Rutgers University Law Review

VOLUME 77 COMMENTARIES
Fall 2024

SIDE EFFECTS MAY INCLUDE MISINFORMATION: USING A DUAL AGENCY APPROACH TO FILL THE TELEMEDICINE REGULATORY GAP

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I. INTRODUCTION

The internet will promise you a cure for anything. These promises are typically brought to heel by the regulatory agencies that enforce advertising law. As is to be expected from the imperfect process of integrating grand concepts such as law into flawed mechanisms such as language, however, some promises escape scrutiny.

Unregulated prescription drug advertisements are this type of lucky promise. A certain type of business model, operating a platform that connects patients to medicine, emerged sometime during the pandemic.[1] In this model, often referred to as telemedicine,[2] potential patients can

* I sincerely thank Professor Amy Widman for her guidance in the writing of this paper and for the sharing of her expertise in and passion for the field of Administrative Law.

1. *See* discussion *infra* Section III.

2. Telemedicine can refer to other types of internet-based healthcare, not just ones operating on these models. *See* Rachel Ann Tee-Melegrito, *Telemedicine: What to Know,* MEDICALNEWSTODAY (Sept. 30, 2022), https://www.medicalnewstoday.com/articles/telemedicine.

be presented with lists of prescription drugs that they can "apply" for.[3] These patients are coaxed to the platforms by extensive advertising, which has not shied away from explicitly naming prescription drugs in their advertising.[4] Generally, naming prescription drugs in advertising subjects the advertiser to a host of disclosure requirements, ensuring whoever is listening knows, *inter alia*, if this drug can kill them.[5] Telemedicine operations and their advertising campaigns are excluded from this rule.[6]

These drug advertisements should be subject to prescription drug advertising guidelines. The Food and Drug Administration ("FDA") is typically tasked with regulating prescription drug advertising and bringing enforcement actions against violators of those rules.[7] However, granting exclusive control to this agency has shortcomings.[8] To counteract those shortcomings, the expertise of the other major player in advertising regulation, the Federal Trade Commission ("FTC"), can be leveraged. A regulatory scheme that emphasizes both agencies' relevant expertise by having the Federal Trade Commission enforce the Food and Drug Administration's standards allows for an inclusive approach to tackling this new iteration of regulatory evasion.

II. ADVERTISING REGULATION

The FTC and the FDA share jurisdiction over the marketing of food, drugs, devices, and cosmetics, which are considered a high priority to regulate for health and safety reasons.[9] The FTC primarily deals with *advertising* of these products, that is, dissemination that is "likely to

3. *See, e.g.,* Teresa Carr, *Amid Regulatory Gaps, Telehealth Prescribers Flourish*, UNDARK (Nov. 1, 2023), https://undark.org/2023/11/01/telehealth-drugs/. The characterization of "apply" is referring to the criticism of these platforms for "starting from the treatment and asking whether the patient is right for *it*." *Id.*

4. *See id.*; discussion *infra* Section III.

5. *See Prescription Drug Advertising | Questions and Answers: What Must Product Claim Ads Tell You?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers#requirements (June 19, 2015).

6. *See* discussion *infra* Section III.

7. *See* discussion *infra* Section II.

8. *See* discussion *infra* Section IV(B).

9. *See* U.S. FOOD & DRUG ADMIN., MOU-225-71-8003, MEMORANDUM OF UNDERSTANDING BETWEEN THE FEDERAL TRADE COMMISSION AND THE FOOD & DRUG ADMINISTRATION (1971) [hereinafter MEMORANDUM OF UNDERSTANDING]. For history regarding regulation of these particular categories of products, see generally John P. Swann, *How Chemists Pushed for Consumer Protection: The Food and Drugs Act of 1906*, 24 CHEM. HERITAGE no. 2, 2006, at 6–11.

induce, directly or indirectly . . . purchase."[10] In contrast, the FDA primarily deals with *labeling* of these products, that is, "all labels and other . . . printed, or graphic matter" found on or "accompanying" a product.[11] One exception is prescription drug advertising, where the FDA has sole jurisdiction over both labeling and marketing.[12] The two agencies work together to ensure that their overlapping jurisdictions do not result in unharmonious rulings.[13]

The FTC's Bureau of Consumer Protection sources its statutory authority over advertising through its enabling statute, which grants the agency jurisdiction over "unfair" and "deceptive" practices generally.[14] In essence, the Bureau serves to protect the public from advertisers who lie.[15] They do this by subjecting a questionable advertisement to either a "deceptive" or an "unfair" analysis.[16] The former centers around the truth or falsity of claims made within an advertisement, while the latter focuses on foreseeable potential injury and the cost-benefit of requiring the companies to alter their actions.[17]

The FDA has sole authority over regulating prescription drug advertising.[18] Prescription drug advertising is "information, other than labeling, that promotes a drug product and is sponsored by a manufacturer."[19] In contrast to the FTC, which subjects all advertising to either an "unfair" or "deceptive" analysis, the FDA approaches prescription drug advertising regulation by category.[20] First, the advertisement must be created by a pharmaceutical drug company to be regulated.[21] Then, the advertisement is classified into one of three

10. 15 U.S.C. § 52(a); *see also* FED. TRADE COMM'N, HEALTH PRODS. COMPLIANCE GUIDANCE 2 (2022) [hereinafter HEALTH PRODUCTS COMPLIANCE GUIDANCE].

11. MEMORANDUM OF UNDERSTANDING, *supra* note 9; 21 U.S.C. § 321(m); *see also* 21 U.S.C. § 321(k) (defining "label").

12. MEMORANDUM OF UNDERSTANDING, *supra* note 9; *see also* 21 U.S.C. § 352(n) (section of the federal Food and Drug Act dealing with prescription drug advertising guidelines).

13. MEMORANDUM OF UNDERSTANDING, *supra* note 9.

14. 15 U.S.C. § 45(a)(1).

15. *See* Annie V. Maher & Leslie Fair, *The FTC's Regulation of Advertising*, 65 FOOD & DRUG L.J. 589, 590 (2010).

16. *Id.*

17. See *id.* at 595, 600 (describing both the "deceptive" and the "unfair" standard).

18. Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 670 (2006). *But see infra* text accompanying note 87.

19. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 428 (2002).

20. *See* Maher & Fair, *supra* note 15, at 589–90.

21. *See* Kristina L. Bitzer, Comment, *Online and Off-Label: Closing the Regulatory Gap in Online Direct-to-Consumer Drug Promotion and Prescribing,* 42 N. ILL. U. L. REV. 164, 178 (2021).

categories: "product claim" ads, "reminder" ads, and "help seeking" ads.[22] This distinction serves to further limit the FDA's reach: Only "product-claim" advertisements, which include a product's name with claims of therapeutic effectiveness, are subject to FDA regulatory requirements.[23]

Substantially, the FDA regulates advertisements by requiring certain actions and prohibiting others. A "product claim" advertisement is required to list the drug's generic name and formula, and present a shortened "major statement" with "adequate provision" for the full product's labeling.[24] This "major statement" only has to contain "the product's most important risk-related information in the audio or audio and visual parts of the advertisement."[25] Because the underlying motivation of allowing prescription drug advertisements to be presented directly to the public is to educate the consumer,[26] the FDA has additional provisions requiring advertisements to be accurate and fair, both in their content and in presentation.[27]

The two agencies have a history of working together due to their overlapping jurisdiction over the marketing of food, drugs, devices, and cosmetics. Explicitly, the agencies are united in a Memorandum of Understanding, the goal of which was to define the scope of their individual responsibilities and display their express agreement to working together in "the common objective of preventing injury and deception to the consumer."[28] Further, when their jurisdiction does overlap, they accord deference to one another's findings.[29]

22. *See Basics of Drug Ads,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads (June 19, 2015).

23. Ziad F. Gellad & Kenneth W. Lyles, *Direct-to-Consumer Advertising of Pharmaceuticals,* 120 AM. J. MED. 475, 477 (2007).

24. Palumbo & Mullins, *supra* note 19, at 430–31. "Adequate provision" essentially means including a way to access the information contained in the full product labeling, such as a phone number or website. *Id.*

25. *OPDP Frequently Asked Questions (FAQs)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-frequently-asked-questions-faqs (May 31, 2023).

26. *See* Donohue, *supra* note 18, at 685–88.

27. *See* 21 C.F.R. § 202.1. The agency has a total of 20 enumerated actions that make a prescription drug advertisement per se "false, lacking in fair balance, or otherwise misleading," and 13 enumerated actions that may make an advertisement "false, lacking in fair balance, or otherwise misleading." *Id.* at (e)(6)–(7).

28. MEMORANDUM OF UNDERSTANDING, *supra* note 9.

29. *See Enforcement Policy Statement on Food Advertising*, FED. TRADE COMM'N (May 13, 1994), https://www.ftc.gov/legal-library/browse/enforcement-policy-statement-food-advertising ("The Commission has previously indicated that where a claim is subject to the joint jurisdiction of the FTC and the FDA, it will accord significant deference to the FDA's standards."). *See generally* Sarah Duranske, *This Article Makes You Smarter! (or, Regulating Health and Wellness Claims),* 43 AM. J. L. & MED. 7 (2017).

III. DIRECT TO CONSUMER TELEMEDICINE

Direct-to-consumer ("DTC") telemedicine, a novel approach to accessing medical treatment, skyrocketed during and after the pandemic.[30] In contrast to traditional telehealth, which served as a gap-filler way to access your primary care physician with whom you had an established relationship,[31] these telemedicine platforms connect you with a doctor-on-demand that prescribes you medication.[32] Many platforms do not even require a visit with a physician; instead, a self-reported questionnaire is sent for review to a medical professional, typically approved, which then results in the prescription being sent to a local pharmacy or the drugs being delivered directly.[33] Significant concerns have been raised with this practice.[34]

These platforms promote the prescription drugs they offer in order to draw users.[35] Drugs advertised by DTC telemedicine platforms vary widely, from routine topical acne treatment to experimental drugs such as ketamine.[36] The latter side of the spectrum includes platforms advertising black-box drugs and controlled substances, both categories requiring heightened warnings due to their high risk of danger.[37] Yet because telemedicine platforms solely serve as an intermediary connecting patients to pharmacies and medical professionals, and

30. *See* Carr, *supra* note 3.

31. *See* Gabriela Weigel et al., *Opportunities and Barriers for Telemedicine in the U.S. During the COVID-19 Emergency and Beyond,* KFF (May 11, 2020), https://www.kff.org/womens-health-policy/issue-brief/opportunities-and-barriers-for-telemedicine-in-the-u-s-during-the-covid-19-emergency-and-beyond/.

32. *See* Suzanne G. Bollmeier et al., *Direct to Consumer Telemedicine: Is Healthcare from Home Best?*, 117 MO. MED. 303, 306 (2020).

33. Bitzer, *supra* note 21, at 175–76.

34. *See, e.g.,* Rolfe Winkler & Joseph Walker, *Startups Make It Easier to Get ADHD Drugs. That Made Some Workers Anxious.*, WALL ST. J. (Mar. 26, 2022, 12:00 AM), https://www.wsj.com/articles/startups-make-it-easier-to-get-adhd-drugs-that-made-some-workers-anxious-11648267205; Justin M. Dubin et al., *Guideline-Discordant Care Among Direct-to-Consumer Testosterone Therapy Platforms*, 182 JAMA INTERNAL MED. 1321, 1321 (2022) (finding a "secret shopper" with no hormonal imbalances was prescribed testosterone by 6 out of 7 telemedicine platforms, in violation of traditional testosterone prescribing guidance).

35. *See, e.g.,* Khadeeja Safdar & Andrea Fuller, *Misleading Ads Fueled Rapid Growth of Online Mental Health Companies*, WALL ST. J. (Dec. 27, 2022; 12:14 PM), https://www.wsj.com/articles/telehealth-cerebral-done-ads-mental-health-adhd-11672161087.

36. *See* Bollmeier et al., *supra* note 32, at 305; NUE.LIFE, https://nue.life (last visited Sept. 8, 2024) (webpage for a telehealth company that provides at-home ketamine mental health therapy).

37. *See* Safdar & Fuller, *supra* note 35.

therefore are not prescription drug companies, they evade FDA regulatory requirements.[38]

The FDA's efforts to minimize the risks of prescription drug advertising are done through thorough research, rulemaking, and enforcement.[39] Advertisements are considered in totality, utilizing a comprehensive regulatory scheme involving a close look at both their external presentations and the implicit and explicit claims, as well as requiring the substantiation of those claims meeting scientific rigor.[40] Because these advertisements are currently completely exempted from these public protections due to this regulatory gap, the FDA's efforts to minimize the risk to public health through direct-to-consumer prescription drug advertising are circumvented.

IV. REGULATORY PROPOSAL

A. Considerations for a Different Statutory Framework

DTC telemedicine is increasingly promoted as a way to access healthcare easily and efficiently.[41] Market valuations of the industry overall remain high and have a positive outlook.[42] Large players such as Amazon have observed the popularity of this model and have been creating their own DTC telehealth and medicine platform options.[43]

38. *See id.*

39. *See* Palumbo & Mullins, *supra* note 19, at 427–30.

40. *See id.*

41. *See* DOXIMITY, 2023 STATE OF TELEMEDICINE REPORT 6, 9 (2023), https://press.doximity.com/reports/state-of-telemedicine-report-2023.pdf; Anastassia Gliadkovskaya, *Most Telehealth Consumers Prefer Virtual Appointments to In-Person Visits for Certain Routine Care, Survey Finds*, FIERCE HEALTHCARE (Sept. 30, 2022; 12:00 PM), https://www.fiercehealthcare.com/digital-health/growing-number-consumers-prefer-telehealth-routine-care-survey-finds ("Among the routine care most respondents prefer via telehealth, 8 out of 10 consumers cited prescription refills. Consumers also cited other routine visits such as reviewing medication options (72%) and discussing test results (71%).").

42. *See* Oleg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?*, MCKINSEY (July 9, 2021), https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality (reporting "[t]elehealth utilization has stabilized at levels 38X higher than before the pandemic. . . telehealth adoption overall has approached up to 17 percent of all outpatient/office visit claims . . . investment in virtual care and digital health more broadly has skyrocketed, fueling further innovation, with 3X the level of venture capitalist digital health investment in 2020 than it had in 2017."); *The New Telehealth Economy*, JP MORGAN, https://www.jpmorgan.com/payments/payments-unbound/volume-2/the-new-telehealth-economy (last visited Mar. 10, 2024).

43. *See Amazon One Medical*, AMAZON, https://health.amazon.com/ (last visited Sept. 8, 2024).

Further, the regulatory landscape is becoming increasingly friendly toward the long-term establishment of direct-to-consumer telemedicine.[44] At the time of writing, the DEA is in the process of relaxing its previous guidance on prescribing controlled substances.[45] Other regulations, such as state licensure requirements and Medicaid policies, are adjusting with consideration of the trend toward virtual visits and the adoption of telemedicine.[46] The apparent regulatory blessing of these operational models of healthcare delivery, as well as the relative success of these particular advertising practices,[47] suggests that the practice of advertising prescription medication by non-prescription drug manufacturers will continue.

This gap provides an opportunity for a new regulatory framework that can both serve to provide advance notice to the industry about compliant advertising practices and provide proper education to the consumer about pharmaceuticals on a wider scale. Current advertising regulation grants one agency both the power to set the standards and the responsibility to enforce them.[48] With regards to pharmaceutical drug advertisements not made by pharmaceutical drug companies, a new framework can be imagined with a different division of labor: the FDA sets the standards, and the FTC enforces these standards.

Granting the duty to create standards to the FDA and that of enforcement to the FTC would allow for proper, consistent information distribution regarding prescription drugs to reach the consumer. A significant reasoning underlying allowing direct-to-consumer prescription drug advertising at all is the desire to educate the consumer and provide them with better control of their health.[49] Creating a regulatory framework that maximizes the ability of the consumer to receive accurate information regarding prescription drugs by leveraging the FTC's vast enforcement arm to ensure companies are not spreading mis- or under- information about prescription drugs is in service of this

44. *See* Jim Sharp, *DEA Issues Extension of Ryan Haight Act Through 2024,* REHAB. & CMTY. PROVIDERS ASS'N (Oct. 11, 2023), https://paproviders.org/dea-issues-extension-of-ryan-haight-act-through-2024/.

45. *See id.* ("Key concerns from stakeholders expressed during the listening sessions were related to in-person visit requirements, the 30-day prescribing limit in the initially proposed rules, and adding various reporting requirements, such as notating on prescriptions that they were prescribed via telemedicine.").

46. *See* Aarti Pandya et al., *The Regulatory Environment of Telemedicine After COVID-19,* 10 J. ALLERGY & CLINICAL IMMUNOLOGY: IN PRACTICE 2500, 2505 (2022) ("There is no reason to anticipate that [relaxation of certain requirements] will end. For these reasons, telemedicine therefore is likely to continue as an important part of medical practice.").

47. *See* Safdar & Fuller, *supra* note 35; Carr, *supra* note 3.

48. *See* discussion *supra* Section II.

49. *See* Donohue, *supra* note 18, at 687–88.

goal. Instead of defining mis- or under- information based on the FTC's generalist advertising standards, thereby creating possible inconsistencies based on the facts unique to a particular advertisement, the advertisements would be regulated by the FDA's categorical and extensively researched requirements and prohibitions.[50] Further, this type of regulatory setup would be more fair for the market by not presenting two separate standards for what is considered a "proper" prescription drug advertisement and by presenting consistent, advance notices on what these advertisements should contain.

B. FDA Alone Is Inadvisable

Granting jurisdiction to the FDA alone to regulate these advertisements is inadvisable.[51] The FDA has jurisdiction over the advertising of prescription drugs produced by prescription drug manufacturers.[52] The telemedicine platforms running questionable advertisements of prescription drugs are not prescription drug manufacturers, and therefore are not subject to FDA jurisdiction.[53] In order to have the FDA fully oversee these advertisements, their jurisdiction would need to be expanded to either eliminate the manufacturer requirement or add an additional category of company that is regulated. The line-drawing required of the latter would be practically difficult and likely an incomplete solution, as it would not be hard to imagine new loopholes evading the technical classifications. The former would be inadvisable because the FTC is better equipped to handle monitoring and enforcement, and it would unsettle the FDA's jurisdiction in other irrelevant areas.

Furthermore, prescription drug manufacturers and telemedicine platforms are situated in different contexts, and therefore, the monitoring required to police them is different. In order to be a prescription drug manufacturer operating in the United States, you are

50. *See* discussion *supra* Section II.

51. Some proposals for regulating these advertisements call for the FDA to come up with a solution for enforcement. *See*, *e.g.*, Khadeeja Safdar & Andrea Fuller, *Senators Push FDA Action Against Misleading Ads Touting Drugs on Social Media*, WALL ST. J. (Feb. 15, 2024), https://www.wsj.com/health/healthcare/senators-push-fda-action-against-misleading-ads-touting-drugs-on-social-media-fc70ec5b (reporting that Senators Durbin and Braun criticized the FDA for the "gaping loopholes in their oversight" and requesting they answer a series of questions regarding their prescription drug advertising policies); Noah Schwartz, *Congressional Leaders Look to Reel in Telehealth Ads Promoting Drugs*, BECKERS HOSP. REV. (Jan. 20, 2023), https://www.beckershospitalreview.com/digital-marketing/congressional-leaders-look-to-reel-in-telehealth-ads-promoting-drugs.html.

52. MEMORANDUM OF UNDERSTANDING, *supra* note 9.

53. *See* discussion *supra* Section III.

required to file a registration with the FDA.[54] This registration is done biannually and requires the company to disclose what drugs they are producing.[55] This centralized data repository means the FDA already has a significant amount of information on each company, which likely informs their advertising enforcement. In contrast, telemedicine companies operate without such centralized registration schemes.[56] In order for the FDA to monitor an ever-growing number of telemedicine startups,[57] it would require the agency to develop an investigatory arm that functions to find advertisements from entities that they do not have any basic information on. Developing such a monitoring arm would undoubtedly take a significant amount of time, effort, and financing for the exclusive use of regulating prescription drug advertising. It is unclear how long this would take and, therefore, how many drug advertisements will evade scrutiny.[58]

In contrast, the FTC engages in enforcement actions against advertisers who have no central repository of data about[59] and regularly updates and keeps abreast of the new media forms of advertising.[60] They

54. *Registration and Listing*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/fda-basics-industry/registration-and-listing (July 7, 2023); Hans Howk, *Drug Manufacturing Licensing Requirements,* WOLTERS KLUWER (Sept. 7, 2023), https://www.wolterskluwer.com/en/expert-insights/drug-manufacturing-licensing-requirements.

55. Howk, *supra* note 54.

56. *See Legal Considerations for Implementing a Telehealth Program*, RURAL HEALTH INFO. HUB, https://www.ruralhealthinfo.org/toolkits/telehealth/4/legal-considerations (last visited Mar. 10, 2024).

57. *See* Imon Chakraborty, Sisira Edirippulige & P. Vigneswara Ilavarasan, *The Role of Telehealth Startups in Healthcare Service Delivery: A Systematic Review*, 174 INT'L J. MED. INFOMATICS 1, 2 (2023).

58. Further, there are critics of the FDA's current prescription drug monitoring arm. *See, e.g.*, Robin Feldman, *Advertising Medicine, Selling the Cure*, 26 STAN. TECH. L. REV. 1, 48, 30–33 (2023); GOV'T ACCOUNTABILITY OFF., PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 17–24 (2002); Bitzer, *supra* note 21, at 181 ("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").

59. FTC engages in advertising enforcement for all kinds of products, from children's toys to frozen yogurt, on all kinds of platforms. *See* LESLIE FAIR, FEDERAL TRADE COMMISSION ADVERTISING ENFORCEMENT 3–68 (2008), https://www.ftc.gov/sites/default/files/attachments/training-materials/enforcement.pdf (listing over sixty pages of FTC advertising enforcement cases organized by topic).

60. *See, e.g., Native Advertising: A Guide for Business*, FED TRADE COMM'N (December 2015), https://www.ftc.gov/business-guidance/resources/native-advertising-guide-businesses [hereinafter NATIVE ADVERTISING GUIDE] (updating definitions in 2015 of FTC's enforcement against "native advertising," a new form of digital advertising that "blends" with the surrounding context); FED. TRADE COMM'N BUREAU OF CONSUMER PROT., ADVERTISING AND MARKETING ON THE INTERNET: RULES OF THE ROAD 1 (2000) (explaining

provide guidance ranging from how to format disclosures in the internet era[61] to modification of endorsement doctrines to adapt to influencer marketing.[62] They are well-versed in topics such as "native advertising," where advertising is blended to look like surrounding content.[63] While the FDA may have developed related skills through their regulation of prescription drug advertisements, their guidance on internet advertising has not been updated since 2014 and is considered to be in its infancy.[64] Granting the FDA full jurisdiction would forgo this well-informed body of substantive experience in monitoring advertising.[65]

Another problem that arises with granting the FDA full jurisdiction by eliminating the pre-requirement of being a "drug manufacturer" is that it would unsettle jurisdiction in other areas. Currently, this limitation ensures that, for example, pharmacies marketing drug price cuts are not subject to advertising laws.[66] Eliminating this limitation risks suddenly and exponentially expanding the jurisdiction of the FDA in unpredictable ways. Considering DTC telemedicine companies evade jurisdiction by considering themselves intermediaries,[67] expanding jurisdiction to cover intermediaries would almost certainly overstep into the acts of pharmacies and physician's clinics.

FTC business guidelines in the 2000's regarding truthful advertising in the context of the internet).

61. *See* FED. TRADE COMM'N, .COM DISCLOSURES: HOW TO MAKE EFFECTIVE DISCLOSURES IN DIGITAL ADVERTISING 1–2 (2013).

62. *See, e.g., Federal Trade Commission Announces Updated Advertising Guides to Combat Deceptive Reviews and Endorsements*, FED. TRADE COMM'N (June 29, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/06/federal-trade-commission-announces-updated-advertising-guides-combat-deceptive-reviews-endorsements; 16 C.F.R. § 255 (updated section); FED. TRADE COMM'N, DISCLOSURES 101 FOR SOCIAL MEDIA INFLUENCERS 3–6 (2019) [hereinafter DISCLOSURES FOR SOCIAL MEDIA] (plain language explanation of social media disclosure requirements).

63. NATIVE ADVERTISING GUIDE, *supra* note 60.

64. *See* Bitzer, *supra* note 21, at 181–82.

65. *But see* FDA ADVERTISING AND PROMOTION MANUAL ¶ 330 (J.W. Schomisch, ed., 2023) [hereinafter FDA ADVERTISING MANUAL] (describing the sharing of information between the FTC and the FDA, therefore, allowing the FDA to access this body of knowledge). However, informational exchange alone is likely not enough to meet the challenges of being tasked with enforcing law against a substantial new number of companies.

66. *See id.* at ¶ 440 ("For example, if a pharmacy chooses to advertise the price it charges for a particular prescription, or if a physician clinic advertises the availability of a treatment, the ads are not subject to FDA regulation, provided that they are neither subsidized nor influenced by the manufacturer, distributor or packer.").

67. *See* Safdar & Fuller, *supra* note 35.

C. FTC Alone Is Inadvisable

The FTC's substantive standards for evaluating the truth or falsity of an advertisement are not a good fit for regulating prescription drug advertisements. For example, consider a questionable advertisement, such as one advertising FDA-regulated antidepressant sertraline for anxiety, stating that it can "help your mental health" with no other disclosures.[68] This advertisement would clearly be in violation of FDA standards, missing disclosure of the "major statement" with "adequate provision" for the "brief summary."[69] If the FTC was purely responsible for the content of the advertisement, they would likely judge it based on their "deception" standard.[70] The first inquiry would consider the advertisement's interpretation by a reasonable consumer.[71] A likely interpretation would be that sertraline is a safe and effective treatment for mental health issues. Is this misleading by not including the "major statement," or, more generally, risk information? The FTC's substantiation doctrine of "competent and reliable [scientific] evidence,"[72] requiring well-designed clinical studies to support claims made in advertising, would appear to be satisfied—sertraline is a commonly used antidepressant.[73] Would the FTC's disclosure doctrine, which either statutorily mandates disclosure of certain facts,[74] or assesses if disclosure is used to mitigate misleading representations,[75] be relevant? Possibly. The disclosure doctrine is principally used to limit a claim that requires qualifications to be truthful.[76] The FTC has required disclosure of facts regarding the safety and side effects of over-the-counter prescription

68. This is based on the questionable advertisement of a particular DTC telehealth company promoting ketamine for "help[ing] [the patient's] brain switch channels." Safdar & Fuller, *supra* note 35. However, advertising ketamine brings up additional challenges as it is not FDA-approved for mental health treatment, and therefore cannot be marketed as such by pharmaceutical companies. *See id.*

69. *See* discussion *supra* section II.

70. *See* Maher & Fair, *supra* note 15, at 601 (noting the FTC primarily uses their deception standard when judging advertising).

71. *See id.*

72. *Id.* at 603.

73. *Cf., e.g.*, Thompson Medical Co., 104 F.T.C. 648, 648, 650 (1984), 1984 WL 565377 (claiming advertiser's aspirin cream advertisement claims were not substantiated because it did not contain aspirin, claims as to its benefit was not supported by research, and it misrepresented itself as new and innovative).

74. 16 C.F.R. § 255.2 (2024).

75. FTC Policy Statement on Deception, *appended to* Cliffdale Assoc., Inc., 103 F.T.C. 110, 174 (1984), 1984 WL 565319.

76. *See id.* (describing disclosures as appropriate in "some cases involv[ing] omission of material information, the disclosure of which is necessary to prevent the claim, practice, or sale from being misleading"). For an example of how disclosures are considered by the FTC in a different context, see generally DISCLOSURES FOR SOCIAL MEDIA, *supra* note 62.

drugs.[77] This would appear to be sufficiently analogous to imply a legal basis for the FTC to require disclosure for these drug advertisements.

Yet if the FTC chose this route, what disclosure would be required? Longstanding agency cooperation suggests the FTC would turn to the FDA for information.[78] Would the standard be the FDA's categorical requirements, or would it be based on the FTC's interpretation of the FDA's standards to create a new understanding of what is appropriate for disclosure or substantiation? Two separate standards for prescription drug advertising would likely result in consumer confusion. This also may trouble pharmaceutical companies, who would be held to a different, more stringent standard of advertising law despite engaging in substantially the same activity. Further, separate standards for advertising depending on the company involved would create inconsistencies between the advertising and the labeling of the pharmaceutical drug, considering the FDA's pharmaceutical drug advertising law claims borrow heavily from the labeling of the drug itself.[79]

The FTC's fact-specific approach to quantifying deceptive advertising is not a good fit with the categorical approach involved in years of pharmaceutical drug advertising regulation. Even just requiring disclosure would still leave out a significant amount of FDA standards governing advertising, including bans on off-label promotion, particular requirements for statistical representations, and guidance for technical misrepresentations.[80] FDA standards have specific enumerations, affirmative requirements, and prohibitions, benefitting both advertisers and ensuring the consumer is fully informed: all part of the compromise allowing direct-to-consumer advertising to exist in the first place.[81]

D. Possible Approaches

The approach that informs the consumer the most, avoids the harm of two standards of prescription drug advertising, and is the most comprehensive in enforcement, is for the FTC to enforce FDA standards for prescription drug advertising. The best way to do this would be

77. *See, e.g.,* Robert C. Spencer, 132 F.T.C. 174 (2001), 2001 WL 36176139 (consent order) (requiring safety warnings in labeling of ephedra).

78. *See* FDA ADVERTISING MANUAL, *supra* note 65, at ¶ 331.

79. *See Glossary of Drug Terms*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms (Jan. 1, 2020) (describing that a brief summary requires the information listed in the "prescribing information," which is then further defined to be the drug labeling).

80. *See* discussion *supra* Section II.

81. *See* discussion *supra* Section II.

through legislation, carving out an exception for all other prescription drug advertising not fully regulated by the FDA and specifying that FDA requirements for disclosure and limitations on advertising should be used. Longstanding joint agency cooperation could then help the FTC understand and interpret FDA guidelines if needed.

Potential legislation could be modeled after the current advertising legislation for tobacco advertising. In order to market tobacco, you must comply with statutorily mandated disclosure guidelines, including a "brief statement" of "relevant warnings, precautions, side effects, and contraindications."[82] Currently, the FDA has the authority to create these standards for tobacco disclosures in advertising, and the FTC has the authority to enforce violations.[83] Under the authority of the Tobacco Control Act, the FDA is empowered to impose these guidelines or any additional restrictions "based on a determination that such restrictions are appropriate to protect the public health."[84] When it comes to advertising, however, the FTC has the authority to charge violators of the Tobacco Control Act who do not include these guidelines as committing an "unfair or deceptive act."[85] This practically means that the FTC's jurisdiction as to these disclosures is limited by the FDA's ability to modify them.[86]

The FTC and the FDA could also amend their Memorandum of Understanding to reflect this distribution of jurisdiction. This would avoid the delays of attempting to pass legislation. Technically, the FTC has legal authority to oversee prescription drug advertisements and is only limited by voluntary agreement of the separation of duties outlined by their Memorandum of Understanding.[87]

Possibly more comprehensive, but more time-consuming, would be to have both agencies jointly research what advertising standards should apply in this category and issue notice-and-comment rulemaking. This

82. 21 U.S.C § 387c(a)(8)(B).

83. JENNIFER A. STAMAN, CONG. RSCH. SERV., IF11321, FEDERAL REGULATION OF TOBACCO: LEGAL FRAMEWORK AND ISSUES FOR THE 116TH CONGRESS (2019).

84. *Id.*

85. *See The Federal Trade Commission and Tobacco,* TOBACCO CONTROL LEGAL CONSORTIUM, https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-ftc&tobacco-2012.pdf (last visited Mar. 10, 2024) ("[A]n advertisement that violates the Tobacco Control Act is an unfair or deceptive act and subject to the jurisdiction of the FTC.").

86. *See id.* ("The Tobacco Control Act, however, limits the FTC's authority to regulate false advertisements of tobacco products as they relate to tobacco product warning labels.").

87. The FTC interprets the language of the Kefauver–Harris Amendment that granted the FDA jurisdiction over drug advertising not as substantially removing their jurisdiction from prescription drug advertising, but instead one they voluntarily agreed not to pursue. *See* FDA ADVERTISING MANUAL, *supra* note 65, at ¶ 331.

approach leverages both agencies' expertise in their respective fields and allows for a tailored set of rules that is adapted to the current advertising environment. The FDA alone could also promulgate rules for the FTC to implement.[88]

V. CONCLUSION

Advertisers operate in a battlefield for your attention.[89] They want you to buy anything from products, to services, to ideas, to lifestyles.[90] These products range from harmless and banal to dangerous and seductive. It is unsurprising that companies will use all kinds of marketing techniques to survive in the oversaturated information ecosystem, including engaging in marketing acts that are questionable at best, and outright lying at worst.[91]

This is where the regulator comes in. Advertising laws and regulations attempt to prevent corporations from exploiting the oversaturated consumer who does not have the time, knowledge, or understanding to be constantly fielding out misinformation and mischaracterizations in the media. It is incumbent on regulators to ensure their safeguards continue to be efficient and effective at tackling new iterations of old issues.

88. *See id.*

89. *See It's All About the Technique,* FED. TRADE COMM'N (July 2013), https://consumer.ftc.gov/articles/0375-its-all-about-technique.

90. *See id.* ("Advertisers create their ads to persuade the target audience to buy, think, or do something.").

91. *See id.*