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## Comment: Online and Off-Label: Closing the Regulatory Gap in Online Direct-to-Consumer Drug Promotion and Prescribing

Kristina L. Bitzer

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# Online and Off-Label: Closing the Regulatory Gap in Online Direct-to-Consumer Drug Promotion and Prescribing

KRISTINA L. BITZER<sup>1</sup>

*The advent of telemedicine led to an evolution in healthcare delivery, making it possible for healthcare professionals to provide remote patient care, thus minimizing or eliminating the need for the patient to visit a physician's office. Recently, online telemedicine has gained significant popularity, especially in light of the COVID-19 pandemic. This Comment focuses upon online direct-to-consumer telemedicine platforms and their modern usage as one-stop-shops for acquisition of medical advice and medication. Specifically, this Comment explores prescription promotion and prescribing as done through these platforms with a special examination of off-label prescriptions. Several modern online direct-to-consumer telemedicine platforms offer prescription medications directly to the patients who visit their websites. The platforms advertise these prescriptions on both their individual websites as well as through social media. Some of the medications offered and promoted by these platforms are not FDA approved for the conditions that they are advertised to treat. This Comment explores regulations and liability considerations surrounding prescription advertising and prescribing, specifically as they relate to online direct-to-consumer telemedicine platforms. Because these platforms claim to be neither medical providers, pharmaceutical companies, nor online pharmacies, they fall into a regulatory gap. This Comment concludes by suggesting that federal legislation or regulations should be promulgated accordingly to bridge this gap, particularly given increased dependence upon these platforms in light of the COVID-19 pandemic.*

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## I. INTRODUCTION

Picture yourself as a young professional during the height of the COVID-19 pandemic circa Spring 2020.<sup>2</sup> Quarantines and shutdowns are occurring nationwide, hospitals are rapidly filling up with patients on ventilators, and American health and governmental authorities instruct you to only leave your home for essentials. You have been working online at your corporate job where operations have continued somewhat normally, albeit remotely. However, there have been layoffs due to the virus's impact on the economy and you want to do everything in your power to avoid being the next person on human resources' hit list. You have a big presentation coming up for work and you *really* want to nail it, but you know that your experience severe anxiety with public speaking and it hinders your performance.

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2. See generally *A Timeline of COVID-19 Developments in 2020*, AM. J. MANAGED CARE (Jan. 1, 2021), <https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020> [<https://perma.cc/38WG-7VZR>].

The thought of doing a presentation in an online format is even more nerve-racking. What if your spotty internet fails? What if an Amazon delivery comes and the dog starts barking? You're freaking out.

You realize that everything has been quite overwhelming and you consider finding a doctor to prescribe some anti-anxiety medication prior to your big presentation. However, the shutdowns are making it difficult to schedule an appointment and, even if you could get in to see someone, you would be afraid to leave the house. One night you're scrolling through Instagram when you see an ad for a website called Hers.<sup>3</sup> This website has a bunch of different prescriptions available for multiple mental health conditions, including a medication called Propranolol which is listed under the heading of "performance anxiety."<sup>4</sup> You do a quick online search and also find a website called Kick<sup>5</sup> which specifically gears its offerings towards people with your exact problem.<sup>6</sup> This site also offers this Propranolol medication<sup>7</sup> which people take before big presentations, exams, or other stressful situations.<sup>8</sup> This sounds like a perfect solution. Moreover, you can obtain medication on the internet without leaving your house—all you have to do is go online, answer some questions, and have a short virtual consultation with a medical professional.<sup>9</sup> They'll send the medication right to your home.<sup>10</sup> You're determined to get this drug, and get it fast. Presentation day will be here before you know it.

Direct-to-consumer (DTC) telemedicine websites like Hers and Kick rapidly made their way into the mainstream prior to COVID-19, but the pandemic afforded them an opportunity to demonstrate their value.<sup>11</sup> These

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3. *Hers for Women's Health*, HERS, [www.forhers.com](http://www.forhers.com) [<https://perma.cc/46EQ-8GQU>].

4. *Propranolol*, HERS, <https://www.forhers.com/well-being/propranolol> [<https://perma.cc/4RCC-BD3X>]; see also Jessica Defino, *The Dangerous Side Effect of Digital Wellness*, FASHIONISTA (Mar. 20, 2019), <https://fashionista.com/2019/03/digital-health-wellness-companies-government-regulations> [<https://perma.cc/4PGM-TR43>].

5. *Kick: Insider's Edge to the Best You*, KICK, <https://www.gokick.com> [<https://perma.cc/ZPR5-K6WE>].

6. See generally Kristen V. Brown & Gerrit De Vynck, *Startups Are Hawking Zolof and Beta Blockers for Off-Label Uses*, BLOOMBERG QUINT (Apr. 4, 2019, 12:57 AM), <https://www.bloombergquint.com/business/startups-are-hawking-zolof-and-beta-blockers-for-off-label-uses> [<https://perma.cc/9LN3-MAYP>].

7. *Feeling Anxious? Propranolol Can Calm Your Body and Ease Your Nerves*, KICK, <https://www.gokick.com/guides/anxiety/propranolol/> [<https://perma.cc/TRC3-NZKS>].

8. *Id.*

9. See generally Yasmin Gagne & Burt Helm, *Buying Prescription Drugs Online is Easier Than Ever. But There Are Side Effects*, FAST CO. (Sept. 11, 2019), <https://www.fastcompany.com/90396205/buying-prescription-drugs-online-is-easier-than-ever-but-there-are-side-effects> [<https://perma.cc/J3XQ-Z53T>].

10. See generally *id.*

11. TARA JAIN & ATEEV MEHROTRA, COMPARISON OF DIRECT-TO-CONSUMER TELEMEDICINE VISITS WITH PRIMARY CARE VISITS, 1 (2020),

sites use direct-to-consumer marketing paired 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.<sup>12</sup> Through these websites, patients can leisurely browse treatments and medications for conditions ranging from migraines,<sup>13</sup> to skincare,<sup>14</sup> to sexual performance,<sup>15</sup> and beyond.<sup>16</sup> Some websites even allow patients to add the medication to their electronic shopping carts, pay for it, enter shipping information, and have the drug's appropriateness evaluated by a provider following payment in order to streamline the process.<sup>17</sup>

These sites appeal to the modern consumer because they are convenient, discreet, and efficient. While the benefits of such a healthcare delivery system are plentiful, especially in the midst of a pandemic, use of this model presents some inherent dangers.<sup>18</sup> Patients often have pre-conceived notions of what medications are right for them based on self-diagnosis<sup>19</sup> or arbitrary internet searches, and direct access to those medications via online platforms removes the initial independent judgment of a medical professional.<sup>20</sup> The model does not allow for a medical professional to perform an in-person, visual examination of the patient nor take important vitals, like blood pressure and heart rate, that are often prerequisite to determining whether a medication is appropriate for a patient.<sup>21</sup> Of further concern is the fact that several medications available through these online DTC medicine platforms are being advertised and prescribed for “off-label,” non-FDA

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<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773813>  
[<https://perma.cc/NL7G-EMRY>].

12. See generally Gagne & Helm, *supra* note 9.

13. See, e.g., *Best Medication for Migraine Headaches*, COVE, <https://www.withcove.com/our-offering> [<https://perma.cc/NG68-3T8T>].

14. See, e.g., *Apostrophe: Acne Treatment That Delivers*, APOSTROPHE, <https://www.apostrophe.com> [<https://perma.cc/NW8M-T6B5>].

15. See, e.g., *Sertraline for Premature Ejaculation*, HIMS, <https://www.forhims.com/drug/sertraline-for-pe> [<https://perma.cc/LD8U-EPQY>].

16. Gagne & Helm, *supra* note 9 (“San Francisco–based Lemonaid Health, founded in 2013 and forerunner [in DTC online medicine], now sells medication for more than a dozen different conditions . . .”).

17. See, e.g., *Zolmitriptan: Immediate Migraine Relief*, COVE, <https://www.withcove.com/products/zolmitriptan> [<https://perma.cc/A9VN-8TX6>] (demonstrating an example of this process); see also Gagne & Helm, *supra* note 9 (explaining that interactions with physicians via DTC medicine platforms often begin after the patient has added his or her desired prescription medication into an electronic shopping cart).

18. See generally Vishal Khetpal, *The Worrisome Rise of Direct-to-Consumer Medicine*, UNDARK (Mar. 28, 2019), <https://undark.org/2019/03/28/digital-health-dilemma/> [<https://perma.cc/FNM6-4SFX>].

19. Gagne & Helm, *supra* note 9.

20. See generally *id.*; see also Khetpal, *supra* note 18.

21. See generally *id.*

approved uses.<sup>22</sup> From a legal standpoint, the advertisement and prescription of these off-label medications by these platforms fall within a regulatory grey area because these websites hold themselves out to be mere communication platforms which connect independent providers with patients.<sup>23</sup> That is, the websites claim that they are not providers of healthcare nor distributors or manufacturers of drugs<sup>24</sup>—which are subject to unique regulation—and explicitly state as much in their individual Terms and Conditions.<sup>25</sup>

This Comment explores off-label advertising and prescribing performed through these sites alongside regulatory and liability considerations. It goes on to analogize these platforms to hospitals which have been historically unsuccessful in claiming that they are mere facilitators of care, simply providing a space for patients to connect with physicians.<sup>26</sup> The Comment concludes by suggesting that Congress or a federal regulatory agency should act to regulate the online DTC medicine platforms specifically in order to protect both patient safety and to ensure continued integrity of the medical profession.

## II. TELEMEDICINE IN THE UNITED STATES

Telemedicine, also sometimes referred to as “telehealth,”<sup>27</sup> can be defined simply as “the use of telecommunication and information technology to provide clinical health care from a distance.”<sup>28</sup> Telemedicine has been an

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22. See Brown & De Vynck, *supra* note 6.

23. Khetpal, *supra* note 18.

24. See Gagne & Helm, *supra* note 9 (explaining how DTC telemedicine companies seek to “insulate themselves from treatment decisions” by claiming that they are merely platforms “facilitating interactions between patients and physicians.”).

25. See, e.g., *Kick Terms of Use*, KICK (Sept. 2018), <https://www.gokick.com/terms/> [<https://perma.cc/WPW8-HBVR>] (“We offer an online communication platform for Providers and their patients to connect via the Site through the use of synchronous and asynchronous telecommunications technologies. The Site facilitates communication between patients and Providers. Kick does not provide medical advice or care.”); *Hims: Terms & Conditions*, HIMS (Dec. 17, 2020), <https://www.forhims.com/terms-and-conditions> [<https://perma.cc/8XFN-T9F6>] (“We are a technology company that makes available to individuals who register as users of the Service (“Users”) certain products and services sold or offered by Hims or by third-party medical providers, pharmacies, or other vendors. [. . .] With respect to the Labs, Pharmacies, the Medical Groups and the Providers, we act solely as a technology platform to connect you with the products and services offered by the Labs, Pharmacies, Medical Groups and Providers through the Service.”).

26. See *infra* text accompanying notes 323-54.

27. Alexis S. Gilroy, *Digital Health Transactions—An Overview of Unique Considerations for Any Deal Lawyer Working on a Telemedicine, Telehealth, or Health Transaction*, 2016 HEALTH L. HANDBOOK 12 (2016).

28. Hamidreza Shirzadfar & Fatemeh Lotfi, *The Evolution and Transformation of Telemedicine*, 3 INT’L J. BIOSENSORS & BIOELECTRONICS 303 (2017).

invaluable resource for remotely connecting providers and patients for decades.<sup>29</sup> The modern concept of telemedicine has its roots as far back as the early 1900s, when the inventor of the electrocardiogram proposed the use of the telecardiogram.<sup>30</sup> In the 1920s, the radio was used to give medical advice to medical crews on ships.<sup>31</sup> By the 1940s, medical records were able to be transferred electronically to a location over twenty-four miles away through use of a telephone line.<sup>32</sup> Advancements in telemedicine technology were plentiful during the 1950s through the 1970s with the advent of teleradiology systems and, soon thereafter, video medicine systems.<sup>33</sup> During this time, the United States government sponsored a telemedicine project that sought to utilize satellite-based communications in order to provide health services to astronauts in space as well as to Native Americans on a remote reservation.<sup>34</sup>

Since then, telemedicine has quickly evolved and grown to meet the ever-changing needs of patients and providers.<sup>35</sup> Hospitals and doctors' offices use telemedicine services to connect providers to each other, as well as to patients.<sup>36</sup> For example, rural healthcare providers with limited resources may use telemedicine to transmit real-time data and health information to facilities with more expansive capabilities and specialties in order to provide life-saving treatment.<sup>37</sup> Modern telemedicine capabilities are even used to render remote emergency service through mechanisms such as mobile stroke units, utilizing remote communication and transmission of diagnostic imaging to provide time-sensitive treatment.<sup>38</sup> Furthermore, telemedicine resources have been crucial in connecting rural and underserved patients with healthcare services that would otherwise be unavailable to

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29. See generally *id.*

30. Thomas S. Nesbitt, *The Evolution of Telehealth: Where Have We Been and Where Are We Going?*, in *THE ROLE OF TELEHEALTH IN AN EVOLVING HEALTH CARE ENVIRONMENT* 12 (Tracy A. Lustig ed., 2012).

31. *Id.*

32. *TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE* 36 (Marilyn J. Field ed., 1996).

33. *Id.* at 36-39.

34. *Id.* at 39.

35. See generally Nader Amer, Comment, *Dr. Tele-Corporation: Bridging the Access-to-Care Gap*, 123 *DICK. L. REV.* 481, 488-89 (2019).

36. *Id.*

37. *Id.*

38. See generally Ketevan Berekashvili, *Mobile Stroke Units and Telemedicine for Delivering Acute Stroke Treatment in Resource Rich and Poor Environments and to Vulnerable Populations*, 3 *INTERNAL MED. REV.*, no. 4, 2017, at 1, <https://internalmedicinereview.org/index.php/imr/article/viewFile/455/pdf> [<https://perma.cc/7XV6-8HW7>].

them.<sup>39</sup> For example, there is a shortage of both psychiatrists and dedicated mental health treatment centers in the United States.<sup>40</sup> Telemedicine has made it possible for psychiatrists to provide both care and prescription access to patients that may otherwise be forced to go without.<sup>41</sup> Providers in multiple specialties can perform either telephonic or video-based visits with patients that may otherwise forgo treatment due to lack of area resources, mobility impairments, or difficulty finding time to travel to and from physicians' offices.<sup>42</sup> Telemedicine services are typically categorized as either synchronous—that is, occurring in real time, often via telephone or face-to-face—or asynchronous,<sup>43</sup> sometimes also referred to as “store-and-forward,”<sup>44</sup> often facilitated through online questionnaires.

While telemedicine has long played an important role in providing vital medical services to hard-to-reach patients, the COVID-19 pandemic demonstrated telemedicine's value more than ever.<sup>45</sup> As the COVID-19 virus continued to spread in early 2020, many patients were afraid to enter doctors' offices or hospitals for fear that they would contract the virus or carry it home to a loved one.<sup>46</sup> Medical offices operated on limited hours

39. See generally American Telemedicine Association, *Direct to Consumer (DTC) Asynchronous Telemedicine: Improving Access and Empowering Patients*, FOLEY & LARDNER, [https://www.foley.com/-/media/files/insights/health-care-law-today/dtc-async\\_final.pdf?la=en](https://www.foley.com/-/media/files/insights/health-care-law-today/dtc-async_final.pdf?la=en) [<https://perma.cc/4BSJ-4ZEP>] (explaining how telemedicine bridges health care access gaps in rural and underserved communities).

40. See generally Robert Caudill, *Update on Developments with Ryan Haight and Online Prescribing*, AM. PSYCHIATRIC ASS'N (Mar. 22, 2018), <https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/blog/update-on-developments-with-ryan-haight-and-online-prescribing> [<https://perma.cc/9W84-QRJQ>].

41. *Id.*

42. Amer, *supra* note 35, at 490-93.

43. American Telemedicine Association, *supra* note 39. “[The American Telemedicine Association] defines asynchronous as a non-real time, technology- assisted exchange of structured information between a patient and provider with the intent to diagnosis, treat and/or triage.” *Id.*

44. Gilroy, *supra* note 27.

45. See generally Matthew Gavidia, *Telehealth During COVID-19: How Hospitals, Healthcare Providers Are Optimizing Virtual Care*, AJMC (Mar. 13, 2020), <https://www.ajmc.com/view/telehealth-during-covid19-how-hospitals-healthcare-providers-are-optimizing-virtual-care> [<https://perma.cc/45M3-AG8J>].

46. Mark É. Czeisler et al., *Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns*, 69 MWWR: U.S. DEP'T HEALTH & HUMAN SERVS. 1250 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a4-H.pdf> [<https://perma.cc/65A5-7WFQ>] (“Overall, an estimated 40.9% of U.S. adults have avoided medical care during the pandemic because of concerns about COVID-19, including 12.0% who avoided urgent or emergency care and 31.5% who avoided routine care.”); see also John M. Glionna, *Health Crisis Looming Inside a Health Crisis: People Are Avoiding Going to the Doctor*, L.A. TIMES (July 29, 2020, 5:00 AM), <https://www.latimes.com/california/story/2020-07-29/coronavirus-people-avoid-visits-to-doctor> [<https://perma.cc/ET62-EEBQ>].



and reduced staff so as to comply with social distancing recommendations, and hospitals faced staff and budget reductions.<sup>47</sup> As patients weighed the benefits of obtaining medical treatment against the risks of contracting the virus, telemedicine quickly became an unsung hero of the COVID-19 pandemic.<sup>48</sup> In the first quarter of 2020 alone, the number of telemedicine visits increased by 50 percent when compared with the first quarter of 2019.<sup>49</sup> During the pandemic, the Centers for Medicare and Medicaid Services (CMS) expanded its Medicare reimbursement policy so as to reimburse providers for telemedicine visits at an equivalent rate to that of in-person medical visits, thus expanding remote care for elderly citizens.<sup>50</sup> During this time, telephonic and online remote visits, for multiple demographics, went from occasional to relatively commonplace for many symptoms and conditions.<sup>51</sup> The majority of these visits were those wherein patients were seeking care for non-COVID-19-related conditions.<sup>52</sup> Through these remote visits, patients could receive continuing care for chronic conditions, as well as evaluation of and treatment for routine minor illnesses.<sup>53</sup> Telemedicine services also provided crucial resources for physicians in vetting patients with potential COVID-19 symptoms.<sup>54</sup> Through visits via phone or video, physicians were able to evaluate patients' symptoms and, if necessary, send them for COVID-19 testing at designated locations, thus eliminating the need for the patient to present in person to the practitioner's office, potentially exposing others to infection.<sup>55</sup>

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47. Nancy Cleeland, *Hospitals Face Staffing Shortages, Reduced Budgets in Coronavirus Pandemic*, SHRM (Apr. 7, 2020), <https://www.shrm.org/resourcesandtools/hr-topics/employee-relations/pages/hospitals-face-staffing-shortages-reduced-budgets-in-coronavirus-pandemic.aspx> [https://perma.cc/9WNV-FTDZ].

48. See generally Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic*, 69 *MWWR*: U.S. DEP'T HEALTH & HUMAN SERVS. 1595 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6943a3-H.pdf> [https://perma.cc/BY9Z-GLTQ].

49. *Id.*

50. Allison Inzerro, *CMS Unveils Temporary Change Allowing Wider Use of Telehealth During COVID-19 Pandemic*, *AJMC* (Mar. 17, 2020), <https://www.ajmc.com/view/cms-unveils-temporary-change-allowing-wider-use-of-telehealth-during-covid19-pandemic> [https://perma.cc/4B4Y-7AZ4].

51. See Koonin, *supra* note 48.

52. *Id.*

53. See *Using Telehealth to Expand Access to Essential Health Services During the COVID-19 Pandemic*, CDC (June 10, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html> [https://perma.cc/72LV-YCZH].

54. *Id.*

55. *Id.*

### III. THE RISE OF DIRECT-TO-CONSUMER ONLINE TELEMEDICINE

While traditional telemedicine services have been in existence for quite some time, telemedicine's synthesis with a direct-to-consumer (DTC) model of marketing and delivery is a newer phenomenon and is experiencing rapid growth in popularity.<sup>56</sup> The concept of DTC marketing is geared towards selling a product, in this case medical care and services, directly to the ultimate buyer without the use of an intermediary such as a storefront, or, in this case, the office of a medical professional.<sup>57</sup> The DTC sales model itself is nothing new. In fact, one of the earliest forms of DTC marketing, the mail order catalog, is said to date as far back as fifteenth-century Venice.<sup>58</sup> Marketing and delivery of medical care in this manner is nothing new, either. Around the turn of the twentieth century, Americans could place an order for heroin—used to treat a variety of ailments—through the Sears, Roebuck catalog and receive, along with their medication, needles and syringes for personal administration.<sup>59</sup>

Contemporary pharmaceutical companies have long engaged in DTC marketing practices in the United States, as well.<sup>60</sup> Since the late 1990s, the prevalence of direct-to-consumer advertising (DTCA) by drug companies has skyrocketed<sup>61</sup> primarily due to changes promulgated by the U.S. Food and Drug Administration (FDA) which relaxed DTCA guidelines.<sup>62</sup> DTCA also increased in prevalence as the baby boomer generation began to age and as patients became increasingly involved in their own health care deci-

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56. See generally Tanisha Pina, *There's a New Crop of Wellness Brands Bringing Women's Health Care into the Digital Space*, FASHIONISTA (Nov. 1, 2018), <https://fashionista.com/2018/11/wellness-brands-womens-health-care-digital-medical-services> [https://perma.cc/9C54-N2SJ].

57. Mollie Levy, Comment, *Marketing Medicine to Millennials: Preparing Institutions and Regulations for Direct-to-Consumer Healthcare*, 55 CAL. W. L. REV. 521, 523 (2019).

58. See *History of Advertising: No 184: A Sears Roebuck Catalogue*, CAMPAIGN (Feb. 14, 2017), <https://www.campaignlive.com/article/history-advertising-no-184-sears-roebuck-catalogue/1423746> [https://perma.cc/GM52-2WT4].

59. Joe McKendry, *Sears Once Sold Heroin*, ATLANTIC (Mar. 2019), <https://www.theatlantic.com/magazine/archive/2019/03/sears-roebuck-bayer-heroin/580441/> [https://perma.cc/FG8P-XT8V].

60. Kristina Klara et al., *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-Label Promotion and Adherence to FDA Guidelines*, 33 J. GEN. INTERNAL MED. 651 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5910340/> [https://perma.cc/6V27-769J]. “Since 1985, the US Food and Drug Administration (FDA) has allowed direct-to-consumer (DTC) advertising of drugs.” *Id.*

61. Crystal Adams, *Fair Balance and Adequate Provision in Direct-to-Consumer Prescription Drug Online Banner Advertisements: A Content Analysis, An Entry in the Journal of Medical Research*, PUBMED CENT. (Feb. 18, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4777882/> [https://perma.cc/EF92-ZEAH].

62. *Id.*

sion making.<sup>63</sup> Drug manufacturers, who previously aimed their marketing efforts towards doctors, began focusing such efforts on consumers.<sup>64</sup> Consequently, DTCA has steadily increased in recent years.<sup>65</sup> As of a 2016 study, DTCA spending in the United States reached \$6 billion annually, up from \$1.3 billion less than ten years prior.<sup>66</sup> Presently, the United States is the only country in the world, with the exception of New Zealand, that allows DTCA.<sup>67</sup> There is no doubt that most, if not all, Americans<sup>68</sup> have seen the cheery, colorful<sup>69</sup> ads on television or in magazines, full of happy people who found the right prescription medication to relieve their ailments.<sup>70</sup> The ads tell the viewers that they, too, should ask their doctors about these drugs.<sup>71</sup> These ads seek to market products directly to a targeted patient population so that these patients, in turn, can arrive at their respective doctors' offices with a request for a specific prescription medication in mind.<sup>72</sup>

Given Americans' abundant access to and usage of the internet,<sup>73</sup> there has never been a better time nor forum for DTC sales, including sales of

63. *The Impact of Direct-to-Consumer Advertising*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2015), <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/impact-direct-consumer-advertising> [https://perma.cc/44EY-6LJ4]; see also Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILLBANK Q. 659, 682 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690298/pdf/milq0084-0659.pdf> [https://perma.cc/W35V-5L3N].

64. Donohue, *supra* note 63, at 659.

65. Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 J. AM. MED. ASS'N 81 (2019), <https://jamanetwork.com/journals/jama/fullarticle/2720029> [https://perma.cc/2MCG-DETE].

66. *Id.*

67. Zachary Brennan, *PhRMA Criticizes FDA's 'Unnecessary' Research on Drug Advertising and Promotion*, REGUL. FOCUS (Aug. 16, 2017), <https://www.raps.org/regulatory-focus/news-articles/2017/8/phrma-criticizes-fda-s-unnecessary-research-on-drug-advertising-and-promotion> [https://perma.cc/7FJD-2EWP].

68. Donohue, *supra* note 63, at 659 ("American consumers are bombarded daily with advertisements for prescription drugs that treat high cholesterol, diabetes, depression, pain, erectile dysfunction, and a host of other conditions.").

69. See Klara, *supra* note 60, at 656 ("The FDA stated that ads for . . . drugs included distracting scenes and music as well as running text on screen during the risk presentation . . . all of which are discouraged by FDA guidance, as they impair the viewer's ability to absorb risk information."); see also Reenita Das, *Are Direct-to-Consumer Ads for Drugs Doing More Harm Than Good?*, FORBES (May 14, 2019, 11:17 AM), <https://www.forbes.com/sites/reenitadas/2019/05/14/direct-to-consumer-drug-ads-are-they-doing-more-harm-than-good/?sh=272d60a54dfc> [https://perma.cc/FXR6-ZUUK] ("The advertisement released by Bristol-Myers Squibb for Opdivo . . . is full of flashy images of open skies and vast planes, suggesting an open road to a healthy future.").

70. See generally Das, *supra* note 69.

71. *Id.*

72. *Id.*

73. See Letter from Pharmaceutical Research and Manufacturers of America (PhRMA) to FDA (Aug. 11, 2017), <https://www.regulations.gov/document?D=FDA-2017->

medical products and services,<sup>74</sup> to thrive.<sup>75</sup> Recently, many startups have realized the lucrative nature of advertising and selling products in a DTC format on the internet.<sup>76</sup> Products offered by these startups run the gamut from bras<sup>77</sup> to razors,<sup>78</sup> orthodontic devices<sup>79</sup> to eyeglasses,<sup>80</sup> and more. These companies gear their sales models towards the younger, “digital native” generations which demand an efficient buying experience at an affordable price point.<sup>81</sup> As a result, this online DTC sales and delivery model has become wildly popular among Millennials and Generation Z, generations that exhibit clear preferences for fast and easy online transactions.<sup>82</sup>

Therefore, it makes sense that these generations’ preferences for marketing and delivery of general healthcare services would follow suit.<sup>83</sup> Millennials and members of Generation Z are less likely than their predecessors to see a doctor regularly,<sup>84</sup> but they also require treatment for basic, everyday health conditions. While some DTC online platforms scratched the surface of American healthcare, offering products like invisible braces<sup>85</sup> and contact lenses,<sup>86</sup> there was room for ambitious startups to reach into the underoccupied space of DTC primary care.<sup>87</sup> Consequently, health-focused

N-0493-001 [<https://perma.cc/8EWT-9VQY>] (outlining data regarding increased use of the internet in recent years among several demographics, particularly as it pertains to consumers’ ability to obtain risk information about pharmaceutical products).

74. Gagne & Helm, *supra* note 9. “As consumers, we’re used to accessing almost everything else online,” says Paul Johnson, cofounder and CEO of Lemonaid [an online DTC telemedicine provider]. “Why shouldn’t we access healthcare online if it’s clinically appropriate and done the right way?” *Id.*

75. *See generally id.*

76. *See generally* Emily Heyward, *How the Smartest DTC Brands Will Evolve, and What They Can Teach You*, INC. (June 2020), <https://www.inc.com/magazine/202006/emily-heyward/direct-to-consumer-dtc-digital-native-brand-ecommerce-red-antler.html> [<https://perma.cc/AM2H-2D5J>].

77. *See, e.g., Bras and Underwear for Every Body*, THIRDLOVE, <https://www.thirdlove.com> [<https://perma.cc/XRX4-E3M2>].

78. *See, e.g., Billie: The New Body Brand*, BILLIE, <https://mybillie.com> [<https://perma.cc/9D89-YZVZ>].

79. *See, e.g., Clear Aligners, Teeth Straightening and Oral Care*, SMILEDIRECTCLUB, <https://smiledirectclub.com> [<https://perma.cc/ZC6Q-VE7K>].

80. *See, e.g., Glasses and Prescription Eyeglasses*, WARBY PARKER, <https://www.warbyparker.com> [<https://perma.cc/A36Q-7W5U>].

81. *See generally* Heyward, *supra* note 76; *see also* Levy, *supra* note 57, at 523.

82. *See* Levy, *supra* note 57, at 535.

83. *See generally* Gagne & Helm, *supra* note 9.

84. *Id.* “Only 45% of 18-to-29-year-olds even *have* a primary-care physician, according to a poll from the Kaiser Family Foundation, often due to lack of access or health insurance.” *Id.*

85. *See, e.g., Clear Aligners, Teeth Straightening and Oral Care*, *supra* note 79.

86. *See, e.g., Hubble Contacts*, HUBBLE, <https://www.hubblecontacts.com/> [<https://perma.cc/K8TN-HSTP>].

87. Khetpal, *supra* note 18.

technology companies<sup>88</sup> were founded and thus designed these online DTC telemedicine platforms in order to connect patients with primary-care healthcare services.<sup>89</sup> These platforms are one of the various mobile health, or “mHealth,” technologies that have recently made their way to the forefront of modern medicine.<sup>90</sup> Services offered by these platforms include, but are not limited to, migraine prevention and treatment,<sup>91</sup> birth control,<sup>92</sup> mental healthcare,<sup>93</sup> sexual performance,<sup>94</sup> and acne treatment,<sup>95</sup> as well as a variety of associated prescriptions.<sup>96</sup>

These platforms allow patients to access a variety of prescriptions from the convenience of their preferred electronic devices, providing simple, one-stop shops.<sup>97</sup> The platforms advertise their services and drug offerings on their own webpages; they also run ads on popular social media platforms, like Facebook and Instagram, in an effort to reach target patients.<sup>98</sup> DTC telemedicine platforms differ from typical telemedicine services in that the patient does not have to first call and schedule an appointment with a provider as she would with a traditional telemedicine visit.<sup>99</sup> Rather, the patient accesses the website, sees the ad, banner, or link for the medication that she wants, clicks on the desired product, and is typically<sup>100</sup> guided through a series of questions in order to ascertain the appropriateness of the medication, including self-reported vitals such as blood pressure and heart rate.<sup>101</sup> The questionnaire is then forwarded to a medical professional—e.g., physician, nurse practitioner, or physicians’ assistant—who then evaluates the patient’s request and reconciles it with the answers in the question-

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88. See, e.g., *Thirty Madison: A Human-First Healthcare Company*, THIRTY MADISON, <https://thirtymadison.com/> [<https://perma.cc/4Q24-7PC8>].

89. Khetpal, *supra* note 18.

90. Gilroy, *supra* note 27 (“[mHealth] is not only a ‘form of telemedicine using wireless devices and cell phone technologies’ but also a ‘tool’ through which health care professionals may practice telehealth and telemedicine.”).

91. See, e.g., *Best Medication for Migraine Headaches*, *supra* note 13.

92. See, e.g., *Order Birth Control Online with Free, Fast Shipping*, NURX, <https://www.nurx.com/> [<https://perma.cc/63MG-8HSJ>].

93. See, e.g., *Hers for Women’s Health*, *supra* note 3.

94. See, e.g., *Telehealth for a Healthy, Handsome You*, HIMS, <https://www.forhims.com> [<https://perma.cc/722X-WT7F>].

95. See, e.g., *Apostrophe: Acne Treatment That Delivers*, *supra* note 14.

96. See JAIN & MEHROTRA, *supra* note 11. Studies show that users most frequently access primary-care based DTC telemedicine platforms for prescription treatment of urinary tract infections, erectile dysfunction, or to access contraception. *Id.*

97. See Defino, *supra* note 4.

98. *Id.*

99. See Gagne & Helm, *supra* note 9.

100. *Id.* This depends on the mechanism by which the prescription and consultation process operates on a site-by-site basis. *Id.*

101. *Id.*

naire.<sup>102</sup> In some cases, a virtual visit may be performed via telephone or video chat.<sup>103</sup> Nevertheless, the telemedicine services provided by these platforms are most frequently provided in an asynchronous, questionnaire-based format.<sup>104</sup> One physician,<sup>105</sup> contracted to provide services for the men's health website Hims, reports that he reviews fifteen to twenty patient files per hour and approves about 70 percent of patient requests.<sup>106</sup> His initial review of a request for a prescription takes about three to five minutes.<sup>107</sup> The review of a request for erectile dysfunction medication consists of verifying the patient's photo ID, checking the patient's questionnaire for reports of any underlying health conditions such as heart problems, and providing commentary and insight into the proposed treatment plan.<sup>108</sup> If the request is for something more innocuous, such as medication for hair loss or acne treatment, the doctor will view photos of the patient after quickly reviewing the patient's questionnaire.<sup>109</sup>

This DTC medicine marketing system effectively works the same way as a prescription drug television commercial or magazine ad does,<sup>110</sup> but with an efficient twist: it presents patients with medications that may be suitable for them, but allows the patient to make the initial prescription choice and have the selection evaluated by a practitioner on the back end.<sup>111</sup> This system eliminates the need to call a physician's office and wait for an appointment and it is easy and discreet.<sup>112</sup> While these platforms were rap-

102. *Id.*

103. *Id.* (“[This is] similar to what companies such as Dollar Shave Club and Glossier do for razors and cosmetics, except instead of circumventing traditional retailers, the telemedicine startups skip the brick-and-mortar pharmacy and replace the in-person doctor's exam with an online one, sometimes via a video or a phone call, but often merely through an online questionnaire and brief email correspondence.”).

104. Health Care Law Today Podcast, *Episode 4: Direct to Consumer (DTC) Telehealth: Does the Industry Need More Regulation?*, FOLEY & LARDNER, transcript (Dec. 11, 2019) [hereinafter HCLT Podcast] <https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf11/GetRenderedPdfByUrl/DTC%20Telehealth%20Does%20Industry%20Need%20More%20Regulation.pdf?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2019%2f12%2fdtc-telehealth-does-industry-need-more-regulation?format=pdf&attachment=false> [https://perma.cc/JZ9J-MJHH].

105. Gagne & Helm, *supra* note 9.

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. Defino, *supra* note 4. “[N]ot only [has the U.S.] *not* outlawed direct-to-consumer ads [like most other countries in the world], but [it has] pretty much invented a new level of medical marketing [in DTC online medicine].” *Id.*

111. *See generally* Gagne & Helm, *supra* note 9.

112. *Id.*

idly gaining popularity prior to the COVID-19 era,<sup>113</sup> they proved to be invaluable resources in the midst of the pandemic.<sup>114</sup> As lockdowns and stay-at-home orders ensued, these platforms provided convenient, on-demand access to patients' everyday health needs.<sup>115</sup> Some even expanded their offerings to include COVID-19 screenings and assessments.<sup>116</sup> These websites' newfound popularity, along with their ease of use and accessibility, makes it likely that they will continue to thrive in a post-pandemic environment, as well.<sup>117</sup>

#### IV. JUST A PLATFORM

##### A. NOT A MEDICAL PROVIDER

While the online DTC telemedicine companies offer telemedicine services and prescription medication to the patients who access their websites, most DTC telemedicine companies claim that they are not providers of medical care.<sup>118</sup> That is, they claim that when the patients register as users on the companies' websites, these patients are not entering into a physician-patient relationship with the DTC telemedicine company itself, but merely a "direct customer relationship."<sup>119</sup> The DTC telemedicine company holds itself out to be a mere intermediary providing a platform for providers, pharmacies, and patients to connect.<sup>120</sup> The patient is, rather, entering into a physician-patient relationship with certain medical groups with whom the DTC telemedicine companies partner to provide medical care for registered users of their websites.<sup>121</sup> The companies claim that they do not "control or interfere with"<sup>122</sup> the medical services offered by these independent physicians' groups and are thus not responsible for things like the "quality and appropriateness of the care" rendered by these practitioners.<sup>123</sup> In fact, certain websites, like Hims and its affiliate Hers, claim that they have not even

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113. See generally *id.*

114. See JAIN & MEHROTRA, *supra* note 11.

115. *Id.*

116. Mary Ann Azevedo, *Startups Pager, Hims & Hers Boost Telehealth Offerings to Address COVID-19 Pandemic*, CRUNCHBASE (Apr. 2, 2020), <https://news.crunchbase.com/news/startups-pager-and-hims-hers-boost-telehealth-offerings-to-address-covid-19-pandemic/> [<https://perma.cc/AR6Z-LUA3>].

117. See generally *id.*

118. See Gagne & Helm, *supra* note 9 (explaining how DTC telemedicine companies seek to "insulate themselves from treatment decisions" by claiming that they are merely platforms "facilitating interactions between patients and physicians.").

119. *Hims: Terms & Conditions*, *supra* note 25.

120. See Gagne & Helm, *supra* note 9; see also Defino, *supra* note 4.

121. Gagne & Helm, *supra* note 9.

122. See, e.g., *Hims: Terms & Conditions*, *supra* note 25.

123. See, e.g., *Kick Terms of Use*, *supra* note 25.

entered into contracts with these groups.<sup>124</sup> These websites claim that they are merely neutral forums wherein patients can connect with providers, albeit one wherein the patient enters into a consumer-based relationship with the website itself.<sup>125</sup>

Such a setup ostensibly helps the DTC telemedicine companies avoid allegations of engagement in the corporate practice of medicine, which is explicitly forbidden in several states.<sup>126</sup> The corporate practice of medicine doctrine, in its broadest form, prohibits corporate entities from employing physicians to provide medical care to patients.<sup>127</sup> It also prohibits these entities from controlling or interfering with the practice of medicine.<sup>128</sup> While versions of the doctrine vary among the states where it is in effect, its central goals remain the same: to encourage medical practitioners to maintain professional autonomy and to discourage practitioners from having to divide their loyalties between profit and patient care.<sup>129</sup> Theoretically, the DTC telemedicine companies are not engaging in the corporate practice of medicine because they partner with “independent” medical practitioners to provide care to users of the websites. Because these practitioners are charged with making the ultimate prescribing decision for the patient, the DTC telemedicine companies can assert that they are not controlling nor interfering with the physician-patient relationship. Consequently, this setup helps the DTC telemedicine companies deny liability for the acts of the providers, a matter which is discussed in further detail in Part V, below.

#### B. NOT A PHARMACEUTICAL COMPANY

Just as the DTC telemedicine companies claim that they are not providers of medical care, they also deny that they are pharmaceutical companies.<sup>130</sup> This is because the DTC telemedicine companies are not the manufacturers of any of the drugs that they promote or sell.<sup>131</sup> Therefore, they are not subject to the unique regulatory schemes to which pharmaceutical companies are subject.<sup>132</sup>

Nevertheless, the marketing tactics employed by DTC telemedicine companies are not dissimilar from those utilized by pharmaceutical companies. The DTC telemedicine companies promote both name-brand and ge-

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124. *Hims: Terms & Conditions*, *supra* note 25.

125. *See, e.g., id.*

126. NAT'L HEALTH LAWS. ASS'N, CORPORATE PRACTICE OF MEDICINE: 50-STATE SURVEY (1996).

127. *Amer*, *supra* note 35, at 498.

128. *Id.* at 499.

129. *Id.* at 499-500.

130. *See Defino*, *supra* note 4.

131. *See, e.g., Hims: Terms & Conditions*, *supra* note 25.

132. *Defino*, *supra* note 4. *See also* HCLT Podcast, *supra* note 104.



neric versions of prescription drugs on their own websites, as well as through other channels, including social media. For example, on the websites Hims and Hers, users can click on headings including, but not limited to, “Primary Care,” “Sex,” “Skin,” and “Mental Health.”<sup>133</sup> Under those headings, users will find lists of prescription medications used to treat several conditions coupled with witty phrasing and playful photos.<sup>134</sup> Included with this promotional material are descriptions of the medication’s use, limited safety information, a link to access additional safety information, a notice to users regarding a physician consultation, and a button to begin the consultation.<sup>135</sup> This promotional process is an efficient, streamlined form of DTCA, similar to that which Americans are accustomed to seeing on television or in magazines. The DTC telemedicine companies also advertise on social media platforms<sup>136</sup> including Instagram and Facebook.<sup>137</sup>

DTCA by pharmaceutical companies is primarily regulated by the FDA.<sup>138</sup> The FDA has authority to oversee promotion of prescription drugs under the Food, Drug, and Cosmetic Act (FDCA).<sup>139</sup> Over the years, the FDA’s efforts have largely focused on ensuring that pharmaceutical companies, in advertising their products directly to patients, create a “fair balance”<sup>140</sup> between benefit and risk information as it pertains to drugs advertised, particularly in broadcast advertisements.<sup>141</sup> This is so patients are not misled into thinking that an advertised medication has overwhelming benefits with few risks and can thus make more informed healthcare decisions.<sup>142</sup>

Over approximately the last four decades, American patients have become increasingly involved in their healthcare decision making as a result of various factors, including but not limited to the patients’ rights movement of the 1970s<sup>143</sup> and the aging of the baby boomer generation.<sup>144</sup> Thus,

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133. *Telehealth for a Healthy, Handsome You*, *supra* note 94.

134. *See, e.g., Stendra (avanafil) Tablets*, HIMS, <https://www.forhims.com/erectile-dysfunction/stendra> [<https://perma.cc/BJ45-UARB>] (welcoming users to the landing page for Stendra, an erectile dysfunction medication, with a tagline reading “fast and furious” followed by photos of eggplants of various sizes as well as a suggestive cactus).

135. *Id.*

136. *See* Defino, *supra* note 4; Gagne & Helm, *supra* note 9.

137. *See, e.g., Apostrophe, 6 Reasons to Ditch the Dermatologist’s Office and Use Apostrophe*, FACEBOOK (Jan. 7, 2021, 1:11 PM), [www.facebook.com](https://www.facebook.com) [<https://perma.cc/D7KL-6QPF>] (a Facebook ad promoting the use of antibiotics for acne treatment).

138. *See* 21 U.S.C. §§ 351-360.

139. *Id.*

140. Adams, *supra* note 61; 21 C.F.R. § 202.1(e)(5)(ii) (2021).

141. U.S. FOOD & DRUG ADMIN., *supra* note 63.

142. *Id.*

143. Donohue, *supra* note 63, at 662.

144. U.S. FOOD & DRUG ADMIN., *supra* note 63.

DTCA provided another avenue for patients to be active participants in their medical care.<sup>145</sup> Nevertheless, influential entities including the American Medical Association (AMA) have long cautioned<sup>146</sup> the use of DTCA due to the ads' potentially negative effects on a populace comprised primarily of non-physicians.<sup>147</sup> Even pharmaceutical companies themselves were once hesitant to endorse DTCA of their products, arguing that "DTCA would hurt the doctor-patient relationship, confuse an unsophisticated public, and lead to higher drug costs."<sup>148</sup>

Consequently the FDA concluded that, if DTCA would be permitted, patients should be equipped with information so that they could make informed decisions about the products advertised.<sup>149</sup> The FDA's "fair balance" requirement came as part of its 1999 final guidance<sup>150</sup> to the pharmaceutical industry regarding advertising prescription drugs in broadcast media, including television and radio.<sup>151</sup> DTC pharmaceutical advertisements often contain an abundance of attractive imagery and happy patients alongside statements which proclaim a medication's abundant benefits.<sup>152</sup> This positive imagery makes it so that a patient's attention could easily be drawn away from any risks or dangers of an advertised medication.<sup>153</sup> Therefore, the FDA promulgated guidelines stating that pharmaceutical companies engaging in broadcast DTCA should provide, within those broadcast advertisements, a "major statement"<sup>154</sup> regarding the medication's side effects and contraindications.<sup>155</sup> This statement must be spoken aloud and clearly articulate the drug's most important risks.<sup>156</sup> Additionally, "adequate provision"<sup>157</sup> must be made so as to disseminate all other relevant information

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145. Donohue, *supra* note 63, at 662.

146. *Id.* at 665. As early as the early 1900s, the AMA cautioned physicians against prescribing "drugs that were 'advertised directly to the laity.'" *Id.*

147. See, e.g., Press Release, Am. Med. Ass'n, AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices (Nov. 17, 2015), <https://www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices> [<https://perma.cc/4WJY-XULH>].

148. Donohue, *supra* note 63, at 678.

149. *Id.* at 662.

150. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), <https://www.fda.gov/media/75406/download> [<https://perma.cc/E3VP-DH2G>].

151. Adams, *supra* note 61.

152. Klara, *supra* note 60, at 656.

153. *Id.*

154. 21 U.S.C. § 352(n); *Drug Advertising: A Glossary of Terms*, U.S. FOOD & DRUG ADMIN. (Jan. 19, 2020) [hereinafter FDA Glossary], <https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#M> [<https://perma.cc/G24K-SK92>].

155. Adams, *supra* note 61; 21 U.S.C. § 352(n)

156. Adams, *supra* note 61.

157. 21 C.F.R. § 202.1(e)1 (2021).

about the medication—namely that which is included on the drug’s FDA-approved labeling.<sup>158</sup> This must appear in the ad itself, or alternatively, a “brief summary” of all risks and side effects must be provided.<sup>159</sup> “Brief summaries” are still required in printed pharmaceutical ads and would realistically take several minutes to recite in a broadcast ad.<sup>160</sup> Thus, pharmaceutical ads in broadcast form typically make “adequate provision” through providing an alternate means of accessing full information about the drug, such as a 1-800 number, a website, a statement advising patients to ask their doctors about the medication, and/or a citation to an alternative print resource where the information is written,<sup>161</sup> e.g., “[s]ee our ad in *Family Circle*.”<sup>162</sup> Printed advertisements<sup>163</sup> also must include the statement, “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch),<sup>164</sup> or call 1-800-FDA-1088.”<sup>165</sup>

FDA regulation of pharmaceutical promotion on the internet, however, is not quite as clear and has not kept up with rapid advancements in technology and prolific internet usage.<sup>166</sup> The FDA has commented that the internet is not analogous to either print or broadcast methods of advertising.<sup>167</sup> While the FDA previously planned on developing internet-specific guidelines, it suspended the project, citing an inability to keep up with rapid technological developments.<sup>168</sup> Currently, the FDA looks at internet pharmaceutical promotion more or less on a case-by-case basis, determining whether individual promotions constitute “labeling, advertising, or neither” and evaluating them accordingly.<sup>169</sup> It has also issued guidelines which per-

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158. *Id.*

159. *Id.*

160. Adams, *supra* note 61.

161. *Id.*

162. See, e.g., TOP Branding, *Otezla TV Commercial: ‘Little Things Can Be a Big Deal’*, YOUTUBE (May 15, 2020), <https://www.youtube.com/watch?v=Z7HiEPLynkE> [<https://perma.cc/C53P-H8JR>] (demonstrating an example of “adequate provision” in Otezla commercial).

163. *Product Claim Ad (Correct)*, U.S. FOOD & DRUG ADMIN. (Dec. 23, 2015), <https://www.fda.gov/drugs/prescription-drug-advertising/product-claim-ad-correct> [<https://perma.cc/PP86-2L8Z>] (demonstrating an example of a correct product claim ad).

164. *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, U.S. FOOD & DRUG ADMIN. (Feb. 19, 2021), <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program> [<https://perma.cc/TT2V-VY2V>].

165. 21 U.S.C. § 352.

166. J.W. SCHOMISCH, *FDA ADVERTISING AND PROMOTION MANUAL* ¶ 428 (2018), Westlaw 7893161.

167. Consumer-Directed Promotion; Public Meeting, 68 Fed. Reg. 47920, 47922 (Aug. 12, 2003).

168. SCHOMISCH, *supra* note 166.

169. *Id.*

tain to the use of social media for drug promotion,<sup>170</sup> particularly those for advertising on social media platforms with space limitations, like Twitter.<sup>171</sup> These guidelines focus on ensuring that the ads convey truthful and accurate information to viewers, as well as ensuring that risk and benefit information are presented in “fair balance” with each other so as not to mislead the consumer.<sup>172</sup>

The Office of Prescription Drug Promotion (OPDP),<sup>173</sup> a division of the FDA, has performed studies on topics including online DTC drug promotion,<sup>174</sup> which included a study of placement of risk information on DTC prescription drug websites.<sup>175</sup> OPDP researchers also conducted a study on DTC drug promotion via the internet and mobile devices.<sup>176</sup> Ultimately, when evaluating DTC prescription drug promotion in absence of more specifically internet-tailored regulation, both the FDA and the OPDP focus their efforts on ensuring that there is a fair balance between risks and benefits articulated on internet ads.<sup>177</sup> The OPDP also fields complaints from healthcare providers who identify and report false or misleading drug advertisements through its “Bad Ad Program.”<sup>178</sup>

This elaborate framework is in place in order to regulate DTCA by pharmaceutical companies. Decades of care and deliberation has gone into promulgating rules to ensure that risks and benefits are adequately con-

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170. *For Industry: Using Social Media*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2020), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/industry-using-social-media> [<https://perma.cc/YS4K-W79L>].

171. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS—PRESENTING RISK AND BENEFIT INFORMATION FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES (2014), <https://www.fda.gov/media/88551/download> [<https://perma.cc/2JGY-WNRG>].

172. *Id.*

173. *The Office of Prescription Drug Promotion (OPDP)*, U.S. FOOD & DRUG ADMIN. (Jan. 27, 2021), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp> [<https://perma.cc/Z3EL-3R35>].

174. *The Office of Prescription Drug Promotion (OPDP) Research: Examination of Online DTC Drug Promotion (Completed in 2016)*, U.S. FOOD & DRUG ADMIN. (May 7, 2020), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research#examination> [<https://perma.cc/V9UX-PRNR>].

175. Helen W. Sullivan, *Abstract: Placement and Format of Risk Information on Direct-to-Consumer Prescription Drug Websites*, TAYLOR & FRANCIS (Jan. 27, 2017), <https://www.tandfonline.com/doi/full/10.1080/10810730.2016.1258745> [<https://perma.cc/7NHD-37VB>].

176. Kathryn Aikin et al., *Direct-to-Consumer Promotion of Prescription Drugs on Mobile Devices: Content Analysis*, J. MED. INTERNET RSCH. (2017), <https://www.jmir.org/2017/7/e225/> [<https://perma.cc/FLS7-F5RJ>].

177. *See id.*, see also Adams, *supra* note 61.

178. *The Bad Ad Program*, U.S. FOOD & DRUG ADMIN. (Jan. 5, 2021), <https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program> [<https://perma.cc/K32G-739P>].

veyed to consumers.<sup>179</sup> However, although DTC telemedicine companies engage in DTCA both on their individual websites and on social media, this regulatory framework does not directly apply to them because they are not pharmaceutical companies.<sup>180</sup> Rather, the DTC telemedicine companies “comply with content requirements for media platforms [that they] utilize.”<sup>181</sup> Furthermore, there is nothing specifically prohibiting the DTC telemedicine companies from promoting medication for off-label, non-FDA approved uses on both their websites and social media.<sup>182</sup>

### C. NOT AN ONLINE PHARMACY

The DTC telemedicine companies claim that they are not online pharmacies, either. This is because they partner with separate online pharmacies to fulfill orders for medications prescribed by the independent providers.<sup>183</sup> Nevertheless, DTC telemedicine companies share some common characteristics with online pharmacies, and thus regulatory schemes related to online pharmacies should be examined in turn.

Historically, agencies and legislators have struggled with how to regulate online pharmacies because of the pharmacies’ diverse characteristics.<sup>184</sup> While some operate much like brick-and-mortar pharmacies<sup>185</sup>—the patient visits a doctor, the doctor prescribes a medication, and the online pharmacy fills the prescription order accordingly<sup>186</sup>—others operate in a similar manner to DTC telemedicine companies. In those cases, a patient may go to an online pharmacy’s website, complete a questionnaire, and be remotely prescribed a medication by a physician.<sup>187</sup> The prescription is then fulfilled by the pharmacy.<sup>188</sup> Furthermore, there are online pharmacies known as “rogue” pharmacies which dispense medications without valid prescriptions, as well as foreign online pharmacies from which patients can order medications originating from locations outside of the United States.<sup>189</sup> While regulation of foreign online pharmacies has proven difficult,<sup>190</sup> do-

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179. See Donohue, *supra* note 63, at 665-85.

180. Gagne & Helm, *supra* note 9.

181. Defino, *supra* note 4.

182. *Id.*

183. See, e.g., *Hims: Terms & Conditions*, *supra* note 25.

184. See generally Bob Schultz, *Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem*, 16 SAN DIEGO INT’L L.J. 381, 381-85 (2015).

185. *Id.* at 385.

186. *Id.*

187. *Id.* at 386.

188. *Id.*

189. Schultz, *supra* note 184, at 385-86.

190. *Id.*

mestic online pharmacies are primarily regulated by the FDA under the FDCA<sup>191</sup> and the Drug Enforcement Administration (DEA) under the Controlled Substances Act of 1974 (CSA).<sup>192</sup> Additionally, the Federal Trade Commission (FTC) may take action against online pharmacies whose websites make false or misleading statements, or those who misrepresent the safety or efficacy of a medication.<sup>193</sup>

Congress has legislated in this area as recently as 2008, with patient safety serving as the driving force behind the legislation.<sup>194</sup> The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (hereinafter the “Ryan Haight Act” or the “Act”)<sup>195</sup> amended the CSA and was enacted in response to the tragic death of a teenager who procured prescription drugs from an online pharmacy.<sup>196</sup> Haight was able to purchase prescription painkillers online with a prescription remotely provided by a physician whom he had never met.<sup>197</sup> He subsequently overdosed.<sup>198</sup> The Ryan Haight Act imposed new restrictions upon online pharmacies, targeting “rogue” pharmacies and those that engage in remote prescribing.<sup>199</sup> Its primary aim was to restrict access to dangerous controlled substances,<sup>200</sup> including prescription painkillers, which were being generously prescribed and distributed by means of the internet. Most notably, the Ryan Haight Act mandates, with limited exceptions, that no controlled substance may be dispensed over the internet without a valid prescription from a practitioner who has conducted at least one in-person medical evaluation of the patient.<sup>201</sup> The Act also mandates that online pharmacies obtain a separate DEA registration allowing them to operate as internet-based pharmacies dispensing controlled substances.<sup>202</sup> Furthermore, online pharmacies must report the quantity of controlled substances dispensed on a monthly basis unless the amounts dispensed fall below certain designated thresholds.<sup>203</sup> Additionally, each

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191. 21 U.S.C. § 331.

192. 21 U.S.C. §§ 801-904.

193. Kerry Toth Rost, *Policing the “Wild West” World of Internet Pharmacies*, 76 CHI. KENT L. REV. 1333, 1348 (2000).

194. Jeff Karberg, *Progress in the Challenge to Regulate Online Pharmacies*, 23 J.L. & HEALTH 113, 114 (2010).

195. Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820.

196. Karberg, *supra* note 194, at 114.

197. *Id.*

198. *Id.*

199. *Id.* at 116-18.

200. A controlled substance is a drug or substance that is listed in Schedules I through V of the CSA. 21 U.S.C. § 802.

201. 21 U.S.C. § 829(e).

202. 21 U.S.C. § 823(f).

203. *Id.*

pharmacy must prominently display on its website a statement of compliance with the Act<sup>204</sup> as well as certain information and disclosures.<sup>205</sup>

A notable, yet narrow exception to the in-person evaluation requirement exists for “practitioner[s] engaged in the practice of telemedicine.”<sup>206</sup> The Act defines “practice of telemedicine” as “the practice of medicine . . . by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system . . . .”<sup>207</sup> The definition then goes on to enumerate seven specific circumstances wherein a provider has sufficient medical information in order to prescribe a controlled substance to a patient remotely, without conducting an in-person evaluation.<sup>208</sup> These circumstances include those where: (1) the patient is being treated, and is physically located, in a hospital by a separate, licensed practitioner within that facility; (2) the patient is being treated by, and in the presence of, another practitioner in the “usual course of professional practice;” (3) the patient is prescribed controlled substances via telemedicine by a practitioner “who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under

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204. 21 U.S.C. § 831(a).

205. 21 U.S.C. § 831(c). Information and disclosures include:

(1) The name and address of the pharmacy as it appears on the pharmacy’s Drug Enforcement Administration certificate of registration. (2) The pharmacy’s telephone number and email address. (3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted. (4) A list of the States in which the pharmacy is licensed to dispense controlled substances. (5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances. (6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof. (7) The following statement, unless revised by the Attorney General by regulation: “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.”

*Id.*

206. 21 U.S.C. § 829(e)(3)(A).

207. 21 U.S.C. § 802(54).

208. 21 U.S.C. § 802(54)(A)-(G).

its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;” (4) there is a public health emergency; (5) a practitioner has obtained “special registration” status; (6) there is a medical emergency that prevents a patient from being physically present at a Department of Veterans Affairs medical facility; and (7) there exist other circumstances determined by subsequent regulations.<sup>209</sup>

As evidenced by these narrow exceptions, the Ryan Haight Act recognizes telemedicine’s value in remote prescribing while taking care to not overextend the reach of this mode of healthcare delivery, at least in the realm of controlled substances. Furthermore, the Act expressly prohibits online pharmacies from “offering to fill a prescription for a controlled substance based solely on a consumer’s completion of an online medical questionnaire.”<sup>210</sup> Nevertheless, the Act does not impose any significant limitations on the remote prescribing of drugs that are non-controlled substances, that is, drugs that fall outside of Schedules I through V of the CSA.<sup>211</sup> Such drugs include, but are not limited to, “lifestyle drugs” such as those for weight loss and erectile dysfunction.<sup>212</sup> Online prescribing is attractive to those who wish to be discreet in their procurement of medications for conditions of this nature but, some drugs, like those prescribed for erectile dysfunction, can have potentially serious side effects.<sup>213</sup> Thus, critics have noted that while the Ryan Haight Act was a meaningful step towards regulation of online pharmacies, it fell short in controlling predatory prescribing of “non-controlled” substances.<sup>214</sup>

While DTC telemedicine companies are not online pharmacies, it is helpful to examine online pharmacy regulation in light of the proliferation of DTC telemedicine. The concerns that exist regarding remote, questionnaire-driven prescribing in an online pharmacy context also exist in the DTC telemedicine context, albeit not in the realm of controlled substances. However, critics’ concerns regarding the ease of online prescribing of “lifestyle drugs” carry over to DTC telemedicine. DTC telemedicine companies often cater to individuals who seek some level of anonymity or discretion for conditions regarding sexual performance or mental health.<sup>215</sup> Thus, concerns arise when physicians remotely prescribe lifestyle drugs, some of which are prescribed for off-label, non-FDA approved uses, through DTC telemedicine websites in an asynchronous, questionnaire-driven format.

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209. *Id.*

210. 21 U.S.C. § 841(h).

211. *See generally* Karberg, *supra* note 194, at 137-39.

212. *Id.* at 137-38.

213. *Id.* at 138.

214. Schultz, *supra* note 184, at 404-05.

215. Brown & De Vynck, *supra* note 6.



## V. OVERVIEW OF OFF-LABEL DRUG MARKETING AND PRESCRIBING

### A. DEFINITION OF OFF-LABEL PRESCRIPTIONS AND REGULATORY OVERVIEW

Pursuant to its authority under the FDCA, the FDA conducts extensive testing of prescription medications in an effort to ensure that these medications are safe and effective for the conditions that they are intended to treat.<sup>216</sup> However, a certain medication may treat multiple symptoms or conditions, including conditions for which a drug has not been approved by the FDA. Off-label prescriptions are those which are prescribed for uses other than the uses that have been approved by the FDA.<sup>217</sup> These are also sometimes called “non-approved” uses.<sup>218</sup> For example, the beta-blockers atenolol and propranolol, medications which are FDA-approved for treatment of certain cardiac issues, are sometimes prescribed off-label to treat symptoms of anxiety.<sup>219</sup>

Generally, after the FDA approves a drug for use, physicians have broad discretion to prescribe it for this intended (approved) use as well as to treat other conditions, even if the drug has not been FDA approved for those conditions.<sup>220</sup> These physician prescribing practices do not violate federal law or circumvent FDA regulations because the FDA does not regulate the practice of medicine,<sup>221</sup> only the marketing and distribution of drugs.<sup>222</sup> Off-label prescribing has been proven to be critical in some therapeutic areas, like oncology,<sup>223</sup> where the FDA approval process may lag behind research findings.<sup>224</sup> Moreover, off-label prescribing may ultimately lead to FDA approval of additional uses for a medication.<sup>225</sup> For example, Topiramate, also known as Topamax, a drug that was initially FDA-approved solely as an anticonvulsant (an anti-seizure medication) was frequently prescribed off-label for prevention of migraine headaches in those

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216. Monique C.M. Leahy, *Off-Label Use of Prescription Medications*, 124 AM. JUR. TRIALS 487, § 2 (2012); *see also* 21 U.S.C. § 355.

217. Leahy, *supra* note 216, at § 1.

218. *Id.*

219. Zawn Villines, *Beta-Blockers for Anxiety: What to Know*, MEDICALNEWS TODAY (Sept. 19, 2019), <https://www.medicalnewstoday.com/articles/326397> [<https://perma.cc/EYV4-4RAS>].

220. Leahy, *supra* note 216, at § 1.

221. Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. 124 (2016); *see also* 21 U.S.C. § 396.

222. Leahy, *supra* note 216, at § 1.

223. Cortez, *supra* note 221, at 124-25.

224. *Id.* at 133-34.

225. *See* Richard Wenzel, *Ask the Pharmacist: Off-Label Prescribing—Why Drugs Ranging from Antidepressants to Anti-Seizure Medications Are Used for Headache Management*, NAT'L HEADACHE FOUND., <https://headaches.org/2007/11/01/ask-the-pharmacist-archive-mayjune-2007/> [<https://perma.cc/5WZD-QRA2>].

who suffered from chronic migraine.<sup>226</sup> In 2004, the FDA approved Topiramate as a migraine preventative.<sup>227</sup>

While doctors can and do generally prescribe off-label medications for unapproved uses when they deem such uses medically appropriate,<sup>228</sup> pharmaceutical companies are subject to more scrutinous regulation when it comes to promotion of medication for off-label uses.<sup>229</sup> While a 2012 federal court decision held that the FDCA “do[es] not expressly prohibit the ‘promotion’ or ‘marketing’ of drugs for off-label use,”<sup>230</sup> the FDA maintains a functional ban on off-label promotion by prohibiting pharmaceutical advertisements for uses that have not been FDA-approved.<sup>231</sup> Such DTC advertisements could be deemed “false, lacking in fair balance, or otherwise misleading”<sup>232</sup> and, consequently, could subject the pharmaceutical manufacturer to significant penalties.<sup>233</sup> A drug could be deemed mislabeled or misbranded if the “written, printed, or graphic matter . . . accompanying [the drug]”<sup>234</sup> is false or misleading.<sup>235</sup> The Supreme Court has interpreted the language “accompanying [the drug]” to include materials that may explain or supplement the drug; a textual relationship is implied and no physical attachment between the drug and the ancillary materials is necessary.<sup>236</sup>

Therefore, while recent federal court decisions have allowed off-label promotions to be directed towards physicians on the basis of First Amendment protections,<sup>237</sup> pharmaceutical companies must continue to proceed with caution when marketing off-label uses directly to patients through DTCA so that their advertisements are not deemed false or misleading and so that their drugs are not deemed mislabeled or misbranded.<sup>238</sup>

226. *Id.*

227. Jennifer Warner, *FDA Approves Topamax for Preventing Migraines*, WEBMD (Aug. 12, 2004), <https://www.webmd.com/migraines-headaches/news/20040812/fda-approves-topamax-preventing-migraines> [<https://perma.cc/T82X-JQ2K>].

228. Cortez, *supra* note 221, at 124.

229. *See generally id.* at 125-26.

230. *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012).

231. 21 C.F.R. § 202.1(e)(6)(i) (2021).

232. *Id.*

233. 21 U.S.C. § 333(g).

[A]ny such person [individual, partnership, corporation, or association] who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed \$250,000 for the first such violation in any 3-year period, and not to exceed \$500,000 for each subsequent violation in any 3-year period.

*Id.*

234. 21 U.S.C. § 321(m); *see also* 21 C.F.R. § 1.3(a) (2021).

235. 21 U.S.C. § 352.

236. *Kordel v. United States*, 335 U.S. 345, 350 (1948).

237. *See, e.g., United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012).

238. *See generally Cortez, supra* note 221, at 124-28.

## B. PROBLEMS WITH OFF-LABEL PRESCRIBING AND PROMOTION

While there are plentiful benefits<sup>239</sup> to off-label drug prescribing, promotion, and usage, there are dangers as well.<sup>240</sup> A 2012 study found that 79 percent of off-label uses as prescribed by primary care physicians “lacked strong scientific evidence” of efficacy as it pertains to a particular treatment.<sup>241</sup> A subsequent study found that off-label use of medications which lacked strong scientific evidence of efficacy for a particular treatment were associated with a 44 percent greater likelihood of adverse events when compared to approved uses.<sup>242</sup> Types of medications most frequently prescribed off-label include anticonvulsants, antipsychotics, and antidepressants,<sup>243</sup> all of which can lend themselves to dangerous side effects<sup>244</sup> if not prescribed properly and managed carefully in conjunction with a patient’s other medications.<sup>245</sup>

Additionally, there is a societal and governmental concern that off-label use may expose patients, who are increasingly involved in their healthcare decision making,<sup>246</sup> to considerable harm if marketing thereof is not carefully monitored.<sup>247</sup> Studies have shown that DTC broadcast advertisements regularly promote off-label use through the language and graphics used in commercials,<sup>248</sup> and “few ads [are] fully compliant with FDA guidelines for DTC advertising.”<sup>249</sup> Consumer groups have voiced their concerns to the FDA over misleading statements in DTC broadcast ads

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239. See *id.* at 124-25.

240. *Id.* at 125.

241. Tewodros Eguale et al., *Drug, Patient, and Physician Characteristics Associated with Off-Label Prescribing in Primary Care*, 172 ARCHIVES INTERNAL MED. 781, 783 (2012), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1149634?appid=scweb&alert=article> [<https://perma.cc/Q278-7B8C>].

242. Cortez, *supra* note 221, at 125; see generally Tewodros Eguale et al., *Association of Off-label Drug Use and Adverse Drug Events in an Adult Population*, 176 JAMA INTERNAL MED. 55 (2016), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2467782> [<https://perma.cc/G4FR-Z5JC>].

243. Eguale, *supra* note 241, at 781, 783.

244. See, e.g., James M. Ferguson, *SSRI Antidepressant Medications: Adverse Effects and Tolerability*, 3 J. CLINICAL PSYCHIATRY 22 (2001), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC181155/> [<https://perma.cc/L3RP-42WU>]; Jim Thigpen et al., *Behavioral Side Effects of Antiepileptic Drugs*, U.S. PHARMACIST (Nov. 15, 2013), <https://www.uspharmacist.com/article/behavioral-side-effects-of-antiepileptic-drugs> [<https://perma.cc/DF6Z-MM7R>].

245. See Eguale, *supra* note 242, at 59.

246. See *supra* text accompanying notes 143-45.

247. Cortez, *supra* note 221, at 125.

248. See Klara, *supra* note 60, at 656.

249. *Id.* at 657.

which imply off-label uses for purposes such as weight loss.<sup>250</sup> Furthermore, it has been suggested that prohibitions on off-label promotion via DTCA have not been fully enforced by the FDA.<sup>251</sup>

Nevertheless, over the last few decades, pharmaceutical companies have paid tens of billions of dollars to settle actions that alleged illegal off-label marketing of prescription medications, including those marketed directly to physicians.<sup>252</sup> Many of these actions<sup>253</sup> have been brought under the False Claims Act (FCA).<sup>254</sup> The FCA is a broad remedial statute intended to protect the U.S. federal government from fraud.<sup>255</sup> It imposes civil liability on those who cause the government to make payments that should not otherwise be made.<sup>256</sup> In the present context, it has been used to impose substantial penalties upon pharmaceutical manufacturers that “knowingly ‘caused or induced’”<sup>257</sup> physicians to prescribe medications for off-label, non-FDA approved uses, thus causing false or fraudulent claims to be submitted to and, consequently, payments made by Medicaid and Medicare.<sup>258</sup> While the FDCA does not provide a private right of action against pharmaceutical manufacturers who engage in prohibited off-label marketing,<sup>259</sup> the FCA allows “qui tam,”<sup>260</sup> or whistleblower, actions to be brought by individuals who allege violations.<sup>261</sup> Additionally, FCA violations carry penalties between \$5,000 and \$10,000 per false or fraudulent claim submitted, as

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250. See, e.g., Letter from Public Citizen to Thomas Abrams, MD, Director, Office of Prescription Drug Promotion (Mar. 31, 2015), <http://www.citizen.org/documents/2250.pdf> [<https://perma.cc/7H5K-E3QX>].

251. See Klara, *supra* note 60, at 657.

252. Cortez, *supra* note 221, at 125; see generally SAMMY ALMASHAT ET AL., TWENTY-FIVE YEARS OF PHARMACEUTICAL INDUSTRY CRIMINAL AND CIVIL PENALTIES: 1991 THROUGH 2015 (2016), [https://www.citizen.org/wp-content/uploads/2311\\_0.pdf](https://www.citizen.org/wp-content/uploads/2311_0.pdf) [<https://perma.cc/7EK3-TJFU>].

253. ALMASHAT, *supra* note 252, at 10.

254. 31 U.S.C. §§ 3729-3733.

255. Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 54-55 (2005).

256. *Id.*

257. Katherine A. Blair, Comment, *In Search of the Right Rx: Use of the Federal False Claims Act in Off-Label Drug Promotion Litigation*, 23 HEALTH LAW. 44, 47 (2011).

258. *Id.*

259. Rather, the FDA may seize the illegally promoted drugs, issue an injunction against further promotion of the off-label uses, or institute criminal proceedings against the manufacturer. 21 U.S.C. §§ 332-334.

260. U.S. DEP'T OF JUST., FALSE CLAIMS ACT: A PRIMER (2011), [https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS\\_FCA\\_Primer.pdf](https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf). [<https://perma.cc/SC7K-NAD5>]. “The FCA allows private persons to file suit for violations of the FCA on behalf of the government. A suit filed by an individual on behalf of the government is known as a ‘qui tam’ action, and the person bringing the action is referred to as a ‘relator.’” *Id.*

261. ALMASHAT, *supra* note 252, at 10.

well as a provision for imposition of treble damages.<sup>262</sup> Thus, the FCA serves as a powerful tool against off-label promotion.

## VI. CONCERNS WITH OFF-LABEL PROMOTION AND PRESCRIBING IN AN ONLINE DIRECT-TO-CONSUMER FORMAT

### A. *LIKE TRADITIONAL DTCA, BUT NOT REGULATED THAT WAY*

The promulgation of rules for promotion of pharmaceuticals in the United States predated the advent of online direct-to-consumer healthcare.<sup>263</sup> While there is a robust regulatory framework in place to regulate pharmaceutical companies and how they market their products for off-label uses, there is no specific, substantive regulation in place for DTC online telemedicine websites.<sup>264</sup> Furthermore, since most modern online DTC telemedicine companies do not accept insurance,<sup>265</sup> including Medicare or Medicaid, enforcement of illegal off-label promotion under the FCA is also unlikely. Therefore, promotion of prescription medication for off-label uses goes largely unchecked on DTC telemedicine websites, thus lending itself to some inherent dangers.<sup>266</sup>

For example, Hims markets and sells Sertraline, an antidepressant in the Selective Serotonin Reuptake Inhibitor (SSRI) class—also known by its brand name, Zoloft—for off-label use, specifically for treatment of premature ejaculation.<sup>267</sup> As noted in Part III above,<sup>268</sup> sites like Hims target patients from younger generations, specifically Millennials and members of Generation Z. Millennials are typically defined as those individuals born between 1981 and 1996 and Generation Z is defined as those born between 1997 and 2012.<sup>269</sup> Of notable concern is the fact that Sertraline, like several

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262. 31 U.S.C. § 3729.

263. See generally Brown & De Vynck, *supra* note 6.

264. See Gagne & Helm, *supra* note 9.

265. See, e.g., *Will Insurance Cover Prescriptions for Hims and Hers?*, HIMS (Oct. 19, 2017),

<https://support.forhims.com/hc/en-us/articles/115002248351-will-insurance-cover-prescriptions-for-hims-hers-> [<https://perma.cc/EQS7-D8EJ>]; *FAQ: Does Kick Accept Insurance?*, KICK, <https://www.gokick.com/faq/> [<https://perma.cc/AVY6-TF2M>].

266. See Brown & De Vynck, *supra* note 6.

267. *Sertraline for Premature Ejaculation*, *supra* note 15; see also *Sertraline*, DRUGS.COM (Aug. 13, 2020), <https://www.drugs.com/ppa/sertraline.html> [<https://perma.cc/T3NW-YR9M>].

268. See *supra* text accompanying notes 82-89.

269. Michal Dimock, *Defining Generations: Where Millennials End and Generation Z Begins*, PEW RSCH. CTR. (Jan. 17, 2019), <https://www.pewresearch.org/fact-tank/2019/01/17/where-millennials-end-and-generation-z-begins/> [<https://perma.cc/LDT6-DSYY>].

antidepressants,<sup>270</sup> carries a black box warning,<sup>271</sup> also known as boxed warning,<sup>272</sup> notifying patients of potentially serious side effects in individuals up to twenty-four years of age.<sup>273</sup> This warning specifically addresses an increased risk of suicidal ideation or actions among individuals in this age range.<sup>274</sup> As noted above,<sup>275</sup> the FDA has not specifically regulated internet promotion and advertisement of prescription medication. However, it is worth noting that, on Zoloft's website, the black box warning appears immediately upon entry to the site.<sup>276</sup> It is front and center, nearly impossible for the viewer to miss, and immediately juxtaposed with some attractive features of the medication. This is likely to comply with the FDA requirements of "fair balance," so that the viewer of the website does not overlook this medication's most dangerous side effect while reviewing the medication's benefits.

However, on the Hims website, the format is much different.<sup>277</sup> After clicking on "Sertraline for Premature Ejaculation"<sup>RXs,278</sup> under the heading of

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270. See Dien Ho, *Antidepressants and the FDA's Black-Box Warning: Determining a Rational Public Policy in the Absence of Sufficient Evidence*, 14 VIRTUAL MENTOR 483, 484 (2012), <https://journalofethics.ama-assn.org/article/antidepressants-and-fdas-black-box-warning-determining-rational-public-policy-absence-sufficient/2012-06> [<https://perma.cc/GEE3-97QN>].

271. FDA Glossary, *supra* note 154 ("Drugs that have special problems, particularly ones that may lead to death or serious injury, may have this [type of] warning information displayed within a box in the prescribing information.").

272. *Id.*

273. *Important Safety Information and Indications, Zoloft.com Black Box Warning, ZOLOFT*, <https://www.zoloft.com> [<https://perma.cc/48B7-2S9A>]. "WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS[.] ZOLOFT and other antidepressant medicines may increase suicidal thoughts or actions in some people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. Watch for these changes and call your healthcare provider right away if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe. Pay particular attention to such changes when ZOLOFT is started or when the dose is changed." (emphasis in original); *Id.*; see also *Sertraline*, *supra* note 267 (Illustrating the boxed warning which reads, "Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies; consider risk prior to prescribing. Short-term studies did not show an increased risk in patients >24 years and showed a decreased risk in patients ≥65 years. Closely monitor patients for clinical worsening, suicidality, or unusual changes in behavior, particularly during the initial 1 to 2 months of therapy or during periods of dosage adjustments (increases or decreases).").

274. Nat'l All. on Mental Illness, *Sertraline (Zoloft)*, NAMI, [https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Types-of-Medication/Sertraline-\(Zoloft\)](https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Types-of-Medication/Sertraline-(Zoloft)) [<https://perma.cc/8ASJ-PH5D>] ("In short-term studies, antidepressants increased the risk of suicidality in children, adolescents, and young adults when compared to placebo.").

275. See *supra* text accompanying notes 165-76.

276. See *Zoloft.com Black Box Warning*, *supra* note 273.

277. *Sertraline for Premature Ejaculation*, *supra* note 15.

278. *Id.*

“Sex,”<sup>279</sup> the user is welcomed to a page playfully headed “Enjoy the ride.”<sup>280</sup> There, the risk of suicide is not immediately apparent to the user nor contained in the initial list of serious side effects which appears on the page.<sup>281</sup> Indeed, the black box warning is present on the site, but only after the user clicks an embedded link which is easily overlooked and scribed in significantly smaller font.<sup>282</sup> Upon clicking, the user is re-routed to the bottom of the page where he is then alerted to risk of suicide when taking this medication.<sup>283</sup>

Should this platform be subject to the regulations to which pharmaceutical manufacturers are subject, it is unlikely that this would satisfy the FDA’s “fair balance” provision and the other rules that are slowly coming into place for internet advertising.<sup>284</sup> This is because, here, there is a focus on the medication’s benefits and a downplaying of significant risk. In this context, a patient diagnoses himself with premature ejaculation and, upon entering the page for Sertraline, sees the fun “enjoy the ride” heading and a suggestive cactus ad. Just as the FDA and expert commentators have voiced concerns about graphics and imagery in traditional DTCA, be it in broadcast or print, which detract from the risks of the medication, this should be a concern here as well.<sup>285</sup> With Sertraline in particular, the fact that the black box warning regarding the risk of suicide is not immediately apparent is especially troubling. This is because the target demographic for this medication, which includes Millennials and members of Generation Z, encompasses those who are likely to be susceptible to suicidal ideation.<sup>286</sup> This is also a demographic that is unlikely to have visited a physician in person for a full wellness screening, as studies have shown that individuals in this age range are less likely to have a primary care physician.<sup>287</sup>

In this impersonal online format, facilitated by asynchronous telemedicine and largely dependent on patient questionnaires, not only is the opportunity for an in-person, physical screening lost, but other important patient

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279. *Telehealth for a Healthy, Handsome You*, *supra* note 94.

280. *Sertraline for Premature Ejaculation*, *supra* note 15.

281. *Id.* “Some side effects can be serious. If you experience any of the following symptoms call your doctor immediately: seizures, abnormal bleeding or bruising, agitation, hallucinations, fever, sweating, confusion, fast heartbeat, shivering, severe muscle stiffness or twitching, loss of coordination, nausea, vomiting, or diarrhea, rash, hives, swelling or difficulty breathing.” *Id.*

282. *Id.*

283. *Sertraline for Premature Ejaculation*, *supra* note 15.

284. GUIDANCE FOR INDUSTRY, *supra* note 171.

285. Klara, *supra* note 60, at 656.

286. *See supra* text accompanying notes 268-73.

287. *See Gagne & Helm*, *supra* note 9. “Only 45% of 18-to-29-year-olds even *have* a primary-care physician, according to a poll from the Kaiser Family Foundation, often due to lack of access or health insurance.” *Id.*

touchpoints are foregone, as well.<sup>288</sup> For example, when a patient comes into a physician's office for an in-person appointment, the patient has the opportunity to interact with several individuals—from the receptionist, to the medical assistant, to the physician herself—all of whom have individual opportunities to gauge a patient's mental state and general demeanor.<sup>289</sup> These observations can be helpful in making an informed decision about what medication is right for a patient based on his or her individual characteristics.<sup>290</sup> This additional touchpoint of evaluation is lost in the DTC online format and further illustrates why it is crucial that important risk information be prominently displayed and not downplayed by DTC telemedicine websites.

Similar concerns arise when considering websites like Kick, which prominently promote medications like beta blockers for off-label uses like performance anxiety.<sup>291</sup> Beta blockers are medications which are typically used, and FDA-approved, to treat cardiac conditions such as high blood pressure and certain cardiac arrhythmias.<sup>292</sup> While beta blockers like Propranolol, also known as Inderal, are regularly prescribed off-label by physicians for anxiety and panic disorders,<sup>293</sup> such medications come with risks of side effects including, but not limited to, irregular heartbeat (arrhythmia), low heart rate (bradycardia), low blood pressure (hypotension), worsening of existing congestive heart failure, and dizziness.<sup>294</sup>

Kick targets users with sleep and performance anxiety issues, welcoming them to the website's home page with a statement that reads: "Insider's Edge To The Best You[:] Prescription-strength treatments & performance psychology for restorative sleep & confident presentations."<sup>295</sup> A user can then click one of the buttons below the statement to begin an asynchronous, online visit with a provider or can further browse the website to find "Kick Guides To Living Confidently," which address conditions and medica-

288. See Defino, *supra* note 4.

289. *Id.*

290. *Id.*

291. *Feeling Anxious*, *supra* note 7; see also Brown & De Vynck, *supra* note 6.

292. Mayo Clinic Staff, *Beta Blockers*, MAYO CLINIC (Aug. 16, 2019), <https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/beta-blockers/art-20044522> [<https://perma.cc/7PQF-7HDS>].

293. *Drugs & Diseases: Propranolol*, MEDSCAPE, <https://reference.medscape.com/drug/inderal-inderal-la-propranolol-342364> [<https://perma.cc/CQE8-Q6BJ>].

294. WYETH PHARMACEUTICALS, INDERAL (PROPRANOLOL HYDROCHLORIDE) TABLETS: MANUFACTURER'S LABEL 9 (2010), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/016418s080,016762s017,017683s0081bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/016418s080,016762s017,017683s0081bl.pdf) [<https://perma.cc/FE88-94RB>].

295. *Kick: Insider's Edge to the Best You*, *supra* note 5.



tions.<sup>296</sup> The first of those guides listed is entitled “Feeling Anxious? Propranolol Can Calm Your Body And Ease Your Nerves” and the prominent, introductory information therein explains how this medication, a beta blocker, is used by some of the “world’s top performers, speakers, and business professionals,” including pop star Katy Perry.<sup>297</sup> The guide goes on to explain more about the biological mechanism of performance anxiety and how beta blockers, specifically Propranolol, can help overcome the symptoms of this condition.<sup>298</sup> A section of the guide compares beta blockers to traditional anti-anxiety medications, like Xanax and Valium, and explains how beta blockers work for reducing symptoms of performance anxiety, going on to narrate the experience of well-known performers and speakers.<sup>299</sup> The guide even provides statistics about the very high percentage of musicians that have used beta blockers for anxiety and how effective these musicians felt this treatment to be.<sup>300</sup>

This guide is ostensibly an elaborate DTCA for this medication. While it is not conveyed in a traditional DTCA broadcast or print format, it is essentially an online pamphlet. It is hard to deny that page header taglines like “Feel The Fear And Do It Anyway: Unblock Potential With Propranolol”<sup>301</sup> are not akin to slogans or creative phraseology that one would encounter when viewing a television commercial or see in a magazine advertisement made by a pharmaceutical company. However, such a pharmaceutical company would likely violate FDA guidelines in such blatant promotion of an FDA-approved medication for an unapproved use.<sup>302</sup> However, Kick does include a page in this guide that provides information about side effects and which patients should avoid taking this medication,<sup>303</sup> as well as a page about off-label uses in general.<sup>304</sup> This is important information that is easily accessible to the user. Should this innovative form of DTCA be judged

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296. *Kick Guides to Living Confidently*, KICK, [https://www.gokick.com/guides/\[https://perma.cc/GS4Q-Q3FQ\]](https://www.gokick.com/guides/[https://perma.cc/GS4Q-Q3FQ]).

297. *Feeling Anxious*, *supra* note 7.

298. *Id.*

299. *Propranolol: What it Does and What it Doesn't Do*, KICK, <https://www.gokick.com/guides/anxiety/propranolol/#propranolol-what-it-does> [<https://perma.cc/9HG8-W6EU>].

300. *Id.*

301. *Feel the Fear and Do It Anyway: Unblock Potential with Propranolol*, KICK, <https://www.gokick.com/guides/anxiety/propranolol/#feel-the-fear-do-it-anyway-propranolol> [<https://perma.cc/WP8E-PS4Q>].

302. 21 C.F.R. § 202.1(e)(6)(i) (2021).

303. *Propranolol Details: Who Shouldn't Use It*, KICK, <https://www.gokick.com/guides/anxiety/propranolol/#propranolol-who-shouldnt-use> [<https://perma.cc/5CNJ-Z62Z>].

304. Katy Tripses, *What's an Off-Label Prescription?*, KICK (June 13, 2019), <https://www.gokick.com/blog/beta-blockers-faq/whats-an-off-label-prescription/> [<https://perma.cc/DA6F-38LQ>].

by traditional “fair balance” standards, this method of conveying information would likely be in compliance.

There are additional similarities to traditional DTCA by pharmaceutical companies as well. The guide contains a section entitled “Propranolol Details: How To Get It” which informs website users that they may ask either their primary care physician or a psychiatrist about this medication or, if they are “uncomfortable asking for medication,” to use Kick’s services.<sup>305</sup> This is similar to the DTC broadcast advertisement that instructs consumers to ask their doctors if this medication is right for them. However, this system provides a convenient shortcut for the non-confrontational patient who does not want to feel that she is infringing upon the prescribing expertise of her physician. Rather, Kick offers asynchronous telemedicine consultations with licensed providers—albeit providers who are not employed<sup>306</sup> by Kick<sup>307</sup>—so that the patient may avoid these uncomfortable, in-person conversations.

Viewers of ads for beta blockers for off-label use have found this promotional practice to be problematic, as well. When the DTC telemedicine website Hers advertised Propranolol via an Instagram post and touted its use for performance anxiety, viewers became discontent.<sup>308</sup> The ad, which read, “Nervous about your big date? Propranolol can help stop your shaky voice, sweating and racing heart beat” was perceived as both dangerous and offensive, eliciting viewer commentary on social media about the differences between clinical anxiety and situational anxiety and lodging accusa-

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305. *Propranolol Details: How to Get It*, KICK, <https://www.gokick.com/guides/anxiety/propranolol/#propranolol-how-to-get-it> [https://perma.cc/9SG8-BY2F].

306. See *infra* discussion in Part V.

307. *Kick Terms of Use*, *supra* note 25.

Kick does not provide medical advice or care. Kick contracts with Kick Health Medical Group, an independent, physician-owned medical group with a network of United States based Providers who provide clinical telehealth services. Kick Health Medical Group Providers deliver clinical services via the Kick platform to their patients. Providers are independently contracted or employed by the Kick Health Medical Group. Providers are not contracted or employed by Kick. The Providers, and not Kick, are responsible for the quality and appropriateness of the care they render to you. The Providers are independent of Kick and are merely using the Site as a way to communicate with you. Any information or advice received from a Provider comes from them alone, and not from Kick.

*Id.*

308. Defino, *supra* note 4.

tions about unethical drug marketing.<sup>309</sup> Ultimately, Hers issued an apology via another Instagram post, but viewers remained displeased.<sup>310</sup>

Nevertheless, while some DTC telemedicine websites overtly promote FDA-approved medications for off-label, unapproved uses, they are not regulated in the same way that pharmaceutical companies are.<sup>311</sup> This is so despite the fact that the means of advertising medications to patients are very similar to that of traditional broadcast or print DTCA done by pharmaceutical companies. However, in the DTC telemedicine context, promotion of these off-label uses goes largely unchecked by the FDA because DTC telemedicine companies are not subject to the same regulations.

#### B. *PRESCRIBING CONCERNS*

In addition to the concerns about promoting medications for off-label uses via online DTC telemedicine platforms, there are valid concerns about prescribing via these platforms, as well. The barriers to prescription access are less extensive than in a traditional patient-physician prescribing relationship given the online system, making obtaining medication more of a transactional process.<sup>312</sup> While off-label prescribing is regularly and legally performed by physicians at their discretion, such prescribing has traditionally been done following in-person evaluations where medical practitioners are able to make decisions based on a physical and mental assessment of the patient after the establishment of a patient-provider relationship.<sup>313</sup> In the DTC telemedicine context, this practice is streamlined through patient questionnaires and asynchronous telemedicine services which can help avoid the aforementioned “uncomfortable conversations.”

However, these potentially uncomfortable conversations come with in-person touchpoints that are important to ensure safe, effective prescribing.<sup>314</sup> Not only is a medical practitioner able to take essential vital signs, including blood pressure and heart rate, necessary to determine whether beta blocker therapy is appropriate for a patient, the practitioner is also able to evaluate whether the anxiety symptoms the patient is feeling are truly from anxiety.<sup>315</sup> That is, perhaps the chest discomfort one feels during self-

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309. *Id.*

310. *Id.*

311. *Id.*

312. Gagne & Helm, *supra* note 9.

313. *See generally id.*

314. *See generally* Defino, *supra* note 4.

315. Khetpal, *supra* note 18 (explaining how patients may believe that they have one, perhaps relatively benign, condition but may actually be experiencing a more complex medical phenomenon).

diagnosed<sup>316</sup> panic attacks is actually a cardiac event, an underlying condition that must be closely evaluated before commencing beta blocker therapy.<sup>317</sup> Or, perhaps the self-described anxiety is something more serious wherein further, more intensive mental health treatment, like talk therapy, is warranted.<sup>318</sup>

Nevertheless, as discussed in Part IV above, the DTC telemedicine companies claim to be nothing more than platforms wherein patients can connect with medical providers. Consequently, they claim that the patient is not establishing a patient-provider relationship with the DTC telemedicine companies themselves because the companies are not medical providers. Rather, the companies partner with physicians and physicians' groups which are licensed to practice and prescribe in the states wherein the patients are located.<sup>319</sup> Thus, the DTC telemedicine companies take the position that these physicians are the ones establishing the patient-provider relationship and thus assuming liability for patient care and prescribing decisions, all while working within the limited scope of the relationship permitted by the site.<sup>320</sup> This arrangement helps the websites avoid allegations of engagement in the corporate practice of medicine and, theoretically, shields them from liability for allegations of physician malpractice.

However, there are serious questions as to whether this is an ethical or fair practice.<sup>321</sup> In the DTC telemedicine context, the patient is enticed by a prescription drug ad produced by a company that is not formally regulated by the FDA. Often times, the patient is able to choose the medication that he or she wants, add it to an electronic shopping cart, and pay for it. Then, the patient is able to "connect" with a provider through asynchronous means, usually an online questionnaire or email correspondence. While it is true that these providers have the final say in terms of whether or not a prescription is approved,<sup>322</sup> it is concerning that the party potentially bearing the most liability for the transaction—the licensed physician—is effectively moved to the back of the process.<sup>323</sup>

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316. See Gagne & Helm, *supra* note 9. "With these services, the patient self-diagnoses, chooses the treatment, makes the request, and I worry that the doctor might just rubber-stamp it," says Steven Woloshin, director of the Center for Medicine and Media at the Dartmouth Institute." *Id.*

317. See generally *Propranolol*, DRUGS.COM (Oct. 1, 2020), <https://www.drugs.com/pro/propranolol.html#s-34070-3> [<https://perma.cc/X28D-GPYM>].

318. Gagne & Helm, *supra* note 9.

319. *Id.*

320. See generally Khetpal, *supra* note 18.

321. See Brown & De Vynck, *supra* note 6.

322. *Id.*; see also Gagne & Helm, *supra* note 9.

323. See Gagne & Helm, *supra* note 9.

VII. ONLINE DIRECT-TO-CONSUMER TELEMEDICINE COMPANIES'  
ATTEMPTS TO AVOID LIABILITY

While the DTC telemedicine companies do their best to avoid liability for the acts of the physicians with whom they partner to provide medical services,<sup>324</sup> American health law jurisprudence suggests that these platforms may ultimately be unable to do so. Just as these companies claim to serve as mere intermediaries between patients and providers,<sup>325</sup> brick-and-mortar hospitals historically claimed that they were doing nothing more than providing a space in which practitioners could provide care to patients and thus could only be held liable for administrative acts, not medical acts.<sup>326</sup> At that time, hospitals could generally only be liable for injuries to patients caused by unsafe premises or facilities,<sup>327</sup> such as trip-and-fall injuries,<sup>328</sup> but not for injuries caused by physician malpractice. Thus, hospitals enjoyed a certain amount of immunity from the acts of the medical providers that practiced within their walls.<sup>329</sup> Hospitals were able to avoid liability for the acts of physicians practicing within their facilities because the physicians were deemed mere “independent contractor[s]”<sup>330</sup> and no principal-agent relationship existed between the hospital and physicians.<sup>331</sup> Thus, given the lack of an agency relationship, courts held that hospitals could not be liable for the physicians’ medical decisions or resultant mistakes.<sup>332</sup>

However, as medicine evolved and hospitals began offering care on a “fee-for-service”<sup>333</sup> basis, hospitals were viewed as more than mere facilities in which physicians could perform services, but rather as integrated medical corporations with an overarching goal of providing the best possible patient care.<sup>334</sup> As a result, more suits were brought against hospital

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324. *Id.*

325. *Id.*

326. *E.g.*, Jones v. City of New York, 134 N.Y.S.2d 779, 781 (Sup. Ct. 1954).

327. *E.g.*, Charrin v. Methodist Hosp., 432 S.W.2d 572, 574-75 (Tex. Civ. App. 1968).

328. *Id.*

329. *Id.*

330. *E.g.*, Schloendorff v. Soc’y of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914).

331. *Id.*

332. *Id.*

333. Gregory T. Perkes, *Medical Malpractice-Ostensible Agency and Corporate Negligence—Hospital Liability May Be Based on Either Doctrine of Ostensible Agency or Doctrine of Corporate Negligence*, 17 ST. MARY’S L.J. 551, 555-56 (1986).

334. *See, e.g.*, Darling v. Charleston Cmty. Mem’l Hosp., 211 N.E.2d 253, 257 (Ill. 1965).

The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present-

physicians, even those who were ostensibly independently contracted, as they were found to be agents of the hospital through the principles of actual or apparent agency.<sup>335</sup>

For example, in *Scott v. SSM Healthcare St. Louis* a hospital argued that it could not be held vicariously liable for the acts of an independently contracted radiologist that failed to recognize a severe brain infection in a CT scan of an affected patient.<sup>336</sup> The hospital argued that there was no direct employment—or actual agency—relationship present between the radiologist and the hospital because the radiologist was an independent contractor.<sup>337</sup> In support of this argument, it noted that the radiologist’s relationship with the hospital was based upon a written contract, the radiologist was a partner in his own professional healthcare corporation through which he was paid, the hospital did not set the radiologist’s hours, and the hospital did not bill patients directly for the radiologist’s services.<sup>338</sup>

The plaintiffs, however, argued that the radiologist was an agent of the hospital because the hospital “generally controlled, or had the right to control, the conduct of the [radiologist] in his work performed at the hospital.”<sup>339</sup> Specifically, the plaintiffs noted, inter alia, that the contract between the hospital and the radiologist was of infinite duration, the hospital could terminate the contract at any time, the hospital determined the qualifications necessary for radiologists to be employed by the hospital, and the hospital set the prices for the radiologist’s services.<sup>340</sup> In addition, the radiologist was an “active member” of the hospital’s staff, the radiologist’s practice was the exclusive provider of radiology services in the hospital, and the hospital owned all the space and equipment wherein and with which the radiologist practiced.<sup>341</sup> As a result, the court found that the evidence presented was sufficient to create a jury question about whether or not the radiologist was an agent of the hospital and thus whether the hospital could be held vicariously liable for the acts of the radiologist.<sup>342</sup> Ultimately, an award for the plaintiffs was affirmed.<sup>343</sup>

The DTC telemedicine platforms, claiming to be mere neutral spaces in which patients can connect with providers to receive care, are much like

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day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment.

*Id.*

335. Perkes, *supra* note 333, at 556.

336. *Scott v. SSM Healthcare St. Louis*, 70 S.W.3d 560 (Mo. Ct. App. 2002).

337. *Id.* at 567.

338. *Id.*

339. *Id.* at 566-67.

340. *Scott*, 70 S.W.3d at 567.

341. *Id.*

342. *Id.* at 568.

343. *Id.*

the hospitals that held themselves out as mere facilities where doctors could render services. The DTC telemedicine platforms claim to establish a “direct customer relationship”<sup>344</sup> with the user of the platform and, in this way, likely seek to limit their potential liability to technical malfunctions or administrative errors. This is analogous to how hospitals were initially liable only for administrative or premises-related injuries to “users” of the hospital.<sup>345</sup> Furthermore, much like the hospital in *Scott*, which claimed that it could not be liable for the acts of the independently contracted radiologist, these platforms expressly disclaim liability for the acts of the independent providers with whom they partner.<sup>346</sup>

However, just as this argument did not hold up for hospitals in the long run, it is unlikely to do so for the DTC telemedicine platforms. Just as the radiologist in *Scott* was found to be under the direction and control of the hospital, establishing an agency relationship wherein the hospital could be held vicariously liable for the radiologist’s acts, physicians that partner with DTC telemedicine companies could be easily viewed the same way. Just as the radiologist in *Scott* held an exclusive contract with the hospital for radiology services, some physicians’ groups may hold exclusive contracts with the DTC platforms, sometimes even sharing a common name, e.g., Kick and Kick Health Medical Group.<sup>347</sup> Also, just as the radiologist was an active member of the hospital staff, some physicians’ groups share physical office space or overlap leadership with the DTC telemedicine companies.<sup>348</sup> Some DTC telemedicine companies pay physicians on an hourly basis<sup>349</sup> and assign them patients through the platforms’ portals via a matching system.<sup>350</sup> Just as the hospital in *Scott* provided all the space and equipment wherein and with which the radiologist practiced, the physicians that partner with the DTC telemedicine companies operate strictly within

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344. *Hims: Terms & Conditions*, *supra* note 25.

345. *See Jones v. City of New York*, 134 N.Y.S.2d 779, 781 (Sup. Ct. 1954); *Charrin v. Methodist Hosp.*, 432 S.W.2d 572, 574-75 (Tex. Civ. App. 1968).

346. *See, e.g., Cove Terms of Use*, COVE (Mar. 23, 2020), <https://www.withcove.com/legals/terms-of-use> [<https://perma.cc/4XD2-S658>].

347. “Kick does not provide medical advice or care. Kick contracts with Kick Health Medical Group, an independent, physician-owned medical group with a network of United States based Providers who provide clinical telehealth services. Kick Health Medical Group Providers deliver clinical services via the Kick platform to their patients.” *Kick Terms of Use*, *supra* note 25.

348. *See Gagne & Helm*, *supra* note 9 (explaining that Ro, a multifaceted direct-to-consumer telemedicine company, maintains its primary physician network through Roman Pennsylvania Medical with whom it shares office space. Additionally, Roman Pennsylvania Medical’s owner is Ro’s clinical director).

349. *Id.* (“Hims partners with an outside firm called Bailey Health, which pays physicians between \$120 and \$150 an hour.”).

350. *Id.* (explaining how a physician contracted by Hims logs into the Hims online portal “to see which customer the system has matched him with.”).

the parameters of the platform. Because of their contracts with and commitments to the DTC telemedicine companies, doctors effectively operate on “islands of care” within the parameters of the companies.<sup>351</sup> Doctors are unable to address secondary issues that may arise during the course of a consultation and are generally unable to “add information to a patient’s home medical record.”<sup>352</sup> They are limited in terms of the scope of advice that they may offer and in their ability to follow up with patients’ progress. Also, as one physician commentator<sup>353</sup> notes, “[the doctors] surely must feel some pressure to push their employer’s [the DTC medicine website’s] products.”<sup>354</sup> This further illustrates the extent to which the physicians function under the control of the DTC telemedicine companies.

In summary, there are clear congruencies between hospitals’ attempts to limit liability for the acts of “independent” physicians and those attempts currently being made by the DTC telemedicine companies. Even if these companies are viewed as mere facilitators of care at the present time, there is evidence that the companies are becoming increasingly popular, particularly in light of the COVID-19 pandemic.<sup>355</sup> They are increasingly expanding their offerings to include a broad array of testing<sup>356</sup> and prescriptions, and they induce patients to use their services through DTCA, just as a hospital may do through advertisements on a roadside billboard or in a local magazine. Therefore, just as hospitals eventually came to be viewed as integrated medical corporations, it is likely that the DTC telemedicine companies will follow suit. Liability for the acts of contracted physicians will follow, and for that reason it is important that Congress or regulatory agencies govern DTC telemedicine operations specifically. Such oversight will ultimately help protect patients, DTC companies themselves, and help to preserve the integrity and reputation of the medical profession.

### VIII. RECOMMENDATIONS FOR REGULATION OF DIRECT-TO-CONSUMER TELEMEDICINE WEBSITES

#### A. WHY FEDERALLY REGULATE DTC TELEMEDICINE COMPANIES?

As discussed above,<sup>357</sup> DTC telemedicine websites have grown in popularity over the years, particularly during the COVID-19 pandemic.

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351. Khetpal, *supra* note 18.

352. *Id.*

353. *Id.* The author, Vishal Khetpal, was a third-year medical student when he authored this article and is currently an internal medicine physician. See VISHAL KHETPAL, <https://vishalkhetpal.com> [<https://perma.cc/NL9T-L6WF>].

354. Khetpal, *supra* note 18.

355. JAIN & MEHROTRA, *supra* note 11.

356. Azevedo, *supra* note 116.

357. See *supra* text accompanying notes 113-17.



These websites may, indeed, become part of the post-pandemic “new normal.” Patients, particularly those who are members of younger, tech-savvy generations, have come to rely on these websites for fulfilment of everyday prescription medications. Consequently, these patients may continue to depend on this mode of healthcare delivery for monthly prescription refills if they remain satisfied with the DTC telemedicine companies’ offerings. It follows that, given increased reliance on electronic prescription and delivery of medication, these individuals—who statistically lacked a primary care provider prior to turning to DTC telemedicine<sup>358</sup>—may be less likely to visit a doctor’s office for routine screenings. For this reason, it is essential that either Congress or a regulatory agency take appropriate measures to protect patients as they continue to have their healthcare needs met through this novel delivery system.

Regulation of DTC telemedicine is in the best interest of the medical profession, as well. Doctors are afforded broad latitude to prescribe as they see fit, even when it comes to medications for off-label uses.<sup>359</sup> If adverse events transpire as a result of injudicious online drug promotion and subsequent DTC prescribing, physicians may be viewed as lacking in their abilities to make proper decisions about patient care. This could undermine public trust in the medical profession and lead to imposition of legal liability on medical practitioners. If Congress or a regulatory agency does not step in on the federal level, common law will likely fill the gaps as lawsuits against providers, or the platforms themselves, come about. Judicial resolution of suits in varied jurisdictions may lend itself to a lack of rule uniformity and confusion for all parties involved. Therefore, regulation of DTC telemedicine companies at the federal level should be strongly considered.

B. *SUBJECT DTC TELEMEDICINE COMPANIES TO SIMILAR REGULATION AS THAT TO WHICH PHARMACEUTICAL COMPANIES ARE SUBJECT*

As discussed above,<sup>360</sup> the DTC telemedicine platforms are engaging in an elaborate form of DTCA on a regular basis which is much like the DTCA long utilized by pharmaceutical manufacturers. Nevertheless, while pharmaceutical manufacturers’ DTC advertisements are subject to an elaborate composition of legislation and agency regulations, online telemedicine DTCA is left largely unchecked.<sup>361</sup> The DTCA method employed by DTC telemedicine companies ostensibly poses more, or at least comparable, risks

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358. See Gagne & Helm, *supra* note 9.

359. Cortez, *supra* note 221, at 124. “[P]hysicians may prescribe products independently from, and occasionally in defiance of, the approved labeling.” (internal quotations omitted). *Id.*

360. See *supra* text accompanying notes 262-310.

361. See *supra* text accompanying notes 262-65.

to patient welfare than those posed through DTCA by pharmaceutical manufacturers. This is because DTC telemedicine companies' patients have one-stop-shop access to medications, including those advertised and prescribed for off-label, non-FDA approved uses, without visiting a doctor in person or undergoing a physical screening.<sup>362</sup> Furthermore, these websites frequently utilize exclusively asynchronous telemedicine technology wherein the patient's interaction with the physician is limited to questionnaires and email correspondence.<sup>363</sup>

The rules for DTCA by pharmaceutical companies were put in place to protect patients while consequently allowing them to be informed participants in their care.<sup>364</sup> Such rules are particularly crucial in the realm of drugs prescribed for off-label uses. Therefore, it seems natural that DTC telemedicine companies should be subject to FDA rules surrounding pharmaceutical promotion, particularly those rules which proscribe ads that are "false, lacking in fair balance, or otherwise misleading."<sup>365</sup> Given the streamlined nature of prescription access through DTC telemedicine websites, the frequent use of mere questionnaires to evaluate patients' health histories, and the limited scope in which the physicians with whom the DTC telemedicine companies can operate, it is crucial that the United States government make every effort to ensure that patients are well informed about the medications advertised to them. Since a regulatory framework of this nature is already in place for pharmaceutical companies, it is logical to bring DTC telemedicine companies, which employ similar drug promotion tactics, under the umbrella of this governance.

Furthermore, some experts speculate that as DTC telemedicine platforms continue to proliferate and thrive, they will ultimately be acquired by pharmaceutical manufacturers.<sup>366</sup> In this event, FDA rules applicable to pharmaceutical companies may govern by default, in some respects. However, since pharmaceutical companies have not historically transacted business nor promoted medications in this one-stop-shop, DTC manner via the internet, existing guidelines will likely need to be enhanced or adjusted to better reflect this mode of healthcare delivery. Therefore, regardless of whether DTC telemedicine companies remain autonomous startups or if they are acquired by pharmaceutical companies, the present time is not too soon to consider federal governance of this healthcare model.

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362. See *supra* text accompanying notes 311-13.

363. See *supra* text accompanying notes 320-22.

364. See *supra* text accompanying notes 143-48.

365. 21 C.F.R. 202.1(e)(6) (2021).

366. See generally Zoë LaRock, *Pharma Could Become More Active in Direct-to-Consumer Drug Delivery in 2020*, BUS. INSIDER (Jan. 2, 2020, 8:47 AM), <https://www.businessinsider.com/pharma-could-set-sights-on-direct-to-consumer-drug-delivery-2020-1> [<https://perma.cc/JPS5-KU7A>].

C. *LOOK TO ONLINE PHARMACY LEGISLATION FOR ADDITIONAL GUIDANCE TO AID IN MODEL LEGISLATION*

In addition to examining existing regulations governing pharmaceutical company operations, lawmakers may look to federal governance of online pharmacies for guidance on how to regulate DTC telemedicine companies. As discussed above,<sup>367</sup> the Ryan Haight Act was enacted in response to grave concerns regarding patient safety in the realm of online prescribing. The Act was promulgated with “rogue” pharmacies in mind, as well as online pharmacies that remotely prescribe through a questionnaire-based system.<sup>368</sup> While the Act ostensibly fell short by failing to regulate non-controlled substances,<sup>369</sup> its primary, substantive provisions may provide a framework for legislation of DTC telemedicine companies. This is because DTC telemedicine companies, like some online pharmacies, similarly rely on online prescribing with limited physician involvement.

For example, model legislation could require something similar, but not identical to, the Ryan Haight Act’s in-person evaluation requirement.<sup>370</sup> However, such legislation would need to be tailored so as to not completely undermine the primary purpose of DTC telemedicine, namely the convenience of on-demand care. Thus, perhaps such a requirement in this context could entail the patient certifying that: (1) he or she has undergone a physical examination with a licensed practitioner within the previous two years, or another appropriate time frame, and (2) that the physical examination revealed nothing that would undermine the safety or efficacy of the medication being remotely prescribed. Such a requirement would arm remotely prescribing physicians with information regarding a patient’s physical condition and potential comorbidities, rather than merely relying on self-reported vitals. The requirement would be particularly useful where medications prescribed online carry potentially harmful side effects, including beta blockers and antidepressants prescribed for off-label uses. The legislation could also encourage patients to coordinate DTC telemedicine services with an in-person, primary care physician for follow-up and monitoring so as to ensure that the medication is appropriate and that any adverse side effects are promptly recognized and addressed.

The Ryan Haight Act’s monthly quantity reporting requirement<sup>371</sup> may also serve as a useful model. Just as the Ryan Haight Act requires online pharmacies to report the quantity of controlled substances dispensed on a monthly basis unless the amounts dispensed fall below certain designated

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367. *See supra* text accompanying notes 193-99.

368. *See supra* text accompanying notes 194-99.

369. *See supra* text accompanying notes 210-13.

370. *See supra* text accompanying note 200.

371. *See supra* text accompanying note 202.

thresholds, perhaps DTC telemedicine companies which frequently facilitate prescriptions for off-label use medications should be required to report prescriptions sold at a certain frequency. A specific rule for reporting may depend on further analytics including, but not limited to, the specific medications sold, potentiality for adverse side effects, reports of adverse reactions, and the frequency at which such a medication is prescribed in an in-person, traditional healthcare setting. Consequently, an ancillary benefit of legislation of this nature is that it may provide an avenue to expansion of online pharmacy governance into the realm of non-controlled substances.

#### IX. CONCLUSION

Notwithstanding the foregoing discussion, given tangential influences from regulatory agencies including the FDA, FTC, and DEA, as well as state medical boards, it has been argued that a regulatory gap does not exist in the area of DTC telemedicine.<sup>372</sup> Commentators contend, rather, that this is a heavily regulated space.<sup>373</sup> Nevertheless, the fact remains that there is no specific legislation or agency regulations governing DTC telemedicine company operations. The tangential influences from several entities create a proverbial “too many cooks in the kitchen” situation which increases the likelihood that important issues, including patient safety and confidence in physician prescribing practices, will fall through the cracks. In this event, common law is likely to fill these cracks on a case-by-case basis with jurisdiction-specific rulings that carry the potential to create confusion and inconsistency on a large-scale basis. As DTC telemedicine companies continue to gain popularity in a post-pandemic environment, it is essential that lawmakers act at the federal level in order to protect patients and preserve the integrity of the medical profession.

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372. HCLT Podcast, *supra* note 104.

373. *Id.*

## APPENDIX A

## Table of Acronyms

AMA – American Medical Association  
CMS – Centers for Medicare and Medicaid Services  
CSA – Controlled Substances Act  
DEA – Drug Enforcement Administration  
DTC – Direct-to-consumer  
DTCA – Direct-to-consumer advertising  
FCA – False Claims Act  
FDA – U.S. Food and Drug Administration  
FDCA – Food, Drug, and Cosmetic Act  
FTC – Federal Trade Commission  
OPDP – Office of Prescription Drug Promotion  
OTC – Over-the-counter  
PhRMA – Pharmaceutical Research and Manufacturers of America  
SSRI – Selective Serotonin Reuptake Inhibitor