Washington Journal of Law, Technology & Arts

Volume 18 | Issue 4 Article 3

6-11-2023

"TIKTOK TOLD ME I HAVE ADHD": REGULATORY OUTLOOK FOR THE TELEHEALTH REVOLUTION

Kaitlin Campanini
Pace University Elisabeth Haub School of Law

Follow this and additional works at: https://digitalcommons.law.uw.edu/wjlta

Part of the Computer Law Commons, Entertainment, Arts, and Sports Law Commons, Health Law and Policy Commons, Intellectual Property Law Commons, and the Internet Law Commons

Recommended Citation
Kaitlin Campanini, *"TIKTOK TOLD ME I HAVE ADHD": REGULATORY OUTLOOK FOR THE TELEHEALTH REVOLUTION*, 18 WASH. J. L. TECH. & ARTS (2023).
Available at: https://digitalcommons.law.uw.edu/wjlta/vol18/iss4/3

This Article is brought to you for free and open access by the Law Reviews and Journals at UW Law Digital Commons. It has been accepted for inclusion in Washington Journal of Law, Technology & Arts by an authorized editor of UW Law Digital Commons. For more information, please contact lawref@uw.edu.

"TIKTOK TOLD ME I HAVE ADHD": REGULATORY OUTLOOK FOR THE TELEHEALTH REVOLUTION

Cover Page Footnote

Incoming Associate, Davis Polk & Wardwell, 2023; J.D., Elisabeth Haub School of Law at Pace University, 2023; Editor-in-Chief, Pace Law Review, 2023; B.A., State University of New York at Oswego, 2019.

This author would like to thank Professor Lauren H. Breslow and Professor Leslie Y. Garfield Tenzer for assisting in the formulation of this topic and contributing thoughtful edits and suggestions throughout the writing process.

This article is available in Washington Journal of Law, Technology & Arts: https://digitalcommons.law.uw.edu/wjlta/vol18/iss4/3

WASHINGTON JOURNAL OF LAW, TECHNOLOGY & ARTS
VOLUME 18, ISSUE 4 — SUMMER 2023

"TIKTOK TOLD ME I HAVE ADHD": REGULATORY OUTLOOK FOR THE TELEHEALTH REVOLUTION

Kaitlin Campanini[1*]

ABSTRACT

Telehealth's expansion during the COVID-19 pandemic has drastically changed the approach to healthcare in the United States. This is particularly true in the behavioral health sector where several behavioral telehealth companies have emerged to treat Attention-Deficit/Hyperactivity Disorder ("ADHD"). These companies utilize a direct-to-consumer ("DTC") model with a virtual platform that connects subscribing patients to medical providers who can treat them for ADHD. Although this telemedicine model emphasizes convenience and efficiency, the reality is that those benefits come at the cost of patient care. The federal regulations promulgated in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to curtail the distribution of controlled substances over the internet are inadequate.

This paper argues that the Drug Enforcement Administration's ("DEA") sparse regulatory structure for telehealth companies has fostered an environment where ADHD telehealth companies prescribe controlled substances with impunity. These companies aggressively advertise to potential consumers, provide low-quality mental health treatment, and overprescribe controlled substances. The DEA and the FDA should enact new requirements to both protect consumers from harmful health practices and improve the quality of telehealth services. Specifically, the DEA should establish drug-specific guidelines for a special registration for telehealth providers under the Ryan Haight Act to be able to prescribe controlled substances through telehealth services. Further, the advertisements made by these companies should be subject to the Food and Drug Administration's ("FDA") oversight under the Federal Food, Drug, and Cosmetic Act.

[1*]Incoming Associate, Davis Polk & Wardwell, 2023; J.D., Elisabeth Haub School of Law at Pace University, 2023; Editor-in-Chief, Pace Law Review, 2023; B.A., State University of New York at Oswego, 2019. This author would like to thank Professor Lauren H. Breslow and Professor Leslie Y. Garfield Tenzer for assisting in the formulation of this topic and contributing thoughtful edits and suggestions throughout the writing process.

TABLE OF CONTENTS

INTRODUCTION 43

I.THE GROWTH OF TELEHEALTH DURING THE COVID-19 PANDEMIC 45

A.FEDERAL REGULATIONS 46

B.STATE REGULATIONS 48

II. THE GROWTH OF ADHD TELEHEALTH COMPANIES EXPOSES REGULATORy GAPS 49

A.DIRECT-TO-CONSUMER TELEMEDICINE 50

B.EXPLOITING REGULATION GAPS 52

i. Unregulated DTC Business Model 52

ii. *Over Prescribing Stimulant Drugs* 53

iii. Advertising Medical Services 56

III.WAYS TO ADDRESS THE REGULATORY GAPS THAT ADHD TELEMEDICINE HAS CREATED 58

A. ESTABLISHING A SPECIAL REGISTRATION FOR TELEMEDICINE UNDER THE RYAN HAIGHT ACT 58

i. Appointment Length *59*

ii. Releasing Medical Information to Providers 60

iii. Telehealth Provider Training 61

B.SUBJECTING DTC TELEMEDICINE ADVERTISEMENTS TO FDA OVERSIGHT 61

CONCLUSION 65

INTRODUCTION

Telehealth[2] is changing accessibility to prescription drugs. And not for the better. The term telehealth describes the practice of providing healthcare services at a distance between the provider and patient through the use of information communication technology.[3] The nature of telemedicine is an "open and constantly evolving science,", which allows it to adapt to healthcare needs as they change in a developing society.[4] This fluid nature of telemedicine is reflected by how quickly physicians and patients in all practice areas were able to transition from in-person to virtual appointments during the COVID-19 pandemic.[5]

The invention of the telephone in 1876 marks the beginning of telemedicine in the United States.[6] The telephone has been used to deliver health services since the mid-nineteenth century, but modern telemedicine really emerged in the late 1960s spurred by the military and space technology sectors.[7] Technological advancements throughout the twentieth century like the television, mobile phones, satellite communications, and the internet have been pivotal for the evolution of modern telemedicine to its current iteration.[8]

The onset of the COVID-19 pandemic launched telemedicine into the forefront of medical care for a significant number of Americans.[9] Many Americans were confined to their homes

---

[2] The World Health Organization ("WHO") has noted that telehealth and telemedicine are terms that have become interchangeable. WORLD HEALTH ORGANIZATION, TELEMEDICINE: OPPORTUNITIES AND DEVELOPMENTS IN MEMBER STATES 9 (2010) ("Some distinguish telemedicine from telehealth with the former restricted to service delivery by physicians only, and the latter signifying services provided by health professionals in general, including nurses, pharmacists, and others. However, for the purpose of this report, telemedicine and telehealth are synonymous and used interchangeably."); *See* Laura C. Hoffman, *Reconnecting the Patient: Why Telehealth Policy Solutions Must Consider the Deepening Digital Divide*, 19 IND. HEALTH L. REV. 351, 356 (2022) (noting that these terms encompass different methods of administering health services through technology, but they have come to be used interchangeably). As such, this author will use these terms alike throughout the paper.

[3] *See* WORLD HEALTH ORGANIZATION, *supra* note 1, at 9 (defining telehealth as "[t]he delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.").

[4] *Id.*

[5] *See* Timothy D. Malouff et al., *Physician Satisfaction With Telemedicine During the COVID-19 Pandemic: The Mayo Clinic Florida Experience*, 5 MAYO CLINIC PROC.: INNOVATIONS, QUALITY & OUTCOMES 771, 775 (2021) ("Our data suggest that physicians have adapted to the implementation of telemedicine technology for clinical consultations and follow-ups. In our study, most respondent physicians felt skilled at using the technology. Interestingly, almost all physicians were open to using telemedicine routinely for follow-up visits after the resolution of the pandemic, with just under half of respondents preferring telemedicine over face-to-face visits.").

[6] *See* WORLD HEALTH ORGANIZATION, *supra* note 1, at 9; TELEMEDICINE: OPPORTUNITIES AND DEVELOPMENTS IN MEMBER STATES 9 (2010); Thomas S. Nesbitt, *The Evolution of Telehealth: Where Have We Been and Where are We Going?*, *in* THE RULE OF TELEHEALTH IN AN EVOLVING HEALTH CARE ENVIRONMENT: WORKSHOP SUMMARY 11, 11 (2012) ("[A]n 1879 article in the Lancet talked about using the telephone to reduce unnecessary office visits").

[7] *See* WORLD HEALTH ORGANIZATION, *supra* note 1, at 9; Maryam A. Hyder & Junaid Razzak, *Telemedicine in the United States: An Introduction for Students and Residents*, 22 J. MED. INT. RSCH. 1, 2 (2020) ("NASA designated "medical monitors" to become well-versed in the astronauts' medical history, while conducting research on the effect of the environment of outer space on the human body.").

[8] *See* John Craig & Victor Patterson, *Introduction to the Practice of Telemedicine*, 11 J. TELEMEDICINE & TELECARE 3, 5 (2005) ("As early as 1964, a two-way closed-circuit television system was set up between the Nebraska Psychiatric Institute in Omaha and the state mental hospital in Norfolk, 112 miles (180 km) away. The system permitted interactive consultations between specialists and general practitioners, and facilitated education and training at the distant site"); WORLD HEALTH ORGANIZATION, *Supra* note 1, at 9. For more information about the evolution of telehealth in the United States, see generally Thomas S. Nesbitt & Jana Katz-Bell, *Chapter 1: History of Telehealth, in* UNDERSTANDING TELEHEALTH 3, 3–14 (2018)

[9] *See* Timothy Callaghan et al., *The Changing Nature of Telehealth Use by Primary Care Physicians in the United States*, 13 J. PRIM CARE COMMUNITY HEALTH ("Prior to the COVID-19 pandemic, telehealth utilization was growing slowly and steadily, although differentially across settings and medical disciplines . . . . The realities of the COVID-

during the height of the pandemic or were otherwise unable to attend in-person medical appointments. The convenience and availability of telemedicine appointments have continued to make it a popular choice for patients seeking medical care. A study conducted on 625 primary care physicians found that the number utilizing telehealth had increased from 5.3% pre-COVID-19 to 46.2% during the pandemic, and over seventy percent of physicians surveyed intend to use telehealth occasionally even after many social distancing restrictions have been removed.[10]

The expansion of telehealth is particularly prevalent in the sector of behavioral telehealth.[11] Specifically, several behavioral telehealth companies have emerged since the pandemic to treat Attention-Deficit/Hyperactivity Disorder ("ADHD").[12] These companies provide a virtual platform to connect patients to a medical provider who can treat them for ADHD, offering a convenient and affordable option for patients to treat their ADHD. However, this conveniency and efficiency come at a price.[13]

Many companies are engaged in practices, both in terms of prescribing and advertising, that current regulations on healthcare providers do not sufficiently address. The companies utilize social media to reach consumers with advertisements that simplify complex ADHD symptoms and

---

19 pandemic dramatically accelerated telehealth use, both in hospital settings where it has historically been used most often, and in outpatient settings where its adoption was far more uneven."); *see also* Oleg Bestennyy et al., *Telehealth: AQuarter-Trillion-Dollar-Post-Covid-19Reality?*,MCKINSEY&CO.(July9,2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality (noting that telehealth use is thirty-eight times higher than it was pre-COVID-19); Center for Connected Health Policy, *State Telehealth Laws and Reimbursement Policies*, THE NAT'L TELEHEALTH POL'Y RES. CTR. (2021), https://www.cchpca.org/2021/10/Fall2021_Infographic_FINAL.pdf (noting that fifty states and the District of Columbia have a definition for telehealth, telemedicine or both); JoAnn Volk et al., *States' Action to Expand Telemedicine Access During COVID-19 and Future Policy Considerations*, COMMW. FUND (June 23, 2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/jun/states-actions-expand-telemedicine-access-covid-19 ("telemedicine use has greatly expanded from a tiny proportion of office visits pre-pandemic to a high of 16 percent of visits at large practices (more than 100 clinicians) by mid-April 2020.").

[10] *See* Callaghan et al., *supra* note 9, at 1. Further, In 2021, 37% of adults in the United States had used telemedicine in the past twelve months. JACQUELINE W. LUCAS & MARIA A. VILLARROEL, NAT. CTR. HEALTH STAT., TELEMEDICINE USE AMONG ADULTS: U.S., 2021 1 (2022). The continued use of telehealth post-pandemic is due to the benefits that have been associated with its growth. Telehealth, by its design, helps eliminate access barriers due to convenience and efficiency of a virtual platform. *See* Allison Gray, *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*, 23 N.C. J.L & TECH. 558, 608 (2022) ("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."); Jena M. Richer, *Victims of Introspection: Insufficient Legal Protections for at-Risk Users of Automated Mental Health Apps*, 44 VT. L. REV. 893, 897 (2020) ("A 2018 review of 145 telemedicine studies revealed that telehealth technology improves access to care.").

[11]*See* Nina Zhang, *Is the Future of Behavioral Health Digital?* HEALTH LAW. 56, 57 (2021) ("With telehealth, patients can talk to a therapist in the privacy of their own homes. Telehealth can also reduce transportation time and eliminate other barriers, such as the need to take time off work and finding childcare."); Oleg Bestennyy et al, *Telehealth: A quarter-trillion-dollar post-COVID-19 reality?* MCKINSEY & CO. (July 9, 2021), http:://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality.

[12] *See, e.g., ADHD Shouldn't Be This Hard. Online Treatment Made Just for You*, DONE FIRST, https://www.donefirst.com (last visited Nov. 30, 2022); *Start Your Journey to Wellness — Anytime, Anywhere*, CEREBRAL, https://get.cerebral.com (last visited Nov. 30, 2022); *Meet With a doctor Over video About ADHD Prescriptions*, CIRCLE MED., https://www.circlemedical.com/what-we-treat/adhd?utm_campaign=[VA]%20ADHD%20B&utm_source=google&utm_medium=cpc&utm_content=544136781577_&utm_term=p_adhd&gclid=Cj0KCQiAm5ycBhCXARIsAPldzoXNFNK1aMsWMmrA54BFwp2V73wH-ZToi5ZUZGaA1f1PWjiYMmW0m3oaAg-ZEALw_wcB&gclid=Cj0KCQiAm5ycBhCXARIsAPldzoXNFNK1aMsWMmrA54BFwp2V73wH-ZToi5ZUZGaA1f1PWjiYMmW0m3oaAg-ZEALw_wcB (Nov. 30, 2022).

[13] *See, e.g., Are Telehealth Startups Overprescribing Adderall?,* ADVISORY BD. (May 5, 2022), https://www.advisory.com/daily-briefing/2022/05/05/adderall. According to STAT News these online telemedicine companies' prescribing practices could significantly impact the emerging digital pharmacy industry, as well as telehealth overall.

lead consumers to believe they have the condition.[14] Diagnosis and treatment is then made very easy through the use of the companies' treatment platform. ADHD is most commonly treated by 'stimulants,'[15] which are schedule II-controlled substances.[16] Taken together, insufficient regulations combined with these prescribing and advertising practices are enabling ADHD telemedicine companies to mislead consumers and overprescribe dangerous controlled substances.

This paper argues that the Drug Enforcement Administration's ("DEA") and the Food and Drug Administration's ("FDA") sparse regulatory structure for telehealth companies has fostered an environment where ADHD telehealth companies prescribe controlled substances with impunity. Part I evaluates both the federal and state regulations that have allowed for the rapid growth of the telehealth industry.[17] Part II discusses how these enabling regulations allowed for the rise of ADHD-specific telehealth companies that use targeted social media marketing to recruit and treat new patients with few standards.[18] It will explain how these companies utilize a direct-to-consumer ("DTC") telemedicine model, which is distinct from traditional telemedicine by marketing directly to patients who then initiate the treatment.[19] Part III turns to how federal law can be modified to regulate these companies and ensure uniformity across state lines.[20] Ultimately, this paper concludes that (1) the DEA should promulgate a special registration for telemedicine under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act") to require drug-specific prerequisites of a telehealth visit before a provider can prescribe Schedule II drugs and (2) that DTC telemedicine companies should be subject to similar federal regulations as pharmaceutical companies when they engage in DTC drug advertising.[21]

I. THE GROWTH OF TELEHEATH DURING THE COVID-19 PANDEMIC

During the COVID-19 pandemic, both federal and state governments relaxed regulations to promote the use of telemedicine. In particular, both federal and state governments amended prescribing and licensing laws to improve access to care by allowing providers to practice across state lines and prescribe controlled substances virtually.[22] This enabled several behavioral

---

[14] *See* Jamie Ducharme, *What's Driving the Demand for ADHD Drugs Like Adderall*, TIME (Apr. 12, 2023), https://time.com/6271049/adhd-diagnoses-rising/ ("About 8% more people in the U.S. filled a stimulant prescription in 2021 versus 2020 . . . . Some experts fear the uptick reflects lax diagnostic standards during the COVID-19 pandemic and a growing trend of people becoming convinced they have ADHD because of content they see on social media.").

[15] *See Attention-Deficit/Hyperactivity Disorder (ADHD) Treatment,* CDC, https://www.cdc.gov/ncbddd/adhd/treatment.html (last visited Nov. 30, 2022) ("Stimulants are the best-known and most widely used ADHD medications."); Leslie Briars & Timothy Todd, *A Review of Pharmacological Management of Attention-Deficit/Hyperactivity Disorder*, 21 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 192, 193 (2016) ("Psychostimulants have been the medications of choice for treating ADHD for more than 60 years. About 75% to 80% of children with ADHD will benefit from the use of psychostimulants. Methylphenidate, dexmethylphenidate, dextroamphetamine, lisdexamfetamine, and the mixed amphetamine salts (dextro- and levo-amphetamine) constitute the psychostimulants currently on the market.").

[16] *See* Nazila Sharbaf Shoar et al., *Dextroamphetamine-Amphetamine*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK507808/ (last updated May 29, 2022) (noting the high potential for abuse of stimulant drugs).

[17] *See* discussion *infra* Part I.

[18] *See* discussion *infra* Part II.

[19] *See* discussion *infra* Part III.

[20] *See* discussion *infra* Part III.

[21] *See* discussion *infra* Part III.

[22] For more information on the other regulations that were amended during the pandemic see generally U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Fed'n of State Med. Bds.,

telehealth companies to begin targeting ADHD treatment because they could now prescribe stimulants—the most common treatment medication—without an in-person visit.

A. FEDERAL REGULATIONS

At the federal level, Congress has charged the DEA with regulating and enforcing medications, including medications used to treat ADHD such as Adderall (mixed amphetamine salts), Ritalin (methylphenidate), and Concerta (Methylphenidate Hydrochloride Extended-Release Tablets).[23] In 2008, Congress expanded the Controlled Substances Act through the enactment of the Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act").[24] The Ryan Haight Act was a response to the growth of rogue online pharmacies. It was specifically named after an eighteen-year-old, Ryan Haight, who overdosed on Vicodin that he obtained through an online pharmacy from a physician prescriber that he never met.[25] This law was an attempt by Congress to regulate the evolving use of the internet in dispensing controlled substances.[26] The Ryan Haight Act prohibits providers from prescribing controlled substances without at least one in-person examination.[27] Although this Act was passed with the intent of regulating rogue internet pharmacies, Congress also unintentionally restricted legitimate telehealth providers.[28]

The Ryan Haight Act enabled the DEA to enact a "special registration" process to allow providers to prescribe controlled substances via telemedicine.[29] This special registration would create an exception to the Ryan Haight's in-person requirement, allowing providers who receive the special registration to prescribe controlled substances through telehealth.[30] Thus, legitimate

---

https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf (last updated Nov. 15, 2022); Nicol Turner Lee et al., Brookings Institution & John Locke Found., *Removing Regulatory Barriers to Telehealth Before and After COVID-19* (2020), https://www.brookings.edu/wp-content/uploads/2020/05/Removing-barriers-to-telehealth-before-and-after-COVID-19_PDF.pdf.

[23] *See* Laura C. Hoffman, *Shedding Light on Telemedicine & Online Prescribing: The Need to Balance Access to Health Care and Quality of Care*, 46 AM. J.L. & MED. 237, 243 (2020); *see also Amphetamines*, DEA.gov, https://www.dea.gov/factsheets/amphetamines (last visited Feb. 1, 2023).

[24] *See* 21 U.S.C.A § 829(e) (West 2016) (providing that "[n]o controlled substance . . . may be delivered, distributed, or dispensed by means of the Internet without a valid prescription" and defining what is meant by "valid prescription"); *see also* 21 U.S.C. § 805(54) (defining what is meant by the "practice of telemedicine").

[25] *See* Jeremy Sherer & Amy Joseph, *Physician Law Evolving Trends and Hot Topics: Telehealth*, 32 HEALTH LAW. 20, 27 (2020); *see also* 21 U.S.C.A § 829 (West 2016).

[26] *See* Sherer & Joseph, *supra* note 23, at 27; 21 U.S.C.A § 829(e) ("No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."); *see generally* Andres Fittler et al, *Evaluating Aspects of Online Medication Safety in Long-Term Follow-Up of 136 Internet Pharmacies: Illegal Rogue Online Pharmacies Flourish and Are Long-Lived* 15 J. MED. INT. RSCH. (2013).

[27] *See* 21 U.S.C.A § 829(e)(2)(A) ("The term 'valid prescription' means a prescription that is issued for a legitimate medical 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; or (ii) a covering practitioner.").

[28] *See* Debroah R. Farringer, *A Telehealth Explosion: Using Lessons From the Pandemic*, 9 TEX. A&M L. REV. 1, 14 (2021) ("Although the Ryan Haight Act hinders only the *prescribing* of controlled substances via telehealth, the requirements and limitations constrict the prescriber's ability to prescribe substances as necessary to treat the patient and may further quell practitioners from utilizing telehealth at all, which possibly limits treatment options."); Sherer & Joseph, *supra* note 23, at 27–28.

[29] *See id.* at 14. The purpose of this registration was to address the unintended restriction that the Ryan Haight Act had on legitimate telehealth prescribers due to the broad language of the statute. *See DEA Misses Deadline for Teleprescribing Special Registration*, NAT'L COUNS. FOR MENTAL WELLBEING, https://www.thenationalcouncil.org/dea-misses-deadline-for-teleprescribing-special-registration/ (last visited Nov. 30, 2022). For more information about the special registration for telemedicine, see generally CONG. RSCH. SERV. R45240, THE SPECIAL REGISTRATION FOR TELEMEDICINE: IN BRIEF (2018).

[30] To receive the special registration, a practitioner must (1) have a legitimate need for the special registration, (2) be registered in the state in which the patient is located, and (3) comply with all federal and state laws. *See* U.S.C. §§

telehealth providers would be able to continue treating patients. Despite this, no provider has been given a special registration and the DEA has not opened up the special registration process.[31] The DEA has said that it would promulgate this special registration for fourteen years.[32] However, the DEA has failed on numerous occasions to follow through on those plans.[33]

In response to the pandemic, the DEA implemented an exception to the Ryan Haight Act that permitted providers to prescribe controlled substances without the requirement of an in-person visit if several conditions are satisfied.[34] This exception requires that:

> The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice; The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and the practitioner is acting in accordance with applicable Federal and State laws.[35]

The DEA allowed the exception to remain in effect until the public health emergency ("PHE") is lifted.[36] The PHE has been extended multiple times, but is set to end May 11, 2023.[37] Thus, providers are free to continue prescribing controlled substances without having an in-person visit. There is uncertainty about what the end of the PHE will mean for telehealth prescribing, but there is a push and an expectation that the amendment to Ryan Haight will be permanent by the DEA enacting a Special Registration for telehealth providers.[38]

823; 831(h)(1); VICTORIA L. ELLIOT, CONG. RSCH. SERV. R45240, THE SPECIAL REGISTRATION FOR TELEMEDICINE IN BRIEF 1–2 (2018); Letter to Hon. Anne Milgram, Administrator, DEA, from American Hospital Association (Dec. 1, 2022), https://www.aha.org/lettercomment/2022-12-01-aha-letter-dea-regarding-request-release-special-registration-telemedicine-regulation.

[31] *See* Dilon Vaughn, *Amending the Ryan Haight Act: Elevating Telemedicine Law to New Heights*, 7 TEX. A&M LAW. REV. 475, 478 (2020).

[32] Letter to Hon. Merrick B. Garland, Attorney General, and Hon. Anne Milgram, Administrator, DEA, from Mark R. Warner, Senator (Aug. 16, 2022), https://www.warner.senate.gov/public/_cache/files/1/c/1cec8036-b470-4ebd-9d9e-123dff876c48/AAB5069A5C4A588DE453DC645A7334D1.2022.08.16-dea-phe.pdf.

[33] *See DEA Misses Deadline for Teleprescribing Special Registration, supra* note 42 (noting that the DEA has missed the deadline to promulgate a special registration); Ryan K. Gorman, *Prescribing Medication Through the Practice of Telemedicine: A Comparative Analysis of Federal and State Online Prescribing Policies, and Policy Considerations for the Future*, 30 S. Cal. Interdisc. L.J. 739 (2021).

[34] Farringer, *supra* note 26, at 27–28.

[35] *See Covid-19 Information Page*, U.S. DEP'T OF JUST. DRUG ENFORCEMENT ADMIN., https://www.deadiversion.usdoj.gov/coronavirus.html, (last visited Nov. 30, 2022); 42 C.F.R. § 410.78(i)(4) (West 2009) (stating that Secretary of Health and Human Services has broad authority to make designations in light of a public health emergency under 42 U.S.C. § 247(d)); 42 U.S.C.A. § 247(d) (West 2019).

[36] *Id.*

[37] *See* Tami Luhby, *These benefits will disappear when Biden ends the Covid national and public health emergencies in May*, CNN (Jan. 31, 2023, 12:29 PM), https://www.cnn.com/2023/01/30/politics/may-11-end-of-covid-and-public-health-emergencies/index.html (this is currently the twelfth time the public health emergency has been extended since it was declared in January 2020); *See also* Susan Morse, *HHS Extends Public Health Emergency for the 11th Time*, HEALTHCARE FIN. (Oct. 14, 2022), https://www.healthcarefinancenews.com/news/hhs-extends-public-health-emergency-11th-time#:~:text=The%20current%2090%2Dday%20extension%20ends%20on%20January%2011%2C%202023.&text=The%20Biden%20Administration%20has%20extended,first%20made%20in%20January%202020.

[38] *See, e.g.*, Letter from American Hospital Association to Hon. Anne Milgram, Administrator, DEA(Dec. 1, 2022), https://www.aha.org/lettercomment/2022-12-01-aha-letter-dea-regarding-request-release-special-registration-telemedicine-regulation ("Flexibilities, including waiving the required initial in-person visit prior to prescribing controlled substances via telehealth and allowing the use of telephone evaluations to initiate buprenorphine prescribing, have proved critical in best supporting our patients. These waivers have improved access to care for patients with substance use disorder where there were already shortages in prescribers even prior to the pandemic."); Letter from Mark R. Warner to Hon. Merrick B. Garland, Attorney General, and Hon. Anne Milgram, Administrator, DEA, from Mark R. Warner, Senator (Aug. 16, 2022), https://www.warner.senate.gov/public/_cache/files/1/c/1cec8036-b470-4ebd-9d9e-

This exception to the Ryan Haight Act enabled ADHD telemedicine companies to develop, because effective treatment for the condition often involves prescribing controlled substances.[39] In addition to federally waiving the requirements of the Ryan Haight Act, many states amended their own laws to increase access to telemedicine services during the pandemic.[40]

B. STATE REGULATIONS

Each state has its own telehealth policies that regulate the practice of telemedicine within the state. With the failure of the DEA to promulgate a special registration, many states have passed their own laws to address the prescribing of controlled substances via telehealth.[41] Many of these policies are in direct conflict with federal policy of the Ryan Haight Act, because they allow telemedicine prescribing practices broader than those allowed under Ryan Haight.[42] Despite the possibility that state prescribing laws exceed the federal law, state actors are, likely, not concerned, because the DEA has taken little action to actually enforce the Ryan Haight Act.[43]

States have taken three main approaches to telehealth prescribing laws: (1) prohibiting prescription of controlled substances with limited exceptions; (2) allowing prescribing within federal limits; and (3) allowing prescriptions with limitations above those required under federal law.[44] In response to the pandemic, many states waived the in-person requirement for their own prescribing laws.[45] Although many of these waivers have expired, many states are still allowing controlled substances to be prescribed via telehealth.[46] This practice enables telehealth companies to treat ADHD across the country while adhering to federal and state law.[47]

123dff876c48/AAB5069A5C4A588DE453DC645A7334D1.2022.08.16-dea-phe.pdf (expressing concern for patients whose treatment will be disrupted or discontinued when the PHE ends).

[39] *See* Caitlin Bradford, *Ensuring the Continued Efficacy of Telepsychiatry: Amending the Ryan Haight Act*, 31 ANNALS HEALTH L. 115, 117 (2021) (noting that the prescription of controlled substances is often "one of the core aspects of psychiatric treatment"); *see* also Leslie Briars & Timothy Todd, *A Review of Pharmacological Management of Attention-Deficit/Hyperactivity Disorder*, 21 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 192, 194 (2016) (noting that the most common treatment for ADHD is stimulants, which is a schedule II controlled substance).

[40] Farringer, *supra* note 26, at 28 (noting that the Ryan Haight Act exception in not controlling on any state laws that further restrict telemedicine prescribing practices).

[41] Hoffman, *supra* note 22, at 247.

[42] Gorman, *supra* note 38, at 740. (The Controlled Substances Act likely preempts any state laws that permit prescribing controlled substances more broadly the Ryan Haight Act. However, it is beyond the scope of this paper to discuss how the Controlled Substances Act preempts state law. For more information, see generally Gorman, *supra* note 38.).

[43] Gorman, *supra* note 38, at 754–56 ("[T]he DEA has not punished a provider for violating the Ryan Haight Act since 2011, when it revoked a practitioner's DEA-registration for prescribing in a manner that defied the public interest.").

[44] Hoffman, *supra* note 22, at 247; *see also* Gabrielle A. Vance, Note, *The Hoosiers Got it Wrong: The Need for States to Enact Stricter Prescribing Regulations Via Telemedicine Services,* 12 WM. & MARY BUS. L. REV. 222, 232–34 (2020) (comparing the prescribing laws of Indiana, Michigan, and Ohio); *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, supra* note 20 (listing the telehealth regulations of each state).

[45] Florida, for example, had limited the prescribing of controlled substances without an in person visit, but amended this curing COVID-19. *See U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, supra* note 20; *see also 50-State Survey: Establishment of a Patient-Physician Relationship Via Telemedicine,* AM. MED. ASS'N (2018), https://www.ama-assn.org/system/files/2018-10/ama-chart-telemedicine-patient-physician-relationship.pdf (noting state laws regarding establishing a patient-provider relationship).

[46] *See, e.g.,* CONN. GEN. STAT. ANN. § 19a-906(c) (West 2022) (allowing all controlled substances to be prescribed via telehealth except opioids); FLA. STAT. ANN. § 456.47 (West 2022) (prohibiting controlled substances to be prescribed via telehealth, but allows them to for psychiatric conditions); *see also* NY Rules and Regulation 80.62 and 80.63(d)(1).

[47] For example, one ADHD telehealth company, Done, is able to treat patients in Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode island, South Carolina, South Dakota, Tennessee, Texas, Utah,

In addition to prescribing laws, state licensure laws require providers to be licensed in the state in which they choose to practice telemedicine.[48] Almost every state suspended many licensure requirements during the pandemic to ensure that people had adequate access to care.[49] The relaxation of an in-person requirement, for example, enabled a clinician in Ohio to provide services to a patient located in New York, even if that clinician is not licensed in New York. While many of these waivers have since expired, there is a push to continue enabling cross-state medical care.[50] Many states are streamlining the process to license out-of-state providers to continue the increased access to care.[51] The ability to offer interstate telehealth care was crucial for the development of ADHD telemedicine companies because these companies can maximize the number of patients each provider treats, regardless of where they are located.[52]

The PHE's lengthy continuation and state legislatures' waivers were paramount to increasing access to needed medical care. However, the limited regulatory structure for telehealth companies has created a climate where ADHD telehealth companies may overprescribe controlled substances without accountability. Further, a recent survey revealed that forty-five percent of patients prefer using telehealth for mental health treatment.[53] The DEA and state governments need to address these regulatory gaps to allow patients to continue accessing life-saving telehealth.

II. THE GROWTH OF ADHD TELEHEALTH COMPANIES EXPOSES REGULATORY GAPS

Vermont, Virginia, Washington, and Wisconsin. *See Do You Support My State?*, DONE FIRST (Sep. 21, 2022, 4:32 PM), https://support.donefirst.com/en_us/do-you-support-my-state-rkTmNX87t.

[48]*See* Kimberly Lovett Rockwell, *Healthcare Law: The Promise of Telemedicine: Current Landscape and Future Directions* 96 MICH. BAR J. 38, 40 (2017); *Telemedicine Policies: Boards by Board Overview*, FED'N OF STATE MED. BDS., https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf (last updated Nov. 2022).

[49]*See Telehealth Licensing Requirements and Interstate Compacts,* Telehealth.HHS.Gov, https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/telehealth-licensing-requirements-and-interstate-compacts/ (last visited Nov. 30, 2022) (stating, "Almost every state has modified licensure requirements/renewal policies for health care providers in response to COVID-19, including out-of-state requirements for telehealth."); *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, supra* note 20 (listing the states that have enacted waivers during COVID-19).

[50]*U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, supra* note 20 (showing the forty-one states with waivers that have currently expired); Linda M. Richmond, *Cross-State Licensure Laws for Telehealth Evolve During Pandemic*, PSYCHIATRIC NEWS (Jan. 27, 2022), https://psychnews.psychiatryonline.org/doi/10.1176/appi.pn.2022.2.5 ("[A] number of states retained some form of waiver of licensure requirements for out-of-state physicians who are providing telehealth services including Arizona, Colorado, Delaware, Idaho, Indiana, Iowa, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Mexico, North Carolina, Oregon, Pennsylvania, Texas, Utah, Washington, West Virginia, Wisconsin, and Wyoming.").

[51]The Interstate Medical Licensure Compact ("IMLC") makes the process for obtaining a medical license in 33 U.S. states and one territory simpler if you already hold your primary license in one of the participating states. *See* Rebecca Pifer, *As Cross-State Telemedicine Waivers Expire, Virtual Care Advocates Focus on Long-Term Policy Changes*, HEALTHCARE DIVE (Jun. 21, 2022), https://www.healthcaredive.com/news/cross-state-telemedicine-waivers-expire-virtual-care-advocates-focus/625389/. (Explaining that some states have reciprocity statutes that permit providers licensed in bordering states to practicing within the state without needing a separate license).

[52]*See* Edward Timmons & Conor Norris, *Potential Licensing Reforms in Light of COVID-19*, 3 HEALTH POL'Y OPEN 2590, 2590–91 (2022) (noting that strict licensing laws limit patients' access to care and COVID-19 highlighted the importance of interstate care).

[53]*See* Carl Reuterskiold, *Technology's Role In Improving ADHD Diagnosis And Treatment*, FORBES (Jan. 17, 2023), https://www.forbes.com/sites/forbestechcouncil/2023/01/17/technologys-role-in-improving-adhd-diagnosis-and-treatment/?sh=7d1d90f51954.

The need for mental health treatment was at an all-time high during the pandemic.[54] The ease with which telehealth enabled patients to access this care demonstrated how conducive digital behavioral health is to many patients seeking treatment.[55] The pandemic created a demand in the healthcare industry that was met by several startup companies offering virtual ADHD treatment. These companies use a platform to connect subscribing patients to a provider through a model that has become known as direct-to-consumer telemedicine.

A. DIRECT-TO-CONSUMER TELEMEDICINE

The concept of Direct to Consumer (hereinafter referred to as "DTC") in the healthcare context traditionally referred to marketing strategies utilized by pharmaceutical companies to advertise to patients.[56] More recently, it has been used to define an approach to delivering healthcare services.[57] DTC telemedicine companies combine DTC marketing with telemedicine technology "to serve as convenient, one-stop shops for patients looking to receive treatment for common conditions from the comfort and safety of their own homes."[58] This approach markets services directly to patients who initiate the encounter, which is distinct from traditional telemedicine "that is made available only through a provider" who has already been treating a patient and developed a relationship.[59] Additionally, DTC telemedicine is different from traditional telemedicine because there is no preexisting patient-provider relationship.[60] DTC telemedicine was initially designed to treat minor conditions.[61] However, as it is expanding into

---

[54]*See* Nina Zhang, *Is the Future of Behavioral Health Digital?* HEALTH LAW. 56, 56 (2021); Joshua A. Gordon & Susan E. Borja, *The COVID-19 Pandemic: Setting the Mental Health Research Agenda,* 88 BIOLOGICAL PSYCHIATRY 130, 130 (2020); Steven Ross Johnson, *Study Shows Rising Demand for Mental Health Treatment During Pandemic*, U.S. NEWS (Sep. 7, 2022), https://www.usnews.com/news/health-news/articles/2022-09-07/study-shows-rising-demand-for-mental-health-treatment-during-pandemic#:~:text=The%20percentage%20of%20U.S.%20adults,National%20Center%20for%20Health%20Statistics ("The percentage of U.S. adults who reported receiving any treatment for their mental health over the past 12 months rose from 19.2% in 2019 to 20.3% in 2020 and then to 21.6% in 2021, according to a report released Wednesday by the Centers for Disease Control and Prevention's National Center for Health Statistics.").

[55]*See* Zhang, *supra* note 60, at 56–57; *see also Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency: Survey Results*, AM. PSYCHIATRIC ASS'N (July 2021), https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Telepsychiatry/APA-Telehealth-Survey-2020.pdf ("[D]ata a showed that patient no-show rates dropped significantly as telehealth became the primary way of keeping appointments with their psychiatrists . . . . 90% of respondents reporting that patients who were seen for the first time via telehealth remain either 'somewhat satisfied' or 'Satisfied' with their care."). Further, 81% of respondent mental health providers plan to continue to see 75–100% of their patients through telehealth. *See id.*

[56]Tania Elliott & Margot C. Yopes, *Direct-to-Consumer Telemedicine*, 7 J. ALLERGY AND CLINICAL IMMUNOLOGY: IN PRACTICE 2546, 2546 (2019); Hoffman, *supra* note 21, at 239 ("The use of DTC is distinguished from other ways of providing telemedicine by the initiation of the encounter by the patient.").

[57]Elliott & Yopes, *supra* note 62, at 2546.

[58]Kristina L. Bitzer, Comment, *Online and Off-Label: Closing the Regulatory Gap in Online Direct-to-Consumer Drug Promotion and Prescribing*, 42 N. ILL. U. L. REV. 164, 167 (2021).

[59]Elliott & Yopes, *supra* note 62, at 2546.

[60]*See* Suzanne G. Bollmeier et al., *Direct to Consumer Telemedicine: Is Healthcare Best from Home?*, 117 MO. MED. 303, 304 (2020); Brandon M. Welch et al., *Patient Preferences for Direct-to-Consumer Telemedicine Services: A Nationwide Survey*, 17 BMC HEALTH SERVS. RSCH. 784, 784 (2017) ("Direct-to-consumer (DTC) telemedicine can provide immediate and convenient access to a care provider that usually costs less than a standard in-person urgent care or emergency room visit."); Kurt C. Strange et al., *Defining and Measuring the Patient-Centered Medical Home*, 25 J. GEN. INTERNAL MED. 601, 601 (2010) (explaining the patient-centered home); *see also Direct to Consumer (DTC) Telemedicine,* NAT'L TELEHEALTH TECH. ASSESSMENT CTR., https://telehealthtechnology.org/wp-content/uploads/2020/09/Direct-to-Consumer-DTC-Telemedicine.pdf (last visited Nov. 30, 2022) ("Assignment of a provider is similar to the UBER or Lyft model.").

[61]*See* Bollmeier et al., *supra* note 62, at 309 (noting that the DTC telehealth model was initially intended to treat minor conditions like hair loss).

the treatment of more chronic conditions, like ADHD, it is crucial to modify current regulations to monitor these companies that are offering a condensed version of healthcare.[62]

There are many companies that prescribe medication remotely;[63] but the two leading companies for ADHD treatment are Done Global, Inc. ("Done") and Cerebral, Inc. ("Cerebral").[64] Done and Cerebral attract, accept, and treat patients through a straightforward procedure: (1) social media advertisements, (2) short online questionnaire, (3) virtual visit, and (4) prescription.[65] Both Done and Cerebral have utilized social media platforms like Instagram and TikTok to lure potential patients to their services with targeted advertisements.[66] Connecting with the provider platform is as simple as swiping up on an advertisement or typing the company's name into a search engine.

After patients enter the company's website, they are prompted to take a brief questionnaire regarding their symptoms and schedule a live virtual visit with one of the company's providers.[67] In these short appointments—typically, thirty minutes—the provider may diagnose the patient and determine a treatment plan.[68] The provider then sends a prescription to the patient's pharmacy.[69] These companies offer continued ADHD treatment in the form of a subscription service that charges the user a monthly fee until it is canceled.[70] While patients continue their subscription, they can typically access 24/7 support, visits with their clinician as needed, and receive monthly prescriptions for their medication.[71]

Dr. Judith Joseph, a board-certified psychiatrist, worked with two patients to understand how online ADHD treatment works.[72] One patient, Emily, had been diagnosed with ADHD for years, and the other patient, Madeline, has not been diagnosed with ADHD and does not have the condition. Emily and Madeline both took the two-and-a-half minute questionnaire on Done answering truthfully.[73] Both patients were prompted to schedule a telemedicine evaluation with a clinician after their questionnaire.[74] Emily met with a nurse practitioner who reviewed her

---

[62] *Id.*

[63] *See, e.g., Birth Control Online*, NURX, https://www.nurx.com/birthcontrol (last visited Nov. 21, 2022) (prescribing various birth control methods online); *Diagnosis and Treatment From the Migraine Experts*, COVE, https://www.withcove.com/ (last visited Nov. 21, 2022) (prescribing medication for migraines online); *Depression & Anxiety Medication*, FORHERS, https://www.forhers.com/psychiatry (last visited Nov. 21, 2022) (prescribing medication for depression and anxiety online).

[64] *See* DONE FIRST, *supra* note 12; CEREBRAL, *supra* note 12; *see also* Anni Layne Rodgers, *The Tattered Promise of ADHD Telehealth*, ADDITUDE (July 14, 2022), https://www.additudemag.com/cerebral-adhd-telehealth-diagnosis-medication-report/.

[65]. *See* Bollmeier et al., *supra* note 62, at 306; DONE FIRST, *supra* note 12; CEREBRAL, *supra* note 12.

[66]. *See* Kieran Press-Reynolds, *TikTok is Running 'Predatory' Advertisements From Companies That Oversimplify ADHD, Watchdog Group Says*, INSIDER (Feb. 9, 2022, 11:59 AM), https://www.insider.com/tiktok-adhd-ads-predatory-cerebral-done-attention-deficit-hyperactivity-disorder-2022-2.

[67] *See* Bollmeier et al., *supra* note 62, at 305 ("What patients have to complete online to get a prescription varies by site . . . . Typical steps include completing an online questionnaire (to rule out any contraindications) followed by a live virtual visit with a provider (physician, nurse practitioner, or physician assistant.").

[68] Done First, for example, states that the appointments will only be thirty minutes. *See, e.g.,* DONE FIRST, *supra* note 12. While thirty minutes might be sufficient for someone with a diagnosed condition looking for medication management, it isn't sufficient for the many patients who have never previously sought treatment for ADHD. *See* discussion *infra* Part III.A.

[69] *See* Bollmeier et al., *supra* note 62, at 305.

[70] *See* Bollmeier et al., *supra* note 62, at 307. Many of these services take limited forms of insurance. *See* Bitzer, *supra* note 64, at 191. However, they promote themselves as a great option for people who cannot afford insurance.

[71] DONE FIRST, *supra* note 12; CEREBRAL, *supra* note 12.

[72] *See* Sarah Messer & Haley Yamada, *Concerns Grow Over Online ADHD Diagnoses*, GMA (Nov. 29, 2022), https://www.goodmorningamerica.com/wellness/story/concerns-grow-online-adhd-diagnoses-93524226.

[73] *Id.*

[74] *Id.*

prescription history and offered to renew her same prescription.[75] Thereafter, Madeline met with the same clinician and "mention[ed] having some recent stressors that have occasionally affected her concentration."[76] After additional questions, the clinician offered Madeline "a choice from eight medications, including five stimulants and three non-stimulants."[77] The 'symptoms' Madeline described were not sufficient to constitute an ADHD diagnosis.[78] However, both Emily and Madeline were able to obtain medication as part of their *treatment,* as long as they continue paying their subscription.[79]

B. EXPLOITING REGULATION GAPS

Done's and Cerebral's models emphasize convenience, accessibility, and low cost, which make these telemedicine providers a very attractive option for many patients.[80] However, the design and implementation of such telemedicine models highlight significant flaws in the treatment of ADHD. This speedy version of healthcare blurs the line between offering healthcare to patients and selling controlled substances to customers.[81] DTC telemedicine circumvents regulation by exploiting the demand for telehealth services, the relaxed restrictions that have persisted since the onset of the pandemic in 2020, and the outdated guidelines on advertisements for medical services.[82] Together, this exposes two interconnected flaws with the DTC telemedicine model for ADHD treatment: overprescribing of addictive stimulants and predatory advertisements that mislead patients.

i. Unregulated DTC Business Model

The DTC business model that Done and Cerebral utilize fall in a regulatory gray area for a few reasons. First they hold themselves out as being an intermediary communication platform that is connecting patients with independent providers.[83] The companies claim that they are not

---

[75]*Id.*
[76]*Id.*
[77]*Id.*
[78]*Id.*
[79]*Id.*
[80]*See* Bollmeier et al., *supra* note 62, at 306 ("DTC telemedicine visits offer significant advantages to patients seeking care, including: improved access, efficiency, and convenience."); *See* Bitzer, *supra* note 60, at 191 ("These sites appeal to the modern consumer because they are convenient, discreet, and efficient.").
[81]*See* Polly Mosendz & Caleb Melby, *ADHD Drugs Are Convenient To Get Online. Maybe Too Convenient*, BLOOMBERG(Mar.11,2022,5:00AM), https://www.bloomberg.com/news/features/2022-03-11/cerebral-app-over-prescribed-adhd-meds-ex-employees-say ("Search 'buy Adderall' in Google, and the first hit might be a Cerebral ad promising 'ADHD Meds Prescribed Online Treat ADHD Fast & Affordably.'"); *see also* Chetna Desai, *Online Pharmacies: A Boon or Bane*, 48 INDIAN J. PHARMACOLOGY 615, 615 (2016) ("An online pharmacy is an internet-based vendor that sells medicines and includes both legitimate and illegitimate pharmacies.").
[82] Timothy Callaghan et al., The Changing Nature of Telehealth Use by Primary Care Physicians in the United States, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9274427/
[83] *See, e.g.*, *Terms and Conditions*, DONE, https://donehealth.notion.site/donehealth/Terms-and-Conditions-d4698dc31794415cafe5b7498d47bf92 (last visited June 3, 2023) ("Done does not engage in the practice of medicine or mental health care. The Medical Groups and the physicians and other licensed health professionals are solely responsible for the delivery of healthcare services to patients through Done's Service."); *Terms and Conditions*, CEREBRAL, https://cerebral.com/terms-and-conditions#0 (last visited June 3, 2023) ("Cerebral does not provide medical services, including via the Platform. Cerebral operates the technology platform through which you can connect with Providers who render Telehealth Services and receive other available Services. The Providers matched through the Platform are engaged by the Medical Groups, not by Cerebral, and use independent professional judgment in rendering Telehealth Services. Cerebral provides administrative, payment, technological and other

providing medical services and their subscribers are not entering into a provider-patient relationship with the company itself.[84] Further, they claim that they do not control the providers that they are connecting their patients to.[85] This model helps prevent DTC telehealth companies from being engaged in the corporate practice of medicine, which is prohibited in most states.[86] The corporate practice of medicine doctrine "prohibits or limits the ability of corporations to offer or control healthcare services unless the entity is solely comprised of physicians licensed by the state."[87] By maintaining that they are independent from their providers, this helps these companies to deny liability for the provider's actions.

Second, by claiming that they are third-party intermediaries, these companies are not required to comply with federal drug marketing rules.[88] These rules apply to "drug manufacturers, drug distributors, packers, and their representatives", and telehealth companies do not fit within that definition.[89] As such, the FDA cannot regulate advertisements that the companies put out.[90]

ii. *Overprescribing Stimulant Drugs*

The most common medication treatment for ADHD are 'stimulants,'[91] which are a Schedule II controlled substance.[92] The prescribing of stimulant drugs has been increasing for the past twenty years.[93] However, prescriptions soared during the pandemic, increasing sixteen percent between 2019 and 2021.[94] The high demand has contributed to an Adderall shortage across

---

supportive non-clinical services for the Medical Groups and Providers, but Cerebral does not own or have any ownership interest in the Medical Groups and the Medical Groups do not own or have any ownership interest in Cerebral. The Medical Groups and the Providers, and not Cerebral, are responsible for the quality and appropriateness of the care they render to you on the Platform, and any professional advice received from a Provider on our Platform comes from the Provider alone and not from Cerebral.").

[84] *See* CEREBRAL, *supra* note 85 ("By accepting these Terms of Use, you acknowledge and agree that Cerebral is not a health care provider and that by using the Services, you are not entering into a doctor-patient or other health care provider-patient relationship with Cerebral.").

[85] *See id.* ("Cerebral does not participate in the interaction between you and Providers and does not have control over the quality, reliability, legality, integrity, authenticity, accuracy, appropriateness, provision, or failure to provide, or responsiveness of the information provided by or to Providers.").

[86] *See* AM. MED. ASS'N, ISSUE BRIEF: CORPORATE PRACTICE OF MEDICINE 1 (2015), file:///Users/kaitlincampanini/Downloads/corporate-practice-of-medicine-issue-brief_1.pdf.

[87] *See* Kathrine Marous, *The Corporate Practice of Medicine Doctrine: An Anchor Holding America Back in the Modern and Evolving Healthcare Marketplace*, 70 DEPAUL L. REV. 157, 158 (2022).

[88] *See* Carly Small et al, *The Regulatory Outlook for Telehealth Advertising and Promotion*, REGUL. FOCUS 4 (December 22, 2021), https://www.raps.org/RAPS/media/news-images/Feature%20PDF%20Files/21-12_Gashi.pdf.

[89] *See id.*

[90] *See id.*

[91] *See Attention-Deficit/Hyperactivity Disorder (ADHD) Treatment,* CDC, https://www.cdc.gov/ncbddd/adhd/treatment.html (last visited Nov. 30, 2022) ("Stimulants are the best-known and most widely used ADHD medications."); Leslie Briars & Timothy Todd, *A Review of Pharmacological Management of Attention-Deficit/Hyperactivity Disorder*, 21 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 192, 193 (2016) ("Psychostimulants have been the medications of choice for treating ADHD for more than 60 years. About 75% to 80% of children with ADHD will benefit from the use of psychostimulants. Methylphenidate, dexmethylphenidate, dextroamphetamine, lisdexamfetamine, and the mixed amphetamine salts (dextro- and levo-amphetamine) constitute the psychostimulants currently on the market.").

[92] *See* Nazila Sharbaf Shoar et al., *Dextroamphetamine-Amphetamine*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK507808/ (last updated May 29, 2022) (noting the high potential for abuse of stimulant drugs).

[93] *See* Brian J. Piper, *Tends in Use of Prescription Stimulants in the United States and Territories, 2006 to 2016*, 13 PLOS ONE 1, 2 (noting that the use of stimulants to treat ADHD in the United States doubled between 2006 to 2016).

[94] *See* Caleb Melby et al, *Under Scrutiny, Some Telehealth Firms Are Rethinking ADHD Drugs*, BLOOMBERG (May 5, 2022, 6:00 AM), https://www.bloomberg.com/news/features/2022-05-05/telehealth-companies-rethink-booming-adhd-drugs-after-scrutiny#xj4y7vzkg.

the country,[95] which is leaving many individuals without their medications.[96] The shortage is reminding many of the beginning of the opioid epidemic, and experts are urging the government to take action before we have another crisis on our hands.[97] Done's and Cerebral's prescribing practices have contributed to this demand by overprescribing stimulants to their subscribing patients.[98]

The cause of the overprescribing is tied into how these DTC telemedicine companies operate. Done and Cerebral offer solution-oriented healthcare services.[99] They screen out patients who cannot take the medications they offer, rather than investigating the best possible treatment for that patient's particular medical needs.[100] Thus, services may prescribe medications to patients that are contraindicated based on the patients' reported health concerns. For example, one patient was prescribed Adderall—a stimulant—despite telling the nurse practitioner that she had high blood pressure.[101] The patient's blood pressure spiked, and her primary care physician needed to manage it and switched her prescription to a non-stimulant.[102]

Additionally, doctors familiar with these telemedicine models consider the appointments and evaluations to be insufficient to obtain a complete medical history and evaluate a patient for a complicated condition such as ADHD.[103] Finally, these companies have a financial interest in their patients who are paying a monthly fee to access their services, which makes these companies

---

[95] *See FDA Announces Shortage of Adderall,* FDA, https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall (last visited Nov. 30, 2022). The cause of the Adderall shortage has several layers: "A heavily regulated supply chain, a rise in demand for Adderall and continued labor shortages brought on by the pandemic."; *See* Teddy Amenabar, *Doctors Share Advice on Dealing With the Adderall Shortage*, WASH. POST (Oct. 21, 2022, 11:52 AM), https://www.washingtonpost.com/wellness/2022/10/21/adderall-shortage-adhd-alternatives/.

[96] AMENBAR *supra* note 92.

[97] Leo Beletsky, *Op-Ed: Don't Let Adderall Scarcity Trigger a Repeat of the Opioid Epidemic*, L.A. TIMES (Nov. 14, 2022, 4:30 AM), https://www.latimes.com/opinion/story/2022-11-14/adderall-shortage-supply-methamphetamine-addiction-crisis ("For those losing adequate access to prescription amphetamine, illicit alternatives — especially methamphetamine — are readily available."); Kate Knibbs, *America's Adderall Shortage Could Kill People*, WIRED (Oct. 26, 2022, 7:00 AM), https://www.wired.com/story/adderall-shortage-problems/.

[98] Dani Blum, *The Hazards of Prescribing A.D.H.D. Drugs Online,* N.Y. TIMES (May 13, 2022), https://www.nytimes.com/2022/05/13/well/mind/cerebral-adhd-medication-tiktok.html. (Further, the rise in demand is correlated to the "rise of telehealth psychiatric services [like Done and Cerebral, which] has made it easier for patients to access Adderall and other amphetamines used to treat ADHD"); *see* Fenit Nirappil, *Adderall Shortage is so Bad Some People Can't Fill Their Prescriptions*, WASH. POST (Oct. 20, 2022, 6:00), *https://www.washingtonpost.com/health/2022/10/20/adderall-shortage-adhd/.*

[99] Bollmeier et al., *supra* note 62, at 307; *See* Tara Jain et al., *Prescriptions on Demand: The Growth of Direct-to-Consumer Telemedicine Companies*, 322 J. AM. MED. ASS'N 925, 925 (2019).

[100] Bollmeier et al., *supra* note 62, at 306 ("For example, a patient may meet criteria for prescription of oral contraception, but might not learn about the availability of potentially more appropriate or effective contraceptive solutions such as an intrauterine device"); *see also* Jessica Booth, *Done ADHD Review*, FORBES HEALTH (Oct. 11, 2022, 3:28 PM), https://www.forbes.com/health/mind/done-adhd-review/ ("If you already believe you have ADHD, it is a simple website to go to where the hope is to affirm that this is in fact your diagnosis. People come to Done because they believe they have ADHD, and they are going to be motivated to respond to these questions in a way that affirms that they do have ADHD. When not provided in the context of a whole evaluation, these questions feel leading and meaningless.").

[101] Anni Layne Rodgers, *The Tattered Promise of ADHD Telehealth*, ADDITUDE (Dec. 13, 2022), https://www.additudemag.com/cerebral-adhd-telehealth-diagnosis-medication-report/ (Stimulants are known to increase blood pressure and users need to regularly get their blood pressure checked). *See* Jennifer L. Cluett et al., *A Novel Protocol to Assess the Impact of Prescription Stimulants on Blood Pressure in Adults Using Ambulatory Blood Pressure Monitoring*, 23 J. CLINICAL HYPERTENSION 1264, 1264 (2021).

[102] Rodgers, *supra* note 89.

[103] Bollmeier et al., *supra* note 62, at 304; Varun Ranpariya et al., *Direct-to-Consumer Teledermatology Growth: A Review and Outlook for the Future*, 109 CUTIS 211, 215 (2022) ("Direct-to-consumer care models also seemingly redefine the physician-patient relationship by turning patients into consumers. Patient interactions may seem transactional and streamlined toward sales. For these platforms, a visit often is set up as an evaluation of a patient's suitability for a prescription, not necessarily for the best treatment modality for the problem."). *See also* Booth, *supra* note 93 ("ADHD is not a simple diagnosis…. [A]n ADHD diagnosis requires more than one evaluation, and that the diagnosis should take place over time. It should ideally require a nuanced evaluation by an experienced professional over time.").

more inclined to encourage the prescribing of addictive medications that will increase customer retention.[104]

The questionable prescribing practices of Done and Cerebral have been exposed by consumers and past employees. Current and past patients are sharing their experiences with these companies on social media, and many have highlighted how easy it is to get a prescription.[105] One patient of Done—a mother of two—was prescribed Adderall after only a thirty minute evaluation.[106] She described the evaluation as "impersonal" and reported that her "diagnosis was based on an online survey."[107] Another patient who was diagnosed with ADHD, depression, and anxiety by a Cerebral clinician described the experience as "seem[ing] like a pill shop" and that she "could have come in and said any symptoms and they would have given me drugs."[108] Dr. Joseph, whose experience was discussed above, followed up by having a third patient, Jamie, set up an online appointment with Done.[109] Jamie does not have ADHD and told the Done nurse practitioner that she did not have a problem concentrating, which is a very prevalent symptom of ADHD.[110] The provider told Jamie that "she did not meet criteria for any diagnosis", but would "prescribe her medications if she wanted" them.[111] The provider then asked Jamie whether she wanted him to diagnose her, so she could get a prescription.[112]

Providers on both platforms have also reported feeling pressured to prescribe stimulant drugs.[113] The pressure to prescribe is coming from the company employing the providers, as well as the patients who come expecting these prescriptions.[114] One Provider told the Wall Street Journal that "[p]atients clamored for the medication, and [providers] . . . . sometimes struggled to diagnose ADHD during 30-minute video calls."[115] Further, seven former providers for Cerebral told Bloomberg "they worried that Cerebral wasn't merely meeting a demand [for ADHD treatment and stimulants] but was also, by making access so easy, effectively creating it; they described a fear that they were fueling a new addiction crisis."[116] Most notably, Cerebral's ex-Vice President, Matthew Truebe, filed a lawsuit alleging that he was fired after speaking out about

---

[104]*See* Bollmeier et al., *supra* note 62, at 306. In other words, these consumers are coming to the platform seeking ADHD medication, so they will not continue paying for the service, if they aren't prescribed what they are looking for.
[105] *See* Kitty Ruskin, *For Some Women With ADHD, TikTok is the First Place They Felt Heard*, TIME (Sept. 12, 2022, 11:37 AM), https://time.com/6211695/adhd-tiktok-women/; *#ADHD*, INSTAGRAM, https://www.instagram.com/explore/tags/adhd/ (last visited Nov. 30, 2022). #ADHD has 14.5 billion views on TikTok and 3 million posts on Instagram.
[106] Rodgers, *supra* note 94.
[107] *Id.*
[108]*Id.*
[109] Messer & Yamada, *supra* note 73; *see also* supra notes 69–76.
[110] *Id.*
[111] *Id.*
[112] *Id.*
[113]Annie Burkey, *DEA Investigations Telehealth Provider Done for Adderall Prescription Practices: Media Report*, FIERCE HEALTHCARE (Sept. 23, 2022, 3:45 PM), https://www.fiercehealthcare.com/health-tech/dea-investigates-telehealth-provider-done-adderall-prescribing-practices-media-report; Caleb Melby et al., *Under Scrutiny, Some Telehealth Firms Are Rethinking ADHD Drugs*, BLOOMBERG (May 5, 2022, 6:00 AM), https://www.bloomberg.com/news/features/2022-05-05/telehealth-companies-rethink-booming-adhd-drugs-after-scrutiny#xj4y7vzkg.
[114]Mosendz & Melby, *supra* note 110 ("a growth-obsessed startup targeting patients with social media ads and pressuring providers to dispense drugs after too-brief virtual sessions."); Bitzer, *supra* note 64, at 202; Winker & Walker, *supra* note 110.
[115] Rolfe Winkler & Joseph Walker, *Startups Make it Easier to Get ADHD Drugs That Made Some Workers Anxious*, Wall St. J. (Mar. 26, 2022), https://www.wsj.com/articles/startups-make-it-easier-to-get-adhd-drugs-that-made-some-workers-anxious-11648267205?mod=article_inline.
[116] Polly Mosendz & Caleb Melby, *ADHD Drugs Are Convenient to Get Online. Maybe Too Convenient*, BLOOMBERG (Mar. 11, 2022, 5:00 AM), https://www.bloomberg.com/news/features/2022-03-11/cerebral-app-over-prescribed-adhd-meds-ex-employees-say.

Cerebral's unlawful business practices.[117] In the Complaint, Truebe alleges that Cerebral told its providers that their goal is to prescribe stimulants to 100% of their ADHD patients because it increased retention among customers.[118]

Despite the claims made, the DEA has taken no action to regulate the prescribing practices of these companies or online prescribing in general.[119] The DEA has launched an investigation into both Done and Cerebral, but the DEA has yet to file any formal charges.[120] This leaves ADHD telehealth companies free to continue their current practices .[121] In addition to their prescribing practices, these companies have been under scrutiny for their aggressive advertising tactics.

iii. Advertising Medical Services

The most prominent way that companies like Done and Cerebral attract consumers is through advertising on social media platforms.[122] These advertisements appear as users are scrolling on the platform and depict images of people seeking treatment, taking various ADHD medications, and having their symptoms eliminated or lessen.[123] These companies utilize viral trends and memes to increase the effectiveness of the advertisements, target younger audiences, and sell ADHD treatment.[124] Further, these advertisements oversimplify complex ADHD symptoms, mislead consumers into thinking that they have ADHD, and then offer ADHD treatment for it to these audiences.[125]

There are eighteen symptoms of ADHD, and the average person meets at least one or two of those in the criteria.[126] Further, a diagnosis of ADHD requires persistence for at least six months

---

[117]Complaint for Damages, *Truebe v. Cerebral, Inc*, No. CGC-22-599376 (Cal. Super. Ct., April 24, 2022).
[118] *Id.* at 2.
[119] Heather Landi, *Cerebral Under Federal Investigation for Possible Violations of Controlled Substances Law*, FIERCE HEALTHCARE (May 7, 2022, 4:09 AM), https://www.fiercehealthcare.com/health-tech/cerebral-under-federal-investigation-possible-violation-controlled-substances-law (noting that the DEA has made it clear that they are only investigating and have not alleged any violations).
[120]*See* Rolfie Winkler, *DEA Investigating ADHD Telehealth provider Done,* WALL ST. J. (Sept. 16, 2022, 8:04 AM), https://www.wsj.com/articles/dea-investigating-adhd-telehealth-provider-done-11663239601?mod=latest_headlines; Katie Jennings, *Mental Health Startup Cerebral to Stop ADHD Prescriptions For New Patients*, FORBES (May 4, 2022), https://www.forbes.com/sites/katiejennings/2022/05/04/mental-health-startup-cerebral-to-stop-adhd-prescriptions-for-new-patients/?sh=6ed24ae86b7d. Additionally, several pharmacies have unilaterally stopped filling prescriptions sent from providers of these companies. *See* Ike Swetlitz, *ADHD Startups Are Cut Off by Rite Aid, Adding to PharmacyBans*, BLOOMBERG (July 28, 2022), https://www.bloomberg.com/news/articles/2022-07-28/adhd-startups-are-cut-off-by-rite-aid-adding-to-pharmacy-bans.
[121] It is worth noting that Cerebral announced that it would be temporarily suspending the practice of prescribing stimulants to new customers pending investigation into the company's prescribing practices and the lawsuit filed by Matthew Truebe. *See* Jennings, *supra* note 117. As of June of 2023, Cerebral is still not prescribing stimulants. *See Cerebral FAQs*, Cerebral, https://cerebral.com/faqs (last visited June 4, 2023) ("[S]timulants such as Adderall (dextroamphetamine-amphetamine) or Concerta (Methylphenidate) are not offered through Cerebral at this time.").
[122]*See* Theo Wayt, *Startups Push ADHD Meds Through TikTok Ads, Concerning Doctors,* N.Y. Post (Mar. 13, 2022, 1:12 PM); Press-Reynolds, *supra* note 72.
[123] Wayt, *supra* note 119.
[124] *Id.*
[125] Blum, *supra* note 95. The viral advertisements made by these companies do not properly depict the criteria for a diagnosis. *See* Eric W. Dolan, *Misleading Videos About ADHD Are Being Widely Disseminated on TikTok, Study Finds*, PSYPOST (Mar. 10, 2022), https://www.psypost.org/2022/03/misleading-videos-about-adhd-are-being-widely-disseminated-on-tiktok-study-finds-62705 (In a study, "researchers collected the top 100 results for the hashtag "#adhd". . . . The videos were then independently rated by one psychiatrist and one psychiatry resident with clinical experience in the diagnosis and management of ADHD. Twenty-one videos were determined to contain scientifically correct information about any aspect of ADHD, 27 videos described a user's own personal experience with ADHD, and 52 videos included misleading information that lacked scientific evidence.").
[126]*See Attention-Deficit/Hyperactivity Disorder (ADHD): Symptoms and Diagnosis*, *supra* note 122 (describing the symptoms of ADHD); *See* Blum, *supra* note 95 (noting that most people fit a few symptoms in the criteria).

of either five or six symptoms, depending on the patients age.[127] Many of the advertisements circulated by Done and Cerebral emphasize a handful of very generalized ADHD symptoms to encourage viewers to seek treatment directly through the company.[128] According to one past provider on Cerebral, the advertisements will ask things like, "'[h]ave you ever felt overwhelmed?' [or] '[d]o you ever not want to do your homework?,'' which she described as "very basic and universal" things to which people without ADHD can relate.[129] For example, inattentive ADHD, which is more prominent in women, may include symptoms such as not following directions, losing focus, having trouble organizing tasks, being easily distracted, and being forgetful in daily activities.[130] One advertisement by Cerebral characterized these symptoms as "spacey, forgetful, or chatty," which may encourage women to pursue an ADHD diagnosis and medication through the platform.[131]

This method of marketing leads to patients diagnosing themselves with ADHD and seeking treatment with a set view of their diagnosis and what medications are right for them.[132] The patients then have nearly direct access to those medications through Done or Cerebral, which "removes the initial independent judgment of a medical professional" because patients make these appointments for very specific treatment.[133] This ultimately harms the doctor-patient relationship because patients are expecting a diagnosis and treatment that might not be appropriate for their symptoms.[134] This increases the risk that patients will undergo unnecessary, and potentially dangerous, treatment for ADHD.[135] Additionally, patients might fail to undergo needed treatment because patients and providers are overlooking the true cause of their symptoms due to the misinformation advertised.[136]

---

[127]*See Attention-Deficit/HyperactivityDisorder (ADHD): Symptoms and Diagnosis*, CDC, https://www.cdc.gov/ncbddd/adhd/diagnosis.html (last reviewed Aug 9, 2022).

[128] Blum, *supra* note 95; Wayt, *supra* note 119.

[129] Blum, *supra* note 95.

[130] *See Attention-Deficit/Hyperactivity Disorder (ADHD): Symptoms and Diagnosis*, *supra* note 122.

[131] *See* Olivia Little, *TikTok is Enabling Predatory ADHD Advertisers to Target Young Users*, MEDIA MATTERS (Feb. 8, 2022) https://www.mediamatters.org/tiktok/tiktok-enabling-predatory-adhd-advertisers-target-young-users.

[132] Bitzer, *supra* note 64, at 167; *see also The Most Common Symptoms of ADHD,* DONE FIRST, https://www.donefirst.com/adhd/symptoms (last visited Nov. 30, 2022) ("It's important to learn more about your own situation before seeking treatment and Done. offers an online 1-minute assessment test to learn more. That can be a great place to start to then get connected to a medical practitioner to make the official online diagnosis.").

[133] Bitzer, *supra* note 64, at 167. Further, they are vetted by the questionnaire they took to schedule the appointment, so patients are going to the appointment with the understanding they are going to get an ADHD diagnosis and prescription. *See id.*; *see also* Bollmeier et al., *supra* note 62, at 307.

[134] *See* State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 909 (W. Va. 2007) ("[P]hysicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised…. Physicians are under attack for prescribing the pills too often and too readily to inappropriate patients. Physicians argue that it is not their fault; rather, they claim pushy patients, prodded by DTC advertisements, pressed, wheedled, begged and berated them for quick treatments. . . .").

[135] *See* Benedetto Vitiello, *Understanding the Risk of Using Medications for ADHD with Respect to Physical Growth and Cardiovascular Function*, 17 CHILD ADOLESCENT PSYCHIATRIC CLINICS N. AM. 459, 463 (2008) ("Stimulants are sympathomimetic agents that increase noradrenergic and dopaminergic transmission. An effect on heart rate and blood pressure can be considered an intrinsic feature of their pharmacological activity. Hypertension and tachycardia are common in case of overdosing with these compounds."); *See id.* at 464 ("[S]timulants, because of their sympathomimetic activity, may increase the risk for sudden cardiac death at usual therapeutic doses, especially in individuals with predisposing factors . . . . [C]urrent product labeling for methylphenidate and amphetamine preparations informs that sudden deaths have been reported during treatment . . ."); *see also* Briars & Todd, *supra* note 40, at 194 ("In general, the psychostimulants have similar common adverse reactions including decreased appetite, stomach pain, sleep disturbances, and headaches. Less common adverse reactions include labile mood and growth suppression.").

[136]*The Harm of Self-Diagnosis on Social Media*, VIEWPOINT CENTER, https://www.viewpointcenter.com/the-harm-of-self-diagnosis-on-social-media/ (last visited Nov. 30, 2022).

According to one doctor, only 50% of the people that came to her because they saw ADHD content and advertisements on social media actually had ADHD.[137] The dangerous reality is that these advertisements are incentivizing young consumers to take advantage of the ease with which these companies are prescribing stimulants. There is a culture of using Adderall to "focus" during exams or lose weight because it reduces your appetite.[138] This culture views prescription stimulants as "smart pills" or an enhancement instead of an addictive controlled substance.[139] As one expert noted, "students have become convinced that [stimulants] will help them achieve academic success."[140] These advertisements are capitalizing on then enhancement drug culture by marketing these *attractive* side-effects and encouraging people to *get-ahead*. For years, experts have been warning that stimulants are the next opioid epidemic, and ADHD telehealth companies are making that warning a startling reality.[141]

III. WAYS TO ADDRESS THE REGULATORY GAPS THAT ADHD TELEMEDICINE HAS CREATED

Under current regulations, Done, Cerebral, and other telehealth companies can lure patients with aggressive and misleading advertisements to a platform that is overprescribing addictive-controlled substances.[142] Both Done's and Cerebral's prescribing and advertising practices evade regulatory oversight due to outdated laws that weren't prepared for the evolution of DTC telemedicine. To support the continued growth of telehealth, the access to cross-state care, and the protection of patients, the DEA should promulgate a special registration for telemedicine under the Ryan Haight Act to require specific prerequisites for a telehealth visit before a provider can prescribe Schedule II drugs, and DTC telemedicine companies should be subject to similar federal regulations as pharmaceutical companies when they engage in DTC drug advertising.

b. ESTABLISHING A SPECIAL REGISTRATION FOR TELEMEDICINE UNDER THE RYAN HAIGHT ACT

The temporary COVID-19 exception to the Ryan Haight Act has enabled providers to prescribe controlled substances via telehealth without complying with the stringent requirement of

---

[137]Alexis Jones, *TikTok Says I Have ADHD. Should I Believe it?*, POPSUGAR(Apr. 7, 2022), https://www.yahoo.com/lifestyle/tiktok-says-adhd-believe-.

[138]Todd Essig, *Adderall In The Workplace: Why Some Turn To Stimulants For A Career Boost*, FORBES (Oct. 25, 2014), https://www.forbes.com/sites/toddessig/2014/10/25/adderall-in-the-workplace-2-why-some-turn-to-stimulants-for-a-career-boost/?sh=78730b6243ff.

[139]Zachary Friedarichs, Misuse of Prescription Stimulants and Their Effect on Cognition 3 (July 29, 2020) (Graduate Thesis, Augsburg University), https://idun.augsburg.edu/cgi/viewcontent.cgi?article=2036&context=etd; *see also* Andrew Jacobs, *The Adderall Advantage*, N.Y. TIMES (July 15, 2005), https://www.nytimes.com/2005/07/31/education/edlife/the-adderall-advantage.html.

[140]Jacobs, *supra* note 126.

[141] Beletsky, *supra* note 85; *see also* Conor Murray, *Ritalin Drug Shortage Explained: Low Supplies of Adderall and Prescription Startups Fueled Crisis*, FORBES (Jan. 27, 2023), https://www.forbes.com/sites/conormurray/2023/01/27/ritalin-drug-shortage-explained-low-supplies-of-adderall-and-prescription-startups-fueled-crisis/?sh=20db734a421a; Emma Court, *Hidden Fentanyl is Driving a Fatal New Phase in US Opioid Epidemic*, BLOOMBERG (Dec. 13, 2022), https://www.bloomberg.com/graphics/2022-us-fentanyl-opioid-deaths/ (discussing how black-market Adderall is also being laced with Fentanyl).

[142] *See* Press-Reynolds, *supra* note 69; Olivia Little, *TikTok is Still Allowing a Company Accused of Intentionally Overprescribing Stimulants to Advertise on its Platform*, MEDIA MATTERS (May 9, 2022), https://www.mediamatters.org/tiktok/tiktok-still-allowing-company-accused-intentionally-overprescribing-stimulants-advertise-its.

in-person visits.[143] Currently, the exception that allows for telemedicine prescribing is very broad.[144] To maintain the benefits of telemedicine and still protect consumers, the Ryan Haight Act should be amended to establish a special registration for telehealth providers with specific guidelines as it relates to appointment length, release of medical information, and provider training for prescribing controlled substances through telehealth services. As discussed above, the Ryan Haight Act authorized the DEA to establish a special registration for telemedicine "with the goal of increasing patients' access to practitioners that can prescribe controlled substances via telemedicine. . . ."[145] The DEA has failed to finalize a special registration despite having the authority to do so for nearly 14 years.[146] Establishing clear requirements and diagnostic procedures for Done's and Cerebral's providers will help curb the overprescribing of stimulant drugs. These guidelines should follow current drug schedules and each drug's approved uses to determine what must be required of a virtual appointment for a provider to qualify for a special registration and be authorized to prescribe a particular drug. This will ensure that providers comply with recognized treatment standards.

As these proposed guidelines pertain to stimulants, they are Schedule II controlled substances and are approved for the treatment of ADHD and, less commonly, narcolepsy.[147] Schedule II controlled substances have a high potential for abuse, so caution should be taken to ensure that they are only being prescribed to a patient with a legitimate diagnosis.[148] Thus, the special registration should be tied to compliance with prescribing guidelines and diagnostic criteria according to the latest edition of the American Psychiatric Association's Diagnostic and Statistical Manual. This will require adherence to prescribing guidelines for telemedicine providers.

i. Appointment Length

Both Done and Cerebral emphasize speed and efficiency in their treatment plans, with appointments lasting about thirty minutes.[149] While quick treatment might be a selling point for patient-consumers, it does not allow for an adequate ADHD diagnosis or follow-up care for new patients because it lacks the hallmark of a patient-provider relationship.[150] In a non-telehealth context, an assessment for ADHD typically takes between one to three hours and involves

---

[143] *See Covid-19 Information Page*, *supra* note 36; 42 C.F.R. § 410.78(i)(4) (2009); 42 U.S.C.A. § 247(d) (West 2019).

[144] As stated *Supra* Part I.A, the exception to the Ryan Haight Act only requires: "[t]he prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice; The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and The practitioner is acting in accordance with applicable Federal and State laws." *Covid-19 Information Page*, *supra* note 36.

[145] *See* VICTORIA L. ELLIOT, CONG. RSCH. SERV. R45240, THE SPECIAL REGISTRATION FOR TELEMEDICINE IN BRIEF 1 (2018).

[146] Warner, *supra* note 40.

[147] Shoar et al., *supra* note 89 (noting that the FDA approved uses of amphetamine medication).

[148] *See generally* Wendy Klein-Swhwartz, *Abuse and Toxicity of Methylphenidate*, 14 CURRENT OP. PEDIATRICS 219 (2002) (discussing the potential side effects and abuse from stimulant medications as their use is increasing).

[149] DONE FIRST, *supra* note 12; CEREBRAL, *supra* note 12.

[150] Bollmeier et al., *supra* note 62, at 303 ("There is little or no patient-provider relationship or coordination with the patient's primary medical doctor."); Booth, *supra* note 93 (noting that experts do not believe that thirty minutes is sufficient to diagnose ADHD); *see also Q&A: ADHD Expert Offers Clinical Guidance on Prescribing Stimulants*, HEALIO NEWS (July 23, 2018), https://www.healio.com/news/psychiatry/20180720/qa-adhd-expert-offers-clinical-guidance-on-prescribing-stimulants ("Diagnosing, and subsequently treating, adult ADHD requires a multifaceted approach that includes a thorough evaluation, consideration of cooccurring conditions, patient education and weighing of risks and benefits of treatment with stimulants on a case-by-case basis.").

obtaining a comprehensive history of the patient's experience with their symptoms.[151] There must be sufficient time for a provider to establish that there is "clear evidence of [a] clinically significant impairment in social, academic, or occupational functioning" to meet the diagnostic criteria.[152] The initial visits should be longer than thirty minutes to ensure that a proper diagnosis was made because "ADHD is not a simple diagnosis."[153] Further, greater care should be taken for a condition where controlled substances are the first line of defense for treatment.[154] Thereafter, shorter visits may be appropriate for follow-up appointments and medication management.[155] Requiring lengthier visits in order to receive the special registration is one step that can be taken to minimize the risk that a provider is overprescribing because it will allow for a more comprehensive evaluation of a patient's history and symptoms prior to making a diagnosis.

ii. Releasing Medical Information to Providers

In addition to lengthier appointments, telemedicine providers should be required, as part of the special registration, to obtain a signed release of medical information from the patient prior to their appointment to prescribe controlled substances. When patients utilize multiple providers for specific treatment, there is a lack of coordination between providers, and, often, a lack of a complete medical history including medications.[156] This is particularly true for the DTC model because there is no preexisting physician-patient relationship, and the providers only treat within the parameters of the platform.[157] Without the patients' medical records, the provider's diagnosis and treatment is inappropriately limited to the scope of the virtual visit.[158] ADHD is a chronic condition, so an appropriate diagnosis requires a comprehensive understanding of a patient's medical history.[159] This is even more pertinent when diagnosing ADHD in adults because the

---

[151] *See Getting an NHS ADHD Diagnosis*, ADHD AWARE, https://adhdaware.org.uk/what-is-adhd/getting-nhs-diagnosis/#:~:text=The%20assessment%20is%20with%20a,day%20to%20day%20life%20now (last visited Nov. 30, 2022) ("The assessment is looking at the core symptoms of ADHD and matching your life experience and anecdotes of behaviors with the checklist of symptoms for ADHD.").

[152] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DSM-5 CHANGES: IMPLICATIONS FOR CHILD SERIOUS EMOTIONAL DISTURBANCE 19 (2016).

[153] Booth, *supra* note 93.

[154] Shoar et al., *supra* note 89 (noting that stimulants are the most prescribed treatment for ADHD).

[155] .*See* Mario Cruz et al., Appointment Length, *Psychiatrists' Communication Behaviors, and Medication Management Appointment Adherence*, 64 PSYCHIATRIC SERVS. 886, 886 ("Medication management appointments last between 15 and 20 minutes, and patients in ongoing care are seen every one to three months."); Sue Romanick-Scmiedl & Ganesh Raghu, *Telemedicine — Maintaining Quality During Times of Transition*, 6 NATURE REVS.: DISEASE PRIMERS (2020) ("Many conditions, including . . . attention deficit/hyperactivity disorder, require monitoring that could be achieved using telemedicine, provided that the patient has been stable based on prior documentation and individual clinic protocol.").

[156] Bollmeier et al, *supra* note 62, at 303.

[157] Bitzer, *supra* note 64, at 202 (DTC providers "effectively operate on 'islands of care' within the parameters of the companies"); *see also* Hoffman, *supra* note 22, at 250 (noting that insufficient medical information of a telehealth provider can lead to overprescribing).

[158] Bitzer, *supra* note 64, at 202 ("[DTC providers] are limited in terms of the scope of advice that they may offer and in their ability to follow up with patients' progress.")

[159] *See Attention-deficit/hyperactivity disorder (ADHD)*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/adult-adhd/symptoms-causes/syc-20350878 (last visited Nov. 30, 2022). Additionally, ADHD can be misdiagnosed because its presentation often mimics and/or coexists with other disorders such as, depression, anxiety and bipolar disorder. *See* Larry Culpepper & Gregory Mattingly, *Challenges in Identifying and Managing Attention-Deficit/Hyperactivity Disorder in Adults in the Primary Care Setting: A Review of the Literature*, 12 PRIMARY CARE COMPANION J. CLINICAL PSYCHIATRY (2010) ("Diagnosing ADHD in adults can be further complicated by the nonspecific nature of ADHD symptoms, which may overlap with other psychiatric disorders . . . . social phobias . . . (29.3%). . . . bipolar disorder (19.4%), major depressive disorder (18.6%), dysthymia (12.8%), and generalized anxiety disorder (8.0%). To accurately differentiate between ADHD and other psychiatric disorders, clinicians must learn to pay careful attention to the patient's clinical features."); Amy Marschall, *4 Disorders That Can Be*

symptoms must have been present since childhood.[160] Further, a patient's medical records might indicate that certain ADHD treatment would not be suitable for them or that there is another diagnosis that more accurately encompasses the patient's symptoms.[161] Increasing a provider's access to medical information will give the provider more knowledge of the patient before diagnosis and treatment, which may prevent misdiagnosis and overprescribing through telehealth.[162]

iii. Telehealth Provider Training

Finally, the special registration for telemedicine should require training for providers using telehealth to prescribe controlled substances. Providers should be properly trained to diagnose ADHD and treat patients through telehealth before they can engage in online prescribing. One critique of the providers on Done, for example, is that they only need to have one year of experience treating patients with ADHD.[163] This is surprising given that the platform specializes in ADHD treatment;[164] and, as mentioned above, diagnosis is complex because ADHD symptoms often overlap with other conditions.[165] As telehealth continues to grow, requiring specific training geared toward virtual telehealth care will equip providers with the skills necessary to effectively diagnose and treat patients with ADHD, which will reduce the risk of overprescribing.[166]

Experts agree that telehealth is a very effective platform for behavioral healthcare.[167] Despite its effectiveness, it is crucial that the quality of healthcare is not being pushed aside for speed and efficiency. Amending the Ryan Haight Act to include a special registration for telemedicine with specific prescribing guidelines will ensure that companies, like Done and Cerebral, are properly screening and diagnosing patients before they prescribe addictive drugs.[168]

c. SUBJECTING DTC TELEMEDICINE ADVERTISEMENTS TO FDA OVERSIGHT

Done and Cerebral's advertisements are similar to the marketing model of pharmaceutical companies when such companies engage in DTC advertising for prescription drugs.[169] The goal

---

Misdiagnosed ADHD, VERY WELL MIND (Mar. 29, 2022), https://www.verywellmind.com/4-disorders-that-can-be-misdiagnosed-adhd-5221708.

[160] Culpepper & Mattingly, *supra* note 151 ("The diagnosis and evaluation of ADHD in adults is based on clinical assessment, which should include a review of medical history, family history, relationship history, and interviews with a family member when possible.").

[161] For example, a history of addiction might lead a provider to try other medications for ADHD treatment prior to prescribing stimulants due to their potential for abuse. *See generally* Edmund S. Higgins, *ADHD and Substance Abuse: 4 Therapeutic Options for Patients With Addictions*, 11 CURRENT PSYCHIATRY 58, (2002) (discussing treatment options for ADHD patients with a history of substance abuse).

[162] Hoffman, *supra* note 22, at 250.

[163] Booth, *supra* note 93.

[164] *Id.*; *see also* DONE FIRST, *supra* note 12.

[165] Culpepper & Mattingly, *supra* note 151; *Attention-deficit/hyperactivity disorder (ADHD)*, *supra* note 151.

[166] *See* Allison N. Winnike & Bobby Joe Dale III, *Rewiring Mental Health: Legal and Regulatory Solutions for the Effective Implementation of Telepsychiatry and Telemental Health Care*, 17 HOUS. J. HEALTH L. & POL'Y 21, 97 (2017).

[167] *See* Tanya Albert Henry, *Telehealth, In-Person Diagnoses match Up Nearly 90% of the Time*, AM. MED. ASS'N (Oct. 10, 2022), https://www.ama-assn.org/practice-management/digital/telehealth-person-diagnoses-match-nearly-90-time (noting that telehealth diagnoses for behavioral health match in-person diagnoses at a very high rate).

[168] Jain et al., *supra* note 92, at 926 ("Whether these companies provide equivalent care to a traditional in-person visit remains uncertain. Instead of the focus on a singular problem in a DTC telemedicine visit, the traditional primary care visit is often more comprehensive in addressing issues such as preventive services and treatment for chronic illnesses. Moreover, it remains unclear whether companies effectively screen for all possible contraindications with their questionnaire or whether they accurately select conditions amenable to treatment without an in-person physical examination or diagnostic testing.").

[169] Bitzer, *supra* note 64, at 178.

of marketing for both the telemedicine companies and the pharmaceutical companies is to encourage the consumer to seek the advertised treatment.[170] However, Done and Cerebral currently evade the advertising regulations that pharmaceutical companies are subject to because they are not pharmaceutical companies, and they are technically marketing only medical services.[171] To address this regulatory gray area, the advertisements made by these companies should be subject to the FDA's oversight under the Federal Food, Drug, and Cosmetic Act ("FDCA").

The FDA has unique oversight under the FDCA to regulate the marketing of prescription drugs by manufacturers and drug distributors[172] when they engage in DTC drug advertising.[173] Under the FDCA, the FDA requires that prescription drug advertisements (1) be truthful, (2) present a fair balance of the risks and benefits associated with the medications, and (3) state an approved use of the medication.[174] The fair balance standard allows consumers to make an informed decision without being misled into thinking that an advertised medication has overwhelming benefits in relation to risks.[175] However, if the advertisement does not mention a particular drug or treatment, it currently eludes the FDA's oversight.[176] Thus, Done and Cerebral's advertisements are not currently subject to the FDA's oversight because (1) they are not manufacturers or distributors of prescription drugs,[177] and (2) the advertisements do not mention specific drug names.[178]

---

[170]*Id.* at 172 ("The concept of DTC marketing is geared towards selling a product . . . ."); *see also* State *ex rel*. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 909 (W. Va. 2007) ("Advertisements are created to sell products and thus are inadequate sources of information and poor substitutes for medical advice.").

[171]Bitzer, *supra* note 64, at 178–83 (discussing the similarities between DTC drug advertising and DTC telemedicine advertising, but the lack of regulation for the latter).

[172]*See* Carly Small et al, *The Regulatory Outlook for Telehealth Advertising and Promotion*, REGUL. FOCUS 4 (December 22, 2021), ttps://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=205.3 ("A 'manufacturer' is anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug. 'Wholesale distributor' refers to anyone who is engaged in wholesale distribution of prescription drugs." (footnotes omitted)).

[173]*See* 21 U.S.C.A § 301; 21 C.F.R. § 202.1 (West 2008); Carly Small et al, *supra* note 168, at 4. These advertisements are subject to this special scrutiny because of their potentially negative impact on the patient-provider relationship. *See State ex rel. Johnson & Johnson Corp*., 647 S.E.2d at 909 ("[P]hysicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised . . . . Physicians are under attack for prescribing the pills too often and too readily to inappropriate patients. Physicians argue that it is not their fault; rather, they claim pushy patients, prodded by DTC advertisements, pressed, wheedled, begged and berated them for quick treatments. . . ."); *see also* Larkin v. Pfizer, Inc., 153 S.W.3d 758, 770–71 (Ky. 2004) (Wintersheimer, J., dissenting) ("This Court should take notice of the abundantly obvious fact that the development of direct to consumer pharmaceutical advertising has indelibly changed the realities of physician/patient relationships. Anyone who watches television is regularly bombarded with a variety of pharmaceutical products which suggest that the ultimate consumer ask his physician to prescribe a particular advertised product.").

[174]*See* 21 C.F.R. § 202.1; 21 U.S.C.A. 352 (West 2020).

[175]Bruce Patsner, *Problems Associated With Direct-to-Consumer Advertising (DTCA) of Restricted, Implantable Medical Devices: Should the Current Regulatory Approach Be Changed?*, 64 FOOD & DRUG L.J. 1, 2 (2009) ("There is already good evidence that consumers both lack the level of medical sophistication to understand these advertisements, and that the advertisements themselves do not fairly balance benefit and risk information.").

[176]*See Basics of Drug Ads*, FDA (June 19, 2005), https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads (noting that the FDA does not regulate help-seeking or reminder advertisements because they do not mention a particular drug).

[177] Small et al, *supra* note 165, at 4 ("A 'manufacturer' is anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug. 'Wholesale distributor' refers to anyone who is engaged in wholesale distribution of prescription drugs. In contrast, telehealth companies make certain products and services available to individuals through third-party medical providers, pharmacies, or other venders").

[178]*See* Louise Matsakis, *Instagram and TikTok Pull Ads From Startup Cerebral Linking ADHD to Obesity,* NBC NEWS (Jan. 28, 2022), https://www.nbcnews.com/tech/social-media/instagram-tiktok-cerebral-startup-ads-pulled-rcna13476 ("Startups like Cerebral often act as platforms that connect patients to medical providers and are not subject to the same advertising regulations as drug manufacturers. The Food and Drug Administration does not regulate medical ads that don't recommend or suggest the use of a certain drug.").

> The type of advertisements that Done and Cerebral use are categorized as 'help-seeking advertisements,' which depict a condition and its symptoms without naming a specific drug or treatment.[179] These advertisements, instead, encourage the consumers to talk to their provider about treatment options.[180] Combining help-seeking advertisements with DTC telemedicine enables Done and Cerebral to lure patients to their website where medical providers "can conveniently diagnose and deliver prescriptions straight to [them]."[181]

If Done's and Cerebral's advertisements were subject to the same oversight as DTC drug advertisements, the advertisements likely would not comply with the FDA's requirements because the advertisements are often misleading and do not present a fair balance of the benefits and risks of ADHD treatment.[182] Specifically, the advertisements' general depiction of ADHD symptoms inaccurately characterizes the individuals who would benefit from medication.[183] Further, the advertisements make broad promises as to how ADHD medication will improve the patient's daily life. This includes having better focus,[184] better time management,[185] less anxiety,[186] and better eating habits.[187] These empty promises do not acknowledge that everyone has a different experience with treatment, and it often takes time to find the proper treatment for a patient.[188] Finally, the advertisements do not mention any risks associated with ADHD medications or the approved diagnostic criteria.[189] Emphasizing only the vague benefits associated with ADHD medication markets it to consumers only as a potential enhancement instead of also being a potentially dangerous controlled substance. These flaws raise the same concerns that triggered the FDA's regulations over DTC drug advertising.

---

[179] *See* Andrew Andrzejewski, *Direct-to-Consumer Calls to Action: Lowering the Volume of Claims and Disclosures in Prescription Drug Broadcast Advertisements*, 84 BROOK. L. REV. 571, 580–81 (2019); Brandon K. So & Peggy Y. Kim, *Understanding Prescription Drug Advertising*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK574520/ ("Help-seeking advertisements describe a constellation of symptoms and encourage the public to seek advice or help from their physicians."); Crystal Richardson, *Chasing Technology: A Call for FDA Regulation of Pharmaceutical Internet Marketing*, 8 J. HEALTH & BIOMEDICAL L. 249, 281 (2012); *see also Incorrect Help-Seeking Ad*, FDA, https://www.fda.gov/drugs/prescription-drug-advertising/incorrect-help-seeking-ad (last visited Nov. 30, 2022) (depicting an incorrect help-seeking ad).

[180] Andrejewski, *supra* note 171, at 580–81.

[181] *See* Brittany Soultanian Parker, *An FDA Free Zone: Pharmaceutical Companies and the Use of Help-Seeking Advertisements on Social Media Platforms* 6 (Aug. 26, 2021) (M.P.A. thesis California State University Northridge), https://scholarworks.calstate.edu/downloads/12579z531?locale=en.

[182] Small et al, *supra* note 164, at 4–5 (noting the regulatory gap); *See* 21 C.F.R. § 202.1 (West 2008) (requiring a fair balance of the benefits and risks).

[183] Blum, *supra* note 91.

[184] Wayt, *supra* note 115.

[185] *Id.*

[186] *Id.*

[187] *See* Katie Jennings, *Instagram Pulls Ads by Mental Health Startup for Violating its Rules,* FORBES (Jan 21, 2022, 5:46 PM), https://www.forbes.com/sites/katiejennings/2022/01/21/instagram-says-mental-health-startup-cerebral-violated-its-rules-with-adhd-ads-showing-disordered-eating/?sh=6648db5b7c6c ("[The ad] shows a young woman sitting on a bed eating a toaster pastry. It then cuts to her eating a donut surrounded by popcorn, chips, donuts and other foods with the message: 'Those who live by impulse, eat by impulse.' The ad goes on to suggest that obesity is five times more common among adults with ADHD, but that mental health startup Cerebral can provide 'the tools and proper medication to change impulsive habits.' The ad then cuts to the same woman smiling and eating a salad.").

[188] *See* Camille Noe Pagán, *When Your ADHD Meds Stop Working,* WEBMD (Mar. 18, 2021), https://www.webmd.com/add-adhd/adhd-meds-stop-working ("As many as 1 in 10 people don't get results from either of the two main types of stimulants prescribed for ADHD because they don't work with their body chemistry.").

[189] Little, *supra* note 128 ("There are medical risks to incorrectly taking prescribed ADHD medication, including addiction and overdose. TikTok is not only allowing medical companies to misleadingly advertise ADHD treatment plans to young users, but also profiting from it.").

The laws regarding DTC drug advertising were prompted, in part, by the practice of self-diagnosis/self-medication by consumers, and the false therapeutic claims made by drug manufacturers.[190] The concern was that these advertisements "hurt the doctor-patient relationship [and] confuse an unsophisticated public. . . ."[191] Done and Cerebral emphasize these exact concerns by targeting consumers, convincing them they have a specific condition, and then offering them medication to treat it.[192] The advertisements use misleading information and therapeutic claims to encourage self-diagnosis.[193] Thus, instead of patients going to their doctors and requesting a specific advertised drug, patients are going directly to the telehealth companies for the prescription treatment advertised.[194] In both scenarios, the drug may be inappropriate for a patient's medical needs.[195] Further, it is immaterial that these advertisements do not mention a specific drug because information on the website specifies the treatment offered for ADHD. According to Done's frequently asked questions:

> Once our ADHD clinician has recognized that treatment with medication is the best option, a choice between stimulants or non-stimulant medications must be made. Taking patient history into account is important: when the patient has had an adverse reaction to a stimulant, or when stimulants are absolutely contraindicated, we must find another way to treat. Sometimes, a clinician might decide to prescribe non-stimulant medications instead.[196]

Whether a patient has researched ADHD themselves or read more about it through Done, they are likely aware of the most common treatment options.

Under current law, Done and Cerebral can avoid complying with FDA regulations by claiming that they are a merely a platform connecting doctors to patients.[197] That platform, however, enables controlled substance drug treatment to be initiated by an interactive advertisement in a manner that was not possible when the regulations for pharmaceutical advertising were promulgated.[198] To close this regulatory gap, it is vital that DTC telemedicine advertisements are subject to the FDA's oversight. For Done and Cerebral, this will require advertisements that contain an accurate characterization of the complex symptoms of ADHD and a fair balance to the harms of medication. Further, the FDA would be able to request these companies to modify their promotions and bring legal action if they fail to comply.[199] Like the

---

[190]Sally A. Kiss, *Harmful or Helpful? Direct to Consumer Advertising*, 1 THE GRADUATE REV. 7, 7 (2016); Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 659–61 (2006).

[191]Donohue, *supra* note 186, at 679; *see* Bitzer, *supra* note 64, at 180.

[192] Ranpariya et al., *supra* note 100 ("these marketing habits have the potential to take advantage of uninformed patients. Campaigns could potentially medicalize normal experiences and expand disease definitions resulting in overdiagnosis, overtreatment, and wasted resources.").

[193]*See supra* notes 81–93 and text accompanying

See Press-Reynolds, *supra* note 72; *see also State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 909 (W. Va.2007) ("[a]dvertisements are created to sell products and thus are inadequate sources of information and poor substitutes for medical advice.").

[194]Bitzer, *supra* note 64, at 178–80.

[195]*See State ex rel. Johnson & Johnson Corp.*, 647 S.E.2d at 909 ("[S]uperficial and misleading advertisements create unreasonable or inappropriate patient expectations for product effectiveness and often lead patients to request inappropriate products for their medical needs.").

[196]*See ADHD Treatment Options*, DONE FIRST, https://www.donefirst.com/adhd/treatment.

[197] Small et al, *supra* note 168, at 4.

[198] Bitzer, *supra* note 64, at 191.

[199] Small et al, *supra* note 168, at 4–5.(The FDA enforces violations by "issuing warning letters, injunctions, seizures, civil fines, and criminal penalties."). *Id*. at 5.

requirements for drug advertising, this oversight proposal will protect consumers by allowing them to make an informed decision about their medical care with their doctor without the pressure of predatory DTC marketing.[200]

CONCLUSION

The expansion of telehealth during the COVID-19 pandemic has drastically changed the approach to healthcare in the United States. The demand continues to grow as many patients prefer the convenience and ease of a virtual visit. Further, providers agree that telehealth is a very effective tool to treat a wide variety of conditions.[201] The verdict is in: telehealth is an easy alternative to traditional healthcare and is here to stay. However, as the growth and reliance on telehealth continues, it is crucial that the quality of healthcare is not getting overshadowed by a focus on speed, convenience, or economic incentives.

Done's and Cerebral's treatment of patients that may or may not have ADHD highlights these concerns. These telehealth companies utilize a DTC telemedicine model that emphasizes quick treatment at the cost of accurate diagnosis and quality patient care. The DEA and the FDA's sparse regulatory structures for telehealth companies have fostered an environment where ADHD telehealth companies prescribe controlled substances with impunity. These companies aggressively advertise to potential consumers, provide low-quality mental health treatment, and overprescribe controlled substances.

Promulgating the special registration for telehealth providers under the Ryan Haight Act to require drug-specific prescribing guidelines will ensure that companies, like Done and Cerebral, are properly screening and diagnosing patients before they prescribe addictive drugs.[202] The special registration will enable the DEA to monitor the growing telehealth industry and prevent the over prescription of controlled substances through telehealth. Additionally, subjecting DTC telemedicine advertisements to the FDA's oversight under the FDCA will require Done and Cerebral to ensure that all advertisements are honest and provide a fair balance of ADHD treatment. These changes will hold companies like Done and Cerebral to a higher standard that more appropriately reflects the serious condition they aim to treat and the dangerous drugs they are prescribing.

[200] Donohue, *supra* note 186, at 679 (noting the initial concerns regarding DTC drug advertising).

[201] *See* Erik P. Southard et al., *Telemental Health Evaluations Enhance Access and Efficiency in a Critical Access Hospital Emergency Department*, 20 TELEMEDICINE & E-HEALTH, 1, 2 (2014) ("Telepsychiatry has also been reported to have a high level of accuracy and value as an assessment tool.").

[202] Jain, *supra* note 92, at 926.