distributing controlled substances are constantly crossing state lines. It is clear that the Commerce Clause's expansive reach provides Congress with the power to enact legislation on this point.[158] Not only is it possible, but it is also the most efficient way to solve the patchwork state legislation by providing a uniform, cohesive set of legislation that governs all of the states (and preempts those state laws that conflict). This legislation should be aimed specifically at regulating the activities of online pharmacies within the greater context of telemedicine. Other pharmacy regulations will still be left to the states to determine for themselves, preserving the tradition of federalism in this area of the law.

This federal legislation should include stricter standards for operation, higher criminal penalties to increase deterrence, and

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[152] *Renewal of Determination That a Public Health Emergency Exists*, U.S. DEP'T HEALTH & HUM. SERVS. (Jan. 3, 2022), https://aspr.hhs.gov/legal/PHE/Pages/Opioid-3Jan22.aspx [https://perma.cc/N8UM-N8ZK].

[153] *See id.*

[154] *Id.*

[155] S. REP. NO. 110-521, at 8–9 (2008).

[156] *Id.*

[157] *Id.*

[158] U.S. CONST. art. I, § 8, cl. 3.

permanent removal of the in-person requirement, which is currently ineffective due to the ongoing public health emergency. Although the RHA lays out requirements that online pharmacies must meet to be properly registered, more is needed. Specifically, the legislation should explicitly ban the use of questionnaires as a satisfactory basis on which to write a prescription and prescribe a more holistic approach that is accepted within the medical community. In physical doctors' offices, controlled substances are often locked away and even counted to make sure that they are all there, and yet, online pharmacy regulations include no comparable safeguards proportional to the addictiveness and dangers posed by opioids.[159] Providing for stricter standards of operation would provide additional protections while not affecting, and more specifically not encumbering, access to virtual medical care.

In addition to stricter standards of operation, the criminal penalties must be higher. As mentioned in the study discussed in Part V above, the data strongly suggests that a lack of severity of criminal sentences for involvement in illicit online pharmacies is an insufficient deterrent.[160] Additionally, the Senate Report indicated that the penalties for the most commonly distributed controlled substances over the Internet were "too lenient."[161] Specifically, the penalties have to be high enough such that the massive payout these criminals receive for illegally distributing controlled substances is outweighed by the strict penalties resulting in general deterrence. Moreover, the penalties should be applied more consistently across cases in various states. This effort of increasing deterrence of illicit online pharmacies will also expand protections while not affecting those that are in compliance with the relevant statutes. Although heightened criminal penalties may improve deterrence, the primary focus of the legislation should be directing the DEA and related agencies to prioritize the development of enforcement strategies.

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[159] *See* 21 U.S.C. § 829(e).
[160] *See* Guerra & Mackey, *supra* note 131 at e115.
[161] S. REP. NO. 110-521, at 8–9 (2008).

C. The Preferable, Immediate Solution: Increasing Enforcement Through the DEA

The DEA, and more specifically the DCD, is the best situated regulating body to immediately implement guidance that aims to maximize protections against illicit online pharmacies, while minimizing obstacles that inhibit access to virtual medical care to individuals who need it most. In fact, the mission statement of the Division aligns well with this framework, stating, "[t]he mission of DEA's [DCD] is to prevent, detect, and investigate 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."[162] Furthermore, the ability to act more quickly than waiting for Congress, perhaps indefinitely, makes looking to this federal Agency for regulation and guidance the solution best tailored to the time-sensitive nature, given the immense danger produced by illicit online pharmacies.

The Attorney General has delegated broad, sweeping enforcement power to the DEA, which, in turn, has relied upon the DCD to regulate the distribution of controlled substances.[163] One tactic that has been deployed by the DEA as a means of investigation and enforcement includes federal agents submitting fabricated questionnaires.[164] In 2006 and 2007, the DEA also enlisted wholesalers of controlled substances for their help by "pressur[ing] hydrocodone wholesalers to cease supplying the drug to pharmacies with abnormally high-volume ordering patterns."[165] Unfortunately, the aspect of anonymity poses a unique problem within the context of illicit online pharmacies that is difficult for the DEA to overcome.[166] The Agency has attempted to track down the criminal

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[162] U.S. Dep't of Just., *Program Description*, DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/prog_dscrpt/index.html [https://perma.cc/2XR6-SXQ5] (last visited Mar. 7, 2022).

[163] *See supra* Part IV.A.

[164] *See* U.S. v. Darji, 609 F. App'x 320, 324 (6th Cir. 2015).

[165] *Id.*

[166] *Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad*, U.S. GOV'T

masterminds behind these schemes, but information on the illicit pharmacies' websites is often false.[167]

One way to increase the effectiveness of DEA enforcement is to assemble a congressional commission, specifically a task force to develop ways to enhance enforcement. This effort may include the further development of artificial intelligence with the ability to recognize patterns of drug distributor content in limited data sets, such as user habits on the platform of Instagram, in order to locate similar content on the Internet.[168] This technology could be utilized to identify online pharmacies that are not in compliance with the regulations, flagging them for further investigation. As the cases discussed in Section IV above illustrate, these illicit online pharmacies often target customers through advertisements. Thus, delegating resources to investigate the search engines that are producing particular results could be effective.

Additionally, the DEA may need to utilize the expertise of other agencies. For example, the DEA could call upon the Federal Bureau of Investigation ("FBI") to utilize its resources as the "the lead federal agency for investigating cyber-attacks and intrusions"[169] and the Central Intelligence Agency ("CIA") specifically to capitalize on its collection of foreign intelligence[170] to combat international illicit online pharmacies. By utilizing these agencies' resources, in addition to the DEA's, it may be possible to gather more evidence, allowing prosecutors to charge violators with negligent homicide, manslaughter, or murder.

ACCOUNTABILITY OFF. (July 2013), https://www.gao.gov/assets/gao-13-560.pdf [https://perma.cc/2THS-4ZXV].

[167] *Id.*

[168] Rebecca Heilweil, *AI Can Help Find Illegal Opioid Sellers Online. And Wildlife Traffickers. And Counterfeits.*, VOX (Jan. 21, 2020, 8:10 AM), https://www.vox.com/recode/2020/1/21/21060680/opioids-artificial-intelligence-illegal-online-pharmacies [https://perma.cc/BQM2-AHGG].

[169] *See What We Investigate*, FED. BUREAU OF INVESTIGATION https://www.fbi.gov/investigate/cyber [https://perma.cc/H5H2-3GYY] (last visited Feb. 5, 2022) (explaining the FBI's capabilities).

[170] *See About CIA*, CENT. INTEL. AGENCY, https://www.cia.gov/about/ [https://perma.cc/J93W-G3SW] (last visited Feb. 5, 2022) (mentioning the CIA's data-collecting expertise).

On top of additional funding and resources delegated to support the DCD, the DEA can leverage its enforcement power to provide additional clarification of the ambiguous language of the governing statute by implementing a Know Your Customer ("KYC") standard. The governing statute defines a valid prescription as one "that is issued for a legitimate medical purpose in the usual course of professional practice."[171] This ambiguity provides the DCD the opportunity to provide guidance on what "the usual course of professional practice" means within the niche area of online pharmacies. One possible route would be to implement a KYC standard that has been invoked by the Financial Crimes Enforcement Network (known as "FinCEN") and U.S. Securities and Exchange Commission to require financial institutions to "make efforts to prove the identity, suitability, and inherent risks of that individual in order to reduce fraud and abuse."[172]

Translated to the medical field, this standard would require doctors to take additional steps to gain a more holistic picture of patient health that is unobtainable in the questionnaires that are currently utilized on illicit online pharmacy websites. These steps may require physicians to obtain a patient's complete medical history from all providers, review that medical history with the patient, and make sure that there is not an abnormal number of refill requests for controlled substances.[173] The application of the KYC standard to govern prescribing physicians and their patients would provide additional safeguards without placing undue burdens upon those patients who rely on virtual access to medical care.

In addition to investigation and enforcement of regulations, the DCD should also release additional reports and guidance documents to educate both pharmacists and potential consumers about illicit online pharmacies and what to do if they encounter one. A study conducted in 2021 revealed that out of the 347 pharmacist participants, 58% expressed a lack of confidence in counseling patients on how to identify online pharmacies that are operating

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[171] 21 U.S.C. § 829(e)(2)(A)(i).
[172] Basu & Bush, *supra* note 102.
[173] *See id.*

illegally.[174] Further, 75% of the pharmacists were not familiar with resources to help their patients "identify safe and legitimate online pharmacies."[175] Thus, it is just as important to educate pharmacists as it is to educate the ultimate consumers of controlled substances.

Encouraging physicians to discuss where their patients may be getting drugs, making sure they are getting legitimate prescriptions from legal sources, and equipping them with the knowledge to do so is imperative. Although the DCD has a form to fill out on its website to report suspected illicit online pharmacies,[176] the website should also include additional educational materials related to these illegal operations under its listed resources. In conjunction with these efforts, education about the opioid epidemic itself is also crucial. Highlighting the addictiveness and danger that opioids cause and actively trying to discourage individuals from seeking opioids from illegal sources in the first place will help to at least make the illicit online pharmacy schemes less profitable.

Further, the DCD can utilize large corporations that play a role in such schemes to gain information into these complex criminal organizations.[177] Companies, such as Google, and other entities, like the Post Office, are uniquely situated to identify or observe this illegal conduct and should thus bear a level of responsibility for policing online pharmacies, as suggested in Part V above. Since 2018, members of Congress have urged companies such as Google, Microsoft, Yahoo, and Pinterest to direct users only to legitimate pharmacies and prohibit searches of illicit drugs, "[r]equiring each platform to report to law enforcement when that platform receives information indicating that a company wants to advertise the use of or sale of illicit narcotics."[178] Encouraging these corporations to flag

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[174] John B. Hertig, *Evaluation of Pharmacists' Awareness of Illegal Online Pharmacies and Perceived Impact on Safe Access to Medicines*, 5 MED. ACCESS @ POINT CARE 1, 1 (2021), https://journals.sagepub.com/doi/full/10.1177/23992026211005642 [https://perma.cc/Q2N4-MMZG].

[175] *Id.*

[176] *RX Abuse Online Reporting: Report Incident*, DIVERSION CONTROL DIV., https://apps.deadiversion.usdoj.gov/rxaor/spring/main?execution=e1s1 [https://perma.cc/VQ78-QV6T] (last visited Mar. 7, 2022).

[177] *See id.*

[178] *Grassley, Feinstein, Colleagues Urge Tech Companies to Clamp Down on Illegal Online Drug Sales and Advertising*, CHUCK GRASSLEY (Feb. 22, 2018),

this specific type of criminal conduct and report it to the appropriate authorities should be a goal of the DCD's enforcement efforts.[179]

Before the passage of the RHA, the DEA urged Congress that increased enforcement was not enough and that the dangers posed by illicit online pharmacies distributing controlled substances required legislative action.[180] Even today, legislative action from Congress should still be encouraged in conjunction with relying upon the DEA and the DCD in the fight against illicit online pharmacies.

VII. CONCLUSION

The COVID-19 pandemic has accelerated the development of an increasingly virtual world.[181] Schools have been taught remotely at all levels of academia, families open presents for holidays on video calls, and remote workers show no signs of returning to the office. Within this virtual universe, telemedicine has become a vital platform for the administration of medical care, given the ongoing opioid epidemic. Despite its many benefits, the rapid shift to telemedicine has created the perfect breeding ground for illicit online pharmacies to take root and develop into complex criminal

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https://www.grassley.senate.gov/news/news-releases/grassley-feinstein-colleagues-urge-tech-companies-clamp-down-illegal-online-drug [https://perma.cc/7939-9MDG].

[179] *See* 21 C.F.R. §§ 1300, 1301, 1304 (2009); *see also Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008,* DEP'T JUST. (Apr. 6, 2009), https://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf#search=illicit%20online%20pharmacies [https://perma.cc/J6RN-TSU7] ("[N]ew criminal offense added by the Act is 21 U.S.C. 843(c)(2)(A). This provision expressly prohibits using the Internet to advertise illegal transactions in controlled substances. Specifically, this provision states: It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by [the CSA] or by the Controlled Substances Import and Export Act.").

[180] S. REP. NO. 110-521, at 8–9 (2008).

[181] *See How COVID-19 Has Pushed Companies Over the Technology Tipping Point—and Transformed Business Forever*, MCKINSEY & CO. (Oct. 5, 2020), https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/how-covid-19-has-pushed-companies-over-the-technology-tipping-point-and-transformed-business-forever [https://perma.cc/YJR4-A79H].

enterprises. These illicit online pharmacies provide a way for individuals to find a website, complete a questionnaire that is not reviewed in any meaningful way, and receive opioids right on their front step without ever interacting with a physician.

Given the rapid development in technology that has made these illicit online pharmacies possible, it is imperative to have standardized regulation of the distribution of opioids and other controlled substances that accounts for these developments and appreciates the severity of potential consequences. The RHA was designed to amend the CSA to account for online pharmacies but has not achieved its aims. Controlled substance use is still rampant. The RHA's requirement of an in-person evaluation has been circumvented by the declaration of COVID-19 as a public health emergency, providing cause for reevaluating the provision's inclusion in future legislation.

More must be done to maximize protections against illicit online pharmacies. This goal cannot be viewed in isolation but rather must always be balanced against the social cost of placing obstacles that unintentionally prevent access to necessary, virtual medical care. There must be stricter standards of operation that ban the use of questionnaires and prescribe requirements in alignment with generally accepted medical practice. There must also be stricter penalties, but most importantly, there needs to be attention, time, and money diverted towards the development of enforcement strategies developed by the DCD of the DEA and members of a designated task force.

Federal legislation is desirable since telemedicine and online pharmacies transcend state borders. Congress is uniquely situated to standardize the regulation across all states. Although the legislation process at the federal level can be lengthy, it is still the preferable solution given the potential devastating consequences of Congress's failure to act.

If Congress is not receptive to the idea of passing such legislation, a second option is to create a State Model Legislation and encourage its adoption by individual states. This Model Legislation will help address some of the most immediate concerns and may also capture Congress's attention. Ultimately, however, the

preferable short-term solution is to encourage the DCD to increase enforcement and produce additional guidance and educational materials.

Although hopefully the COVID-19 pandemic will eventually come to an end, its impacts on the delivery of medical care will likely persist. The blending of telemedicine with the opioid epidemic has created a deathly combination that will continue to have devastating effects if left to be regulated by a patchwork of state-level legislation. Now is the time to regulate online pharmacies in an effort to mitigate the potential disadvantages of telemedicine, thereby allowing the benefits to flourish and provide more effective and expedient healthcare services to those who need them most.