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Andrew Andrzejewski

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Direct-to-Consumer Calls to Action[1]

LOWERING THE VOLUME OF CLAIMS AND DISCLOSURES IN PRESCRIPTION DRUG BROADCAST ADVERTISEMENTS

INTRODUCTION

Over several decades, prescription drug advertising in the United States has evolved to target both physician and patient audiences,[2] across print, audio, and visual media,[3] including interactive media on the internet.[4] In 2016, the pharmaceutical industry spent $6 billion on direct-to-consumer (DTC) advertisements for prescription drugs, including a daily average of over 1,800 television spots for an annual total of 663,000 commercials.[5] These advertisements are subject to the Food and Drug Administration's (FDA) regulations.[6] Companies that advertise a drug's benefits must balance their claims with risk disclosures in a manner that is not misleading,

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[1] Television commercials often contain "calls to action," which prompt interested consumers to follow up on the information they see in an advertisement by, e.g., visiting the product's website. Tom Goodwin, *TV Advertising Is About to Change Forever*, ADAGE (Oct. 20, 2014), https://adage.com/article/digitalnext/tv-advertising-change-forever/295465 [https://perma.cc/LH5V-2AAW].

[2] Timothy M. Moore, Darshan Kulkarni & Emily T. Wright, *Federal Regulation of Advertising, Promotion, and Distribution Practices*, *in* PHARMACEUTICAL AND MEDICAL DEVICE LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING 3-1, 3-15 (Michael E. Clark ed., BNA 2d ed. 2015). The United States is one of only two countries that allow drug manufacturers to advertise to consumers, the other being New Zealand. Beth Snyder Bulik, *Doctors in New Zealand—The Only Non-U.S. Country that Allows DTC Advertising—Call for Bans*, FIERCEPHARMA (Mar. 20, 2017, 8:00 AM), https://www.fiercepharma.com/marketing/doctors-new-zealand-only-other-country-allows-dtc-advertising-hate-it-too [https://perma.cc/JCE9-9D25].

[3] AM. COLL. OF PHYSICIANS, DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING 6 (2006).

[4] Michael Friedman & James Gould, *Consumer Attitudes and Behaviors Associated with Direct-to-Consumer Prescription Drug Marketing*, 24 J. CONSUMER MKTG. 100, 106 (2007).

[5] Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997–2016*, 321 J. AM. MED. ASS'N 80, 82 (2019).

[6] *See* 21 U.S.C. §§ 352(n), 371(a) (2012); 21 U.S.C. § 353c (2012 & Supp. I 2013); 21 C.F.R. § 202.1 (2018).

does not omit material facts, and directs consumers to additional drug information.[7]

Drug companies, and many doctors, contend that DTC advertisements facilitate meaningful discussions between doctors and patients about their health, otherwise unknown diagnoses, and available treatments.[8] A 2004 study showed that over the course of a year, more than sixteen million patients requested a prescription for a drug after seeing its advertisement.[9] Many doctor visits prompted by DTC advertising yield diagnoses of "high priority conditions such as asthma, high blood pressure[,] or diabetes."[10]

DTC advertisements, however, are increasingly perceived as inadequate vehicles to communicate a drug's benefits and risks.[11] These advertisements serve to inform and persuade consumers, so they do not exclusively appeal to "rational consideration of medical costs and benefits."[12] When an advertisement highlights efficacy, it "can distort and inflate consumers' expectations about what prescription drugs can accomplish."[13] Doctors commonly prescribe a specific drug at the request of a patient, which suggests a possibly "artificial demand for drugs" and a deterioration of the doctor-patient relationship.[14]

The FDA's risk disclosure requirements also have given rise to additional concerns about whether consumers understand risk disclosures and whether risk disclosures minimize dangerous risks.[15] It is not immediately clear whether

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[7] 21 C.F.R. § 202.1(e)(1), (5); Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017).

[8] Victor E. Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 333, 351 (2009); *see also* Friedman & Gould, *supra* note 4, at 106; Dominick L. Frosch et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANNALS FAM. MED. 6, 6 (2007).

[9] AM. COLL. OF PHYSICIANS, *supra* note 3, at 4.

[10] *Id.*

[11] Friedman & Gould, *supra* note 4, at 106.

[12] Frosch et al., *supra* note 8, at 12; *see also* LEONARD J. WEBER, PROFITS BEFORE PEOPLE?: ETHICAL STANDARDS AND THE MARKETING OF PRESCRIPTION DRUGS 168 (2006); Joshua E. Perry et al., *Direct-to-Consumer Drug Advertisements and the Informed Patient: A Legal, Ethical, and Content Analysis*, 50 AM. BUS. L.J. 729, 730 (2013).

[13] Frosch et al., *supra* note 8, at 12. A viewer might even demand a prescription for a specific brand-name medication, regardless of that patient's diagnosis or that drug's intended use. Schwartz et al., *supra* note 8, at 350–51. A recent update showed that pharmaceutical DTC advertising practices in recent years have only exacerbated this problem. Janelle Applequist & Jennifer Gerard Ball, *An Updated Analysis of Direct-to-Consumer Television Advertisements for Prescription Drugs*, 16 ANNALS FAM. MED. 211, 214–16 (2018).

[14] AM. COLL. OF PHYSICIANS, *supra* note 3, at 10.

[15] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017).

the dangerousness of a disclosed risk lies in its severity, frequency, or both.[16] Over-warning for any possible risk could dilute the warnings for the most serious side effects.[17] A related concern is whether consumer confusion about possible adverse events could result in "therapeutic noncompliance" with prescriptions for otherwise safe drugs.[18]

Despite demands to ban the practice,[19] DTC advertisements persist as protected commercial speech.[20] The existence of the FDA's DTC requirements, let alone compliance therewith, depends on a fragile balance between drug manufacturers' ability to challenge them as overly broad speech restrictions and drug manufacturers' interests in FDA regulation.[21] First, FDA regulation and risk disclosures give credibility to DTC advertisements by allowing consumers to assume that the materials were thoroughly vetted.[22] Second, the pharmaceutical industry must consider how FDA requirements interact with its liability exposure, should liability arise from "alleged flaws in communicating information to individual patients."[23]

The FDA, in recent years, has requested comments from the public—the pharmaceutical industry, healthcare providers, and consumers alike—on various iterations of a "limited risks plus disclosure" approach to facilitate communication and comprehension of drug risks in DTC advertisements.[24] President

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[16] *See* Aaron D. Twerski, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 HOFSTRA L. REV. 1149, 1153 (2005).

[17] Kevin R. Betts et al., *Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements*, 14 RES. SOC. & ADMIN. PHARMACY 951, 952 (2018); Niro Sivanathan & Hemant Kakkar, *The Unintended Consequences of Argument Dilution in Direct-to-Consumer Drug Advertisements*, 1 NATURE HUM. BEHAV. 797, 797 (2017).

[18] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599.

[19] *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/content/ama-calls-ban-direct-consumer-advertising-prescription-drugs-and-medical-devices [https://perma.cc/3YBR-X4VJ].

[20] *See infra* Section I.C.

[21] Cory L. Andrews & Wash. Legal Found., *FDA-Mandated Listing of Drug Prices in Ads Would Flunk Legal and Constitutional Tests*, FORBES (Aug. 27, 2018, 10:45 AM), https://www.forbes.com/sites/wlf/2018/08/27/fda-mandated-listing-of-drug-prices-in-ads-would-flunk-legal-and-aonstitutional-tests/ [https://perma.cc/VQ6M-AM6X].

[22] *See* Joanne Kaufman, *Think You're Seeing More Drug Ads on TV? You Are, and Here's Why*, N.Y. TIMES (Dec. 24, 2017), https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html [https://perma.cc/9JSR-PA37].

[23] *See* Schwartz et al., *supra* note 8, at 354–55; *see also infra* Section II.C.

[24] *See* Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017); Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements, 80 Fed. Reg. 1,637, 1,637 (Jan. 13, 2015); Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements, 79 Fed. Reg. 9,217, 9,218 (Feb. 18, 2014).

Donald Trump has also demanded drug price disclosures in these advertisements, which the FDA considered implementing.[25] The Centers for Medicare and Medicaid Services (CMS) subsequently proposed a rule requiring price disclosures in DTC advertisements for drugs on Medicare and Medicaid formularies.[26] Pharmaceutical companies then threatened to challenge CMS's proposed regulation as compelled speech in violation of the First Amendment.[27]

The FDA's recent attention to prescription drug DTC broadcast advertisements shows an enduring focus on risk disclosures. A thoughtful consideration of a broadcast advertisement's purpose and logistical constraints, as well as recent calls for yet another disclosure rule, suggests that this focus is too narrow. The FDA, instead, should regulate broadcast advertisements as limited calls to action that prompt patients to consult the print and electronic written components of a drug's advertising campaign, as well as a physician, for more detailed and tailored information—and nothing more. This would allow a manufacturer to disclose a drug's approved indication in a broadcast advertisement, but otherwise ban efficacy claims and dramatically reduce the volume of required risk disclosures in broadcast advertisements.[28]

This note proceeds in the following parts. Part I summarizes the history of the FDA's DTC advertising regulations and limits thereto. Part II discusses how the current requirements foster both inconsistent advertising practices in the pharmaceutical industry and consumer confusion about drug risks that expose drug manufacturers to potential liability. Part III explains why current proposals are inadequate, in light of the broad problems with DTC advertising that the FDA must address and attendant First Amendment concerns. Finally, Part IV describes an alternative approach of regulating broadcast advertisements as limited vehicles within a broader advertising campaign and why Congress and the FDA should implement this proposal.

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[25] Beth Snyder Bulik, *Price Check at FDA: Trump Pushes for Pharma Ads with Dollar Signs*, FIERCEPHARMA (May 16, 2018, 9:26 AM), https://www.fiercepharma.com/marketing/price-check-trump-administration-pushs-to-ad-drug-prices-to-pharma-ads [https://perma.cc/3VED-UUC3].

[26] Robert Pear, *Trump Rule Would Compel Drug Makers to Disclose Prices in TV Commercials*, N.Y. TIMES (Oct. 15, 2018), https://www.nytimes.com/2018/10/15/us/politics/drug-industry-consumer-price-lists.html [https://perma.cc/H4FP-X339].

[27] *Id.*; Andrews & Wash. Legal Found., *supra* note 21.

[28] *See* Part IV. Federal law does not provide for such an expansive medium-based restriction. *See* 21 U.S.C. § 352(n) (2012); 21 U.S.C. § 353c (2012 & Supp. I 2013); *see also* Part I. Proscriptions on DTC advertising practices that are broader in scope than the FDA's current authority would require congressional approval.

I. THE FDA'S AUTHORITY TO REGULATE PRESCRIPTION DRUG ADVERTISEMENTS

Congress passed the Federal Food, Drug, and Cosmetic Act in 1938 to authorize the FDA to regulate prescription drug safety and labeling.[29] The Federal Trade Commission (FTC) regulated all drug advertisements until 1962, when Congress assigned prescription drug advertisements to the FDA.[30]

A. The Rise of DTC Advertisements and Regulations

Pharmaceutical marketing practices initially targeted doctors, because the FDA did not allow DTC advertisements for prescription drugs until 1985.[31] That year, the FDA authorized DTC advertising that met the same "brief summary" and "fair balance" requirements that applied to advertisements to physicians.[32] An advertisement's benefit and risk information must be "clear, conspicuous, and neutral."[33] It was not clear, however, whether it was appropriate to regulate drug advertisements for patients, who generally lack medical expertise and may be vulnerable to misleading claims, under the same standards as for physicians, who are trained to understand drug information.[34]

The FDA eventually issued a draft guidance in 1997 to describe a voluntary "approach that sponsors can use to fulfill the requirement for adequate provision for dissemination of the approved package labeling in connection with consumer-directed broadcast advertisements for [prescription drugs]."[35] Broadcast

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[29] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 675, sec. 501–05, 52 Stat. 1040, 1049–53 (1938) (codified as amended in scattered sections of 21 U.S.C. §§ 351–360n-1); Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 138–39 (2005).

[30] Schwartz et al., *supra* note 8, at 339, 341; *see also* Drug Amendments of 1962, Pub. L. No. 87-781, sec. 131, § 502(n), 76 Stat. 780, 791 (1962) (codified as amended at 21 U.S.C. § 352(n) (2012)). While the FTC retained jurisdiction over over-the-counter drugs, the FDA later reaffirmed its jurisdiction over prescription drug advertisements in 1971 to avoid any possible "duplication of work and to promote uniformity and consistency of action." Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539, 18,539 (Sept. 16, 1971); *see also* 15 U.S.C. § 52 (2012). The implementing regulations for prescription drug advertising are codified at 21 C.F.R. § 202.1 (2018).

[31] Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677, 36,677 (Sept. 9, 1985); Schwartz et al., *supra* note 8, at 344–45.

[32] Schwartz et al., *supra* note 8, at 345.

[33] 21 U.S.C. § 352(n) (2012).

[34] Moore et al., *supra* note 2, at 3-15.

[35] Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171, 43,172 (Aug. 12, 1997). The FDA finalized this guidance in 1999. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999).

advertisements could demonstrate compliance with the FDA's goal to reach the "most of a potentially diverse audience" by: (1) airing a "major statement" about the drug's key risks in the audio portion; and (2) directing patients to readily accessible places with the drug's approved labeling for more information.[36]

The Pharmaceutical Research and Manufacturers of America (PhRMA) devised its own DTC advertising guidelines in 2005.[37] An updated version of these guidelines, which took effect in 2009, calls on companies to undertake internal efforts to comply with the regulations,[38] and includes a list of signatories that the association updates every year.[39] Some companies pledged to restrict their DTC advertising practices by: (1) observing moratoria on advertisements for a period of time after they introduce a new drug to the market; (2) targeting specific patients for certain therapies; or (3) submitting their advertising campaigns for FDA approval.[40] Since manufacturers voluntarily restricted their advertising campaigns in different ways, however, these efforts were not consistent throughout the industry.[41] Critics even contend that these guidelines "are, perhaps purposefully, vague[,] . . . compliance with the guidelines is voluntary[, and] . . . . the guidelines do not go far enough."[42]

The FDA reconsidered its review process after a subsequent influx of requests from drug companies for comments on planned advertising campaigns.[43] Given logistical

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[36] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2 (1999).

[37] Schwartz et al., *supra* note 8, at 347, 347 n.78. PhRMA is an industry association that represents several major pharmaceutical manufacturers and serves as a platform for members to self-regulate by certifying their commitments to PhRMA principles. *Members*, PHARM. RES. & MFRS. OF AMERICA, https://www.phrma.org/about/members [https://perma.cc/WSW4-SHTD]; PHARM. RES. & MFRS. OF AMERICA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 7 (2018) [hereinafter PHRMA GUIDING PRINCIPLES 2018], http://phrma-docs.phrma.org/files/dmfile/PhRMA_Guiding_Principles_2018.pdf [https://perma.cc/MHS7-C4KM].

[38] PHARM. RES. & MFRS. OF AMERICA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 4, 8 (2008), http://phrma-docs.phrma.org/sites/default/files/pdf/phrmaguidingprinciplesdec08final.pdf [https://perma.cc/94EC-DPGE]. These principles were updated again in 2018 to reflect the industry's commitment to disclosing prices on drug websites. PHRMA GUIDING PRINCIPLES 2018, *supra* note 37, at 6.

[39] *PhRMA Direct to Consumer Advertising Principles – Annual Certifications*, PHARM. RES. & MFRS. OF AMERICA (Aug. 27, 2017), http://phrma-docs.phrma.org/files/dmfile/2017-DTC-Compliance-Certifications-08-27-17.pdf [https://perma.cc/2NBX-MJ7B].

[40] *See* AM. COLL. OF PHYSICIANS, *supra* note 3, at 8 (describing some of the ways that various drug manufacturers voluntarily modified their advertising practices pursuant to PhRMA's guiding principles).

[41] *See id.*

[42] Frosch et al., *supra* note 8, at 12.

[43] AM. COLL. OF PHYSICIANS, *supra* note 3, at 8; *see also* Schwartz et al., *supra* note 8, at 348.

constraints, it limited its review to advertisements for drugs in certain situations. From a promotional perspective, the FDA focused on advertisements for drugs that were featured in DTC broadcasts for the first time.[44] From a medical perspective, the FDA reviewed a drug's advertisements if it newly approved the drug, if it approved the drug for a new use, or if there was new benefit and risk information for the drug.[45]

B. Recent Limits to the FDA's Authority Over DTC Advertisements

Congress expressly prohibited mandatory "prior approval" of advertisements,[46] except when the FDA determines that a manufacturer omitted a drug's important risk information or recent approval date.[47] The FDA may, however, require a pharmaceutical company to submit a television advertisement for review at least forty-five days before its first broadcast so that the agency may recommend changes.[48] If approved, pre-submitted advertisements enjoy a "safe harbor" that gives the manufacturer time to rectify any violations that may arise if the FDA later reassesses the material unfavorably.[49] The FDA's prereview recommendations, if any, put manufacturers on notice of the position that the FDA likely will take when the initial broadcast triggers the agency's authority to require changes or withdrawal.[50] The FDA, otherwise, sees an advertisement only upon release to the public.[51]

The FDA may threaten enforcement action in untitled notices of violation and warning letters, as well as negative press,

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[44] AM. COLL. OF PHYSICIANS, *supra* note 3, at 8.

[45] *Id.*

[46] Drug Amendments of 1962, Pub. L. No. 87-781, sec. 131, § 502(n), 76 Stat. 780, 791–92 (1962) (codified as amended at 21 U.S.C. § 352(n) (2012)); Stephen D. Brody, *Navigating the Challenges Posed by the Current Enforcement Environment Facing Life Sciences Companies*, *in* INSIDE THE MINDS: UNDERSTANDING LEGAL TRENDS IN THE LIFE SCIENCES INDUSTRY: LEADING LAWYERS ON COMPLYING WITH REGULATORY CHANGES AND KEEPING ABREAST OF SUPREME COURT DECISIONS 21, 24 (Aspatore 2014).

[47] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, sec. 901, §§ 503b(c), (e), 121 Stat. 823, 939–40 (2007) (codified as amended at 21 U.S.C. §§ 353c(c), (e) (2012 & Supp. I 2013)); *see also* Brody, *supra* note 46, at 24.

[48] 21 U.S.C. §§ 353c(a)–(b).

[49] Brody, *supra* note 46, at 24.

[50] *See* Moore et al., *supra* note 2, at 3-7.

[51] 21 C.F.R. § 314.81(b)(3)(i) (2018); Schwartz et al., *supra* note 8, at 347; David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 272 (2007); *Prescription Drug Advertising: Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm076768.htm [https://perma.cc/FAY7-CKQR].

after an advertisement airs.[52] The FDA may also condition, or delay, other parts of the drug review process on the manufacturer's compliance with its prereview recommendations.[53] Pharmaceutical companies, who often are repeat players with more than one drug in their portfolios, may therefore find it better for their bottom lines to implement the FDA's recommendations in their advertisements and maintain a good relationship with the FDA, rather than ignore or contest them as exceeding the FDA's authority.[54]

C. Constitutional Challenges to the FDA's Regulation of DTC Advertisements

Pharmaceutical companies can challenge the FDA's advertising regulations as an infringement on their First Amendment speech rights.[55] In *Thompson v. Western States Medical Center*, where pharmacies sued the FDA over an outright ban on advertisements for compounded drugs, the Supreme Court struck down the FDA's "provisions regarding advertisement and promotion [as] unconstitutional restrictions on commercial speech."[56] The regulation of commercial speech is not necessarily unconstitutional, but to withstand scrutiny, it must pass the *Central Hudson* test.[57] There are four steps to the *Central Hudson* test:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the

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[52] MARK HERRMANN & DAVID B. ALDEN, DRUG AND DEVICE PRODUCT LIABILITY LITIGATION STRATEGY 20 (2012); Darshan Kulkarni & Emily T. Wright, *Federal Regulation of Advertising, Promotion, and Distribution Practices*, *in* PHARMACEUTICAL AND MEDICAL DEVICE LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING 3-1, 3-5 (Michael E. Clark ed., BNA 2d ed. Supp. 2017); Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 124 (2014).

[53] Noah, *supra* note 52, at 122–24.

[54] *Id.*

[55] Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?*, 37 AM. J.L. & MED. 388, 388 (2011). Drug manufacturers' advertising practices appear to be protected commercial speech. Perry et al., *supra* note 12, at 734.

[56] Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002).

[57] *Id.* at 367–68 (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 566 (1980)). The Supreme Court previously characterized a state's attempt to restrict a tobacco company's manner of advertising, e.g., by requiring cigarette advertisements to be placed higher than a child's height, as a speech restraint that triggered the *Central Hudson* test, not a "mere regulation of conduct" that triggered lower scrutiny. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 567 (2001).

> regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.[58]

Although the Supreme Court's post-*Western States* First Amendment jurisprudence has not specifically addressed DTC advertising, courts consistently apply the *Central Hudson* test to the FDA's regulation of drug manufacturers' speech.[59] Drug advertisements generally meet the threshold prong because the speech therein concerns prescription drug use, a lawful activity;[60] although certain individual advertisements might be misleading,[61] drug promotion itself "is not inherently misleading."[62]

The FDA then must demonstrate a valid governmental interest in regulating DTC advertisements, supported by empirical evidence.[63] This interest relates to patient access to and comprehension of complete efficacy and risk information for a drug, as well as preventing therapeutic noncompliance with a prescription based on a misunderstanding of drug risks.[64] While courts look down on the FDA's "paternalistic assumption" that restrictions on drug promotion are "necessary to protect the listener[s] from ignorantly or inadvertently misusing the

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[58] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 566 (1980).

[59] Alan Bennett et al., *Back to First Principles: A New Model for the Regulation of Drug Promotion*, 2 J.L. & BIOSCIENCES 168, 175 (2015). It should be noted, however, that recent Supreme Court rulings suggest that heightened scrutiny might replace the *Central Hudson* test. *See* Sorrell v. IMS Health Inc., 564 U.S. 552, 571–72 (2011); Bennett et al., *supra* note 59, at 177–78 (explaining that the *Sorrell* court's invalidation of a speech restriction rested on the government's failure to satisfy either the *Central Hudson* test or heightened scrutiny); *see also* Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2380–81 (2018) (Breyer, J., dissenting) (describing how the majority's failure to distinguish between commercial and non-commercial speech "at the least threatens considerable litigation over the constitutional validity of much, perhaps most, government regulation"); Cory L. Andrews & Wash. Legal Found., *The Dog that Didn't Bark in the Night: SCOTUS's* NIFLA v. Becerra *and the Future of Commercial Speech*, FORBES (July 5, 2018, 11:02 AM), https://www.forbes.com/sites/wlf/2018/07/05/the-dog-that-didnt-bark-in-the-night-scotuss-nifla-v-becerra-and-the-future-of-commercial-speech/ [https://perma.cc/77WY-LCP4] (explaining that the *NIFLA* court's conflation of commercial and non-commercial speech may lead to replacing *Central Hudson*'s intermediate scrutiny with strict scrutiny).

[60] *See* United States v. Caronia, 703 F.3d 149, 165 (2d Cir. 2012).

[61] *See* 21 C.F.R. § 202.1(e)(6)(i) (2018); Vladeck, *supra* note 51, at 272 (explaining that a DTC advertisement may be false or misleading when it omits a drug's safety risks or overstates its efficacy).

[62] Bennett et al., *supra* note 59, at 174. The Second Circuit even carved out an exception for off-label but truthful promotion of a drug, in which a manufacturer advertises an FDA-approved drug for a non-approved use. *Caronia*, 703 F.3d at 168–69; Brody, *supra* note 46, at 33.

[63] George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 425–28 (2003).

[64] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017); Evans & Friede, *supra* note 63, at 426–27.

information," that criticism stems from the FDA's conclusory assumptions about its role in regulating promotional activity that targets *sophisticated* healthcare professionals.[65] Here, drug manufacturers target *unsophisticated* consumers; empirical evidence shows viewer confusion, so the FDA has commissioned more studies to investigate the public's ability to identify and understand risk disclosures.[66]

The key takeaway for drug manufacturers is that restrictions on DTC advertisements "will fail the fourth prong of the *Central Hudson* test, unless there are no less restrictive alternatives that could achieve the same objectives."[67] The restriction must be tailored to the governmental interest in regulating DTC advertisements in the first place.[68] In practice, courts routinely strike down restrictions on drug promotion that are poorly tailored or overly broad.[69] Recently proposed disclosure requirements have also highlighted the fragile constitutional foundation for the FDA's current regulatory framework.[70]

II. THE FDA NEEDS TO CHANGE THE DTC LANDSCAPE FOR PRESCRIPTION DRUGS

The current regulatory regime—a product of decades of legislation, lobbying, and disputes—has created a contentious environment that pits patient advocacy groups, physicians, drug manufacturers, and government officials against each other, even though they all consider public health among their goals. The long-term interests of patients, doctors, pharmaceutical companies, and the FDA demand reform.

A. FDA Regulations Are Ineffective

The FDA's regulations governing prescription drug advertisements apply to advertisements appearing in publications or broadcast over the radio or television.[71] There are three kinds of DTC advertisements: "product-claim" advertisements; "help-

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[65] Wash. Legal Found. v. Henney, 56 F. Supp. 2d 81, 86 (D.D.C. 1999), *appeal dismissed, judgment vacated in part*, 202 F.3d 331 (D.C. Cir. 2000). The D.C. Circuit Court vacated the decision on separate grounds, explaining that the district court's reasoning was sound. *Id.* at 337 n.7.

[66] *See infra* Section II.B.

[67] Bennett et al., *supra* note 59, at 174–75.

[68] *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 566 (1980).

[69] Sorrell v. IMS Health Inc., 564 U.S. 552, 580 (2011); Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002).

[70] *See* Andrews & Wash. Legal Found., *supra* note 21.

[71] 21 C.F.R. § 202.1(*l*)(1) (2018).

seeking" advertisements; and "reminder" advertisements.[72] Pharmaceutical companies use product-claim advertisements to identify a prescription drug and convey the benefits and risks of using that drug.[73] These companies may also use help-seeking advertisements to convey information about a disease without identifying any prescription drug, and reminder advertisements to convey that a prescription drug is on the market without identifying the drug's purpose.[74]

Though the FDA monitors help-seeking and reminder advertisements "to ensure there is no implication of a product claim," the FDA only regulates product-claim advertisements.[75] Product claims are limited to medical uses that the FDA previously approved in the manufacturer's drug application.[76] Specifically, the FDA currently requires that DTC drug advertisements include: (1) a "major statement" in advertisements that outlines "the advertised drug's major side effects and contraindications"; and (2) either a summary of side effects and contraindications, or an "adequate provision" like a toll-free number, print materials, or website address to communicate those risks.[77] The FDA also requires that a major statement provide a "fair balance" of the benefits and risks of taking a particular drug, and prohibits pharmaceutical companies from misrepresenting, omitting, or misleading consumers about a drug's side effects, contraindications, effectiveness, and possible outcomes after using a drug as indicated.[78] The regulations provide for a waiver of specific requirements only on a case-by-case basis, upon "a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading."[79]

While the regulations elaborate on what kind of information should go into the brief summary, drug manufacturers have relied on a combination of the FDA's guidance documents and the industry's own guidelines to ascertain what the regulations

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[72] Schwartz et al., *supra* note 8, at 344.

[73] *Id.*; *see also* Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017).

[74] Schwartz et al., *supra* note 8, at 344.

[75] AM. COLL. OF PHYSICIANS, *supra* note 3, at 5.

[76] *See* 21 C.F.R. § 202.1(e)(6)(i).

[77] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,598; *see* 21 C.F.R. § 202.1(e)(1).

[78] 21 C.F.R. § 202.1(e)(5); Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599.

[79] 21 C.F.R. § 202.1(e)(6).

actually require.[80] The deliberation, promulgation, and enforcement of the FDA's guidance documents are not subject to the same controls that regulations and rules are, and the ability of the FDA to unilaterally rescind or amend these guidelines makes them vulnerable to the political atmosphere.[81] This, in turn, reduces the pharmaceutical industry's ability to rely on the FDA to understand what kind of risks manufacturers must disclose in these advertisements.[82]

But for its authority to require manufacturers to redress omissions of risk or recent approval information, the FDA may only *recommend* changes to DTC advertisements before they are broadcast; it may *require* other revisions only post hoc, i.e., after potential patients would have already seen the advertisements.[83] It is possible that, for a prereviewed submission, a manufacturer would implement the FDA's recommendation to avoid generating a record of warning letters after the advertisement hits the air.[84] Also at play is the FDA's continuous oversight of drug manufacturers, who must avoid unnecessarily antagonizing the FDA to remain competitive.[85] This influence, however, is not as decisive and consistent as a codified set of requirements, because it leaves too much about the appropriateness of the content of DTC advertisements to guesswork and negotiation.[86]

Based on publicly available communications, the FDA has not been especially active or consistent in policing DTC broadcast

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[80] *See generally* 21 C.F.R. § 202.1(e)(4); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999); Draft Guidance for Industry on Direct-to-Consumer Television Advertisements; Pre-Dissemination Review Program, 77 Fed. Reg. 14,811 (Mar. 13, 2012); PHRMA GUIDING PRINCIPLES 2018, *supra* note 37, at 4–6.

[81] Noah, *supra* note 52, at 97.

[82] *See* Pharmaceutical Research and Manufacturers of America, Comment Letter on Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements 7–9 (Nov. 20, 2017) [hereinafter PhRMA Comment Letter], https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-2936-0055&attachmentNumber=1&contentType=pdf [https://perma.cc/YSS9-CA5A].

[83] 21 U.S.C. § 353c(c) (2012 & Supp. I 2013) (explaining that "this section does not authorize the [FDA] to make or direct changes" to the advertisement except in limited circumstances); *id.* § 353c(e) (permitting the FDA to require changes to an advertisement when the FDA determines that the manufacturer's omission of a drug's risk or a drug's recent approval date would be false or misleading); 21 C.F.R. § 202.1; HERRMANN & ALDEN, *supra* note 52, at 20; WEBER, *supra* note 12, at 180–81. Absent prereview, the FDA requires manufacturers to submit their DTC advertising materials as soon as they air, after which the agency may require companies to fix ads that are "false, lacking in fair balance, or otherwise misleading." 21 C.F.R. § 202.1(e)(6); *see also supra* Sections I.A–B.

[84] *See* Moore et al., *supra* note 2, at 3-7.

[85] *See* Noah, *supra* note 52, at 122–24.

[86] *Id.* at 97, 122–24; *see also* Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1028–29 (2008) (attributing judicial recognition of a regulatory compliance defense, in part, to the FDA's comprehensive and demanding regulation); PhRMA Comment Letter, *supra* note 82, at 9–10.

advertisements for prescription medications.[87] A 2013 review of the FDA's enforcement activity in all forms of DTC advertising showed a surprisingly low number of FDA notices of violation and warning letters.[88] That same review's comparison of the advertisements flagged by the FDA to ones that were not flagged, revealed that the FDA missed several advertisements that the authors determined to be misleading or imbalanced.[89] An up-to-date review of the FDA's archived enforcement activity relating to television commercials shows that the FDA sent nine letters to pharmaceutical companies since 2007—seven untitled letters[90] and two warning letters[91]—notifying manufacturers that these commercials breached the regulations. This perhaps means that: (1) drug manufacturers have demonstrated compliance in a vast majority of commercials; (2) the FDA systematically underregulates drug commercials for any number of reasons, e.g., understaffing;[92] or (3) there is a disparity between what courts, the FDA, manufacturers, and patients consider misleading.[93]

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[87] Perry et al., *supra* note 12, at 768. An advertisement may violate regulations and air for months before the FDA sends a notice of violation or warning letter. WEBER, *supra* note 12, at 159.

[88] Perry et al., *supra* note 12, at 766–67.

[89] *Id.* at 768.

[90] Letter from Melinda McLawhorn, Team Leader, Office of Prescription Drug Promotion, U.S. Food & Drug Admin., to Stacy Hennings, Senior Dir., Regulatory Affairs, Advert. and Promotions, Orexigen Therapeutics, Inc. (May 18, 2017); Letter from Melinda McLawhorn, Team Leader, Office of Prescription Drug Promotion, U.S. Food & Drug Admin., to Joanne Robinett, Assoc. Vice President, N. Am. & Global Regulatory Affairs, Sanofi-Aventis (Dec. 12, 2016); Letter from Matthew J. Falter, Team Leader, Office of Prescription Drug Promotion, U.S. Food & Drug Admin., to Bhupesh Desai, Dir., Regulatory Affairs, Advert. and Promotion, Celgene Corp. (Dec. 12, 2016); Letter from Carrie Newcomer, Regulatory Review Officer, Div. of Drug Mktg., Advert. and Commc'ns, U.S. Food & Drug Admin., to Kathleen Grim, Exec. Dir. of Regulatory Compliance, Sepracor Inc. (June 9, 2010); Letter from Sharon M. Watson, Regulatory Review Officer, Div. of Drug Mktg., Advert. and Commc'ns, U.S. Food & Drug Admin., to Gary Wieczorek, Assoc. Dir., Regulatory Affairs, Eisai Med. Res. Inc. (Feb. 3, 2010); Letter from Cynthia Collins, Consumer Safety Officer., Div. of Drug Mktg., Advert. and Commc'ns, U.S. Food & Drug Admin., to Michelle M. Hardy, Senior Dir., U.S. Regulatory Affairs, GlaxoSmithKline (Feb. 18, 2009); Letter from Carrie Newcomer, Consumer Promotion Analyst, Div. of Drug Mktg., Advert. and Commc'ns, U.S. Food & Drug Admin., to Janet A. Lorenz, Manager, Med./Regulatory Advert. & Promotion Grp., Takeda Pharm. N. Am., Inc. (Mar. 5, 2007).

[91] Letter from Robert Dean, Dir., Div. of Consumer Drug Promotion, U.S. Food & Drug Admin., to Ian C. Reed [sic], Chairman and Chief Exec. Officer, Pfizer Inc. (May 24, 2012); Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., and Commc'ns, U.S. Food & Drug Admin., to Reinhard Franzen, President and Chief Exec. Officer, Bayer HealthCare Pharm., Inc. (Oct. 3, 2008).

[92] *See* Schwartz et al., *supra* note 8, at 351 n.99.

[93] *See* Perry et al., *supra* note 12, at 768.

B. Confusing Advertisements

Several physician and patient groups contend that DTC advertising promotes inappropriate negotiations between a patient and a doctor over treatment options.[94] Some critics believe that DTC advertisements are designed to build brand loyalty or "selective demand."[95] Others go so far as to say that drug companies' advertisements "manipulate" consumers into becoming their loyal customers,[96] which, though cynical, reflects the notion that ad campaigns must "focus on the obligation of advertising to sell."[97] An advertisement, after all, is better able to sell a drug's benefits than to warn for its risks.[98]

There is a difference between generating consumer *interest* in a drug to facilitate substantive medical conversations with physicians, and generating consumer *loyalty* to a drug before a patient consults complete information or a medical professional.[99] Though supporters contend that these advertisements serve to empower the patient, many pharmaceutical companies are publicly-held corporations who have a duty to their shareholders that would conflict with any duty to inform their customers.[100] By virtue of their dual purpose to inform and persuade consumers, DTC advertisements do not exclusively appeal to "rational consideration of medical costs and benefits."[101] A focus on optimal outcomes, however, "can distort and inflate consumers' expectations about what prescription drugs can accomplish."[102]

The negative effects on patients who view these ads and retain a distorted understanding of the benefits and risks of a drug, and subsequently demand a prescription from their doctor, may outweigh any informational benefit that DTC advertising

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[94] AM. COLL. OF PHYSICIANS, *supra* note 3, at 10.

[95] Perry et al., *supra* note 12, at 731 (internal quotation marks omitted).

[96] WEBER, *supra* note 12, at 168; Daniel P. Richardson, Note, *The Lost Child of Products Liability: New Thoughts About Advertising and the Learned Intermediary Doctrine*, 27 VT. L. REV. 1017, 1041 (2003).

[97] JON STEEL, TRUTH, LIES, AND ADVERTISING: THE ART OF ACCOUNT PLANNING 14 (1998) (emphasis and quotation omitted). Of course, "advertising works better when it does not tell people what to think, but rather allows them to make up their own minds about its meaning," which leaves open a wide range of possibilities for a drug ad campaign, but this is not a maxim that dictates whether an advertisement should rely on logical persuasion or emotional connections. *Id.* at 6; *see also* WEBER, *supra* note 12, at 168.

[98] Twerski, *supra* note 16, at 1152.

[99] *See* Richardson, *supra* note 96, at 1047.

[100] WEBER, *supra* note 12, at 162–63.

[101] Frosch et al., *supra* note 8, at 12; *see also* WEBER, *supra* note 12, at 168; Perry et al., *supra* note 12, at 730.

[102] Frosch et al., *supra* note 8, at 12. A 2018 update showed that pharmaceutical DTC advertising practices in recent years have only exacerbated this problem. Applequist & Ball, *supra* note 13, at 214–16.

provides.[103] The FDA's elaborate risk disclosure requirements have given rise to concerns about "reduced consumer comprehension, minimization of important risk information, and, potentially, therapeutic noncompliance caused by fear of side effects."[104] Including warnings for all possible side effects could dilute warnings for the most serious side effects.[105] One study, therefore, concluded that most patients perceived DTC advertisements as inadequate vehicles to communicate drug risks and benefits.[106] The less that the FDA does to regulate these advertisements, the greater the potential becomes for both harm to consumers and exposure to liability that drug manufacturers face for alleged misrepresentations and omissions in these advertisements.[107]

C. Legal Consequences from Ineffective Regulations and Confusing Advertisements

A patient who suffers an injury while using a prescription drug may choose to sue the drug manufacturer under various theories of products liability. A manufacturer's marketing campaign opens the door to failure to warn and misrepresentation claims.[108] A plaintiff who brings these claims must show that a drug

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[103] AM. COLL. OF PHYSICIANS, *supra* note 3, at 10.

[104] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017).

[105] Betts et al., *supra* note 17, at 952; Sivanathan & Kakkar, *supra* note 17, at 797.

[106] Friedman & Gould, *supra* note 4, at 106.

[107] *See* Schwartz et al., *supra* note 8, at 354–55 (explaining that "close regulation by the FDA and oversight by individual doctors appropriately preclude holding pharmaceutical manufacturers liable for alleged flaws in communicating information to individual patients"); *see also* David Lazarus, *TV Commercials for Prescription Drugs 'Doing More Harm than Good'*, L.A. TIMES (Apr. 10, 2018, 3:00 AM), https://www.latimes.com/business/lazarus/la-fi-lazarus-direct-to-consumer-drug-ads-20180410-story.html [https://perma.cc/ZN3A-4APZ]; Bronwyn Mixter, *Less Risk Info in Rx Drug Ads Could Cause Liability Issues*, BNA (Aug. 21, 2017), https://www.bna.com/less-risk-info-n73014463442/ [https://perma.cc/T2HX-Z8S3].

[108] HERRMANN & ALDEN, *supra* note 52, at 45, 60. A failure to warn claim arises when a manufacturer fails to disclose the risks associated with a product, rendering the product "unreasonably dangerous." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965); HERRMANN & ALDEN, *supra* note 52, at 359. Using an objective standard, a court determines whether the manufacturer's warning is adequate. HERRMANN & ALDEN, *supra* note 52, at 360. Relatedly, misrepresentation claims require a plaintiff to prove that: (1) the company misrepresented or omitted a material fact; (2) the company knew or believed its statement was false; (3) the plaintiff believed the company's statement to be true; (4) the company intended its statement to induce the plaintiff to act; and (5) the plaintiff detrimentally relied on the company's statement. *Id.* at 60. The Restatement (Second) of Torts explains that this cause of action, which typically applies to misrepresentations about the physical state of real property and chattels that implicate the safety of their use, is "equally applicable to misrepresentation of other matters upon which the *safety* of the person . . . depends," including prescription drugs. RESTATEMENT (SECOND) OF TORTS § 310 cmt. b (AM. LAW INST. 1965) (emphasis added).

manufacturer's "misrepresentation was material, relied upon, and a proximate or legal cause of the relevant injury."[109] When a DTC advertisement allegedly omits risk information, the issue becomes whether the advertisement appropriately influenced the patient to act based on his or her expectations about the drug's remedial effects and adverse events.[110] These claims are governed, and generally precluded, by the learned intermediary doctrine, whose demise would expose drug manufacturers to "expansive and expensive . . . liability."[111] The FDA's DTC advertising regulations inform the legal doctrines that apply, in turn, when an injured patient's lawsuit implicates a drug's DTC advertising campaign.[112]

1. Learned Intermediary Doctrine

The learned intermediary doctrine is a potent weapon that forecloses a drug manufacturer's liability to a patient for failure to warn or misrepresentation when the company adequately warned the patient's prescribing physician.[113] In 1998, the Restatement (Third) of Torts: Products Liability acknowledged a possible exception to the doctrine when drug manufacturers publish and broadcast DTC advertisements, but the Restatement deferred to "developing case law" to determine whether to recognize this as an actual exception to the doctrine.[114] The doctrine has survived most challenges based on

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[109] HERRMANN & ALDEN, *supra* note 52, at 61.

[110] *See id.* at 60.

[111] Twerski, *supra* note 16, at 1153.

[112] Schwartz et al., *supra* note 8, at 354 (explaining that "the learned intermediary doctrine, regulatory compliance [defenses], and federal preemption" help determine failure to warn liability). Since the Supreme Court has recognized DTC advertising as permissible and protected commercial speech, drug manufacturers can challenge the FDA's regulations on First Amendment grounds. Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002). It is, therefore, imperative to consider the legal ramifications of the FDA's regulations for products liability claims because these consequences may factor into a manufacturer's decision whether to contest the FDA's authority to regulate. *See* Y. Tony Yang & Brian Chen, *Legal Considerations for Social Media Marketing by Pharmaceutical Industry*, 69 FOOD & DRUG L.J. 39, 50 (2014); *see also* Cortez, *supra* note 55, at 408.

[113] JAMES A. HENDERSON, JR., AARON D. TWERSKI & DOUGLAS A. KYSAR, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 435 (8th ed. 2016). Courts have agreed that the physician—as someone without whom the patient would be unable to receive a prescription, and as someone with the requisite medical training and contact with the patient to make a calculated judgment about the appropriateness of certain treatment—functions as an "informed intermediary." *See, e.g.*, Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 290 (6th Cir. 2015); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980); Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974). Accordingly, the manufacturer's duty to warn runs to the prescribing physician, but not to the patient. *Yates*, 808 F.3d at 290.

[114] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. e (AM. LAW INST. 1998).

current DTC practices, apart from rulings in New Jersey, West Virginia, and New Mexico.[115]

In *Perez v. Wyeth Laboratories, Inc.*, the New Jersey Supreme Court created an exception to the learned intermediary doctrine, assigning drug manufacturers that engage in DTC advertising a corresponding duty to directly warn consumers as well.[116] The court explained that DTC advertisements mooted several premises of the doctrine, namely that:

> (1) reluctance to undermine the doctor patient-relationship [sic]; (2) absence in the era of "doctor knows best" of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject; are all (with the possible exception of the last) absent in the direct-to-consumer advertising of prescription drugs.[117]

In so doing, the *Perez* court found that the learned intermediary doctrine did not shield drug manufacturers who advertised directly to consumers.[118] West Virginia went even further in 2007 when its highest court wholly rejected the learned intermediary doctrine as obsolete.[119] In line with the *Perez* court's rationale, the court held that DTC advertising "obviates each of the premises [of] the doctrine."[120]

There are two key takeaways from these attacks on the doctrine. First, no other states have replicated West Virginia's outright rejection of the learned intermediary doctrine or New Jersey's DTC advertising exception.[121] To date, most courts have not found that DTC advertising alters doctor-patient relationships so much so that patients have direct and unilateral access to prescription drugs, because prescription drugs still require prescriptions from a learned intermediary.[122] Nor has Congress demonstrated any serious concerns about the possible harms of

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[115] *See* Keri L. Arnold, *The Learned Intermediary Doctrine: A Historical Review*, LAW360 (Oct. 16, 2014, 9:57 AM EDT), https://www.law360.com/articles/587180/the-learned-intermediary-doctrine-a-historical-review [http://perma.cc/NK86-856B].

[116] Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1263 (N.J. 1999).

[117] *Id.* at 1255. Even so, the court limited the fallout from this exception by providing that the manufacturer may satisfy its duty to warn the consumer by complying with federal advertising, labeling, and warning requirements. *Id.* at 1259; *see also infra* Section II.B.2.

[118] *Perez*, 734 A.2d at 1263.

[119] State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 910 (W. Va. 2007).

[120] *Id.*

[121] HENDERSON ET AL., *supra* note 113, at 443. A federal district court in New Mexico came close in a diversity case when it predicted that New Mexico state law would reject the learned intermediary doctrine, but New Mexico's highest court has not ruled as much. Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1214–15 (D.N.M. 2008).

[122] *See In re* Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 812 (E.D. Tex. 2002); Watts v. Medicis Pharm. Corp., 365 P.3d 944, 950–51 (Ariz. 2016); Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 163 (Tex. 2012).

DTC advertising practices,[123] aside from recent discussions about price disclosures in these advertisements.[124] Unless New Jersey or West Virginia law applies, the learned intermediary doctrine may void a claim that a DTC advertisement inadequately communicated the risks of a drug to a patient.[125]

Second, New Jersey and West Virginia's decisions about the implications of DTC advertising for the learned intermediary doctrine seem to have coincided with pivotal moments in the evolution of the FDA's regulatory authority over DTC advertisements.[126] In 1999, the FDA finalized guidance that suggested manufacturers need only disclose a drug's major risks, rather than include an exhaustive brief summary.[127] It is possible that the *Perez* court's ruling that same year was a knee-jerk reaction to the resulting uptick in pharmaceutical advertising practices.[128] Similarly, West Virginia's rejection of the doctrine in 2007 came in the same year that Congress defined limits to the FDA's prereview authority over DTC broadcast advertisements.[129] West Virginia's ruling was at least concurrent with an anxious atmosphere that the FDA was not able to do enough to police the information that patients received from pharmaceutical companies outside of the doctor-patient relationship.[130]

Today, there is increased pressure on the learned intermediary doctrine. First, the evolution of managed care has decreased the availability of doctors to their patients, often resulting in rushed conversations.[131] Second, the rise of urgent

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[123] Schwartz et al., *supra* note 8, at 349.

[124] Robert Pear, *What Big Pharma Fears Most: A Trump Alliance with Democrats to Cut Drug Prices*, N.Y. TIMES (Oct. 20, 2018), https://www.nytimes.com/2018/10/20/us/politics/trump-pharmaceutical-industry-healthcare.html [http://perma.cc/Q2VX-YG3N].

[125] *See, e.g.*, *Watts*, 365 P.3d at 950–51 (explaining that New Jersey's and West Virginia's DTC exceptions to the learned intermediary doctrine have not gained traction).

[126] *Cf.* Schwartz et al., *supra* note 8, at 349 (explaining that early developments of drug regulation were reactions to public safety concerns about prescription drugs).

[127] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 1 (1999); Schwartz et al., *supra* note 8, at 345.

[128] Corey Schaecher, Comment, *"Ask Your Doctor If This Product Is Right for You"*: Perez v. Wyeth Laboratories, Inc.*, Direct-to-Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx® Claims*, 26 ST. LOUIS U. PUB. L. REV. 421, 429 (2007).

[129] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, sec. 901, § 503b, 121 Stat. 823, 939 (2007) (codified as amended at 21 U.S.C. § 353c (2012 & Supp. I 2013)).

[130] *See* Noah, *supra* note 52, at 134.

[131] Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1255 (N.J. 1999).

care clinics[132] and telemedicine[133] raises questions about the substance of doctor-patient relationships in such abbreviated and remote circumstances, respectively, especially when doctors offer prescriptions on demand to patients they have never met.[134] Third, consumers' online access to a drug's official website and the rise of social media, as well as the FDA's abundance of recent guidelines and proposals for online DTC practices,[135] present other convenient avenues for interactions between manufacturers and patients.[136] These new frontiers, combined with DTC practices generally, suggest that courts soon may revisit the question of a manufacturer's duty to warn the patient.[137] If courts abrogate the learned intermediary doctrine, manufacturers must rely on other strategies, like regulatory compliance and preemption, to defend their DTC practices.

2. Regulatory Compliance

The current regime also hinders a drug manufacturer's ability to assert regulatory compliance as a defense.[138] Compliance defenses have merit where the regulation in question is recent and reflects a current standard that is relevant and probative of the claim.[139] That standard should reflect "substantial expertise" and result from "full, fair, and thorough" deliberation.[140] Where a plaintiff alleges deceptive advertising of FDA-approved products, some courts have

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[132] Reed Abelson & Julie Creswell, *The Disappearing Doctor: How Mega-Mergers Are Changing the Business of Medical Care*, N.Y. TIMES (Apr. 7, 2018), https://www.nytimes.com/2018/04/07/health/health-care-mergers-doctors.html [http://perma.cc/P3AZ-3PS6].

[133] Melinda Beck, *How Telemedicine Is Transforming Health Care*, WALL ST. J. (June 26, 2016, 10:10 PM ET), https://www.wsj.com/articles/how-telemedicine-is-transforming-health-care-1466993402 [https://perma.cc/QE87-BBXR].

[134] *Id.*

[135] *See, e.g.*, Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Draft Guidance for Industry, 79 Fed. Reg. 58,357 (Sept. 29, 2014); *see also* Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Draft Guidance for Industry, 79 Fed. Reg. 58,359 (Sept. 29, 2014).

[136] *See, e.g.*, Gilead Sciences, Inc., Comment Letter on Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements 2 (Dec. 14, 2017), https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-2936-0056&attachmentNumber=1&contentType=pdf [http://perma.cc/SE8S-XRVL] (calling on the FDA to allow drug manufacturers to use social media, product websites, and other digital avenues to supplement risk disclosures).

[137] Yang & Chen, *supra* note 112, at 50; Arnold, *supra* note 115.

[138] Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 901–02 (2009) (explaining that the compliance defense is generally unavailable in the DTC context, "unless courts [understand] the manner in which agency expectations operate as de facto requirements").

[139] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (AM. LAW INST. 1998).

[140] *Id.*

considered the drug approval process to be "conduct that is closely regulated . . . [and] beyond the scope of more general state statutes prohibiting deceptive advertising."[141]

Several states recognize a regulatory compliance defense[142] via statute,[143] their courts,[144] or both.[145] This defense creates rebuttable presumptions about drug safety and adequacy of warnings,[146] or otherwise limits or altogether precludes punitive damages against drug manufacturers who demonstrate good faith compliance with FDA requirements.[147] A plaintiff's burden of proof to rebut this presumption may be so high that a court may dismiss a failure to warn claim on the merits.[148] Most jurisdictions, however, do not recognize regulatory compliance as dispositive, since FDA regulations function as floors for corporate conduct.[149]

One problem with invoking a regulatory compliance defense against failure to warn and misrepresentation claims is that the FDA's DTC advertising regulations are "outdated."[150] These requirements have not been subjected to full regulatory scrutiny since before 1997, when the FDA issued a draft of its first DTC advertising guidance.[151] Since 1997, the FDA's regulations for prescription drug DTC advertisements have only been updated

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141 Schwartz et al., *supra* note 8, at 371–72.

142 Schwartz & Goldberg, *supra* note 29, at 174–76.

143 *See, e.g.*, N.J. STAT. ANN. § 2A:58C-4 (West 1987); OR. REV. STAT. § 30.927 (West 1987).

144 *See, e.g.*, Brown v. Super. Ct., 751 P.2d 470, 482–83, 483 n.12 (Cal. 1988) (concluding that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings" and explaining that the FDA closely regulates the standards for drug manufacturing and labeling); Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1259 (N.J. 1999) (explaining that "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims").

145 *See, e.g.*, UTAH CODE ANN. § 78B-6-703 (West 2008); UTAH CODE ANN. § 78B-8-203 (West 2008), *invalidated in part as preempted by* Grange, Jr. v. Mylan Labs., Inc., No. 1:07-CV-107 TC, 2008 WL 4813311 (D. Utah Oct. 31, 2008); Grundberg v. Upjohn Co., 813 P.2d 89, 99 (Utah 1991).

146 *See, e.g.*, N.J. STAT. ANN. § 2A:58C-4 (creating a rebuttal presumption of the adequacy of a manufacturer's warnings after FDA approval); UTAH CODE ANN. § 78B-6-703 (creating a rebuttable presumption that a product prepared in compliance with government regulations is "free from . . . defect").

147 OR. REV. STAT. § 30.927 (precluding punitive damage awards against a drug manufacturer when the FDA reviewed and approved the drug and its label); UTAH CODE ANN. § 78B-8-203 (precluding punitive damage awards where the alleged harm stemmed from a drug that the FDA approved and "recognized as safe and effective").

148 *In re* Accutane Litig., No. 079933, 2018 WL 4761403, at *26–28 (N.J. Oct. 3, 2018) (dismissing 532 plaintiffs' claims for failure to warn where the plaintiffs "failed to show any of [three] bases for overcoming the presumption of adequacy" of FDA-approved warnings).

149 Tobias, *supra* note 86, at 1017–18. Where it is asserted, this defense tends to factor into jury deliberations. Schwartz et al., *supra* note 8, at 369-70; Tobias, *supra* note 86, at 1019.

150 Bennett et al., *supra* note 59, at 170.

151 *See* Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171, 43,171 (Aug. 12, 1997); *see also* Noah, *supra* note 52, at 97–98.

once, pursuant to the FDA Amendments Act of 2007, and that update was directed at animal drugs, not human medications.[152]

Another concern with a regulatory compliance defense is that courts might not be willing to extend the protections of de jure rules to the FDA's "de facto requirements."[153] For example, the FDA's recent requirements do not reflect the "full, fair, and thorough" deliberation that must inhere in a governing standard, because the agency relies on guidance documents.[154] On paper, guidance documents are subject to a public comment period and enable the FDA to respond quickly to scientific advances, so they appear to be products of a deliberative process, as well as reflect recency.[155] The abbreviated nature of this deliberative process, however, pales in comparison to the intensity of promulgation of other administrative law, like regulations and rules.[156]

It also is unclear if the FDA can even enforce de facto requirements because guidance documents are not binding.[157] Nor is it a secret that the FDA lacks the capacity to exhaustively police all advertisements.[158] The FDA's determination of compliance then might be the result of politicking with regulated entities, which undermines the availability of its requirements as a baseline legal standard for a compliance defense.[159]

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[152] *See* 21 C.F.R. § 202.1 (2018); Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, 72 Fed. Reg. 69,108, 69,119 (Dec. 6, 2007).

[153] Noah, *supra* note 138, at 901–02.

[154] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (AM. LAW INST. 1998); Noah, *supra* note 52, at 113–14.

[155] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (AM. LAW INST. 1998); Noah, *supra* note 52, at 101–02, 119.

[156] 5 U.S.C. § 553(b)(A) (2012); Noah, *supra* note 52, at 101–02. Although, for example, the FDA publishes draft guidance documents for public comment, it "need [not] offer detailed responses to public comments" nor defend its positions therein against "close scrutiny by the other two branches of government." Noah, *supra* note 52, at 102.

[157] Guidance documents include a disclaimer that the FDA's recommendations are not binding. *See, e.g.*, U.S. FOOD & DRUG ADMIN., PRODUCT NAME PLACEMENT, SIZE, AND PROMINENCE IN PROMOTIONAL LABELING AND ADVERTISEMENTS: GUIDANCE FOR INDUSTRY 1 (2017).

[158] Reuven Blau, *FDA Sends Record Low Number of Warnings to Drugmakers Found Lying in Ads*, N.Y. DAILY NEWS (Dec. 11, 2017), http://www.nydailynews.com/news/national/record-number-fda-warnings-drugmakers-lie-ads-article-1.3690161 [http://perma.cc/MBM8-MDFF].

[159] Noah, *supra* note 52, at 132–34. The FDA's reliance on guidance documents has given rise to informal enforcement mechanisms, where guidelines are binding insofar as the FDA is able to induce voluntary compliance. *Id.* at 122–24. Congress tried to rectify this legitimacy problem by declaring the FDA's guidelines to be authoritative, but legislators have not extended this authority to other federal agencies. *Id.* at 109–10.

3. Preemption

A related concern is the availability of the preemption doctrine in the DTC advertising context.[160] Preemption occurs in one of three ways: (1) express preemption, where Congress explicitly provides for federal law to supersede state law on a particular matter;[161] (2) implied conflict preemption, where state and federal law either directly conflict with each other to make it impossible to comply with both legal regimes or where state law is an obstacle that frustrates Congress's intentions behind a particular federal law;[162] and (3) implied field preemption, where federal law occupies an entire field of regulation, leaving no room for state law to simultaneously govern this area.[163]

A drug manufacturer's ability to invoke preemption in a failure to warn or misrepresentation claim depends on the extent to which the FDA monitors and polices advertisements and whether there are codified standards that such advertisements must satisfy.[164] At the outset, Congress granted the FDA the authority to review DTC advertising "implicitly by prohibiting misbranding."[165] This moots express preemption because Congress did not explicitly preclude state law claims or parallel heightened state law requirements relating to DTC advertising practices.[166]

Conflict preemption likewise may be beyond reach, because the Supreme Court set a high bar for impossibility for dual compliance with federal and state standards that is currently lacking in the DTC context.[167] There is no direct conflict between FDA regulations and a state law claim, because the FDA's authority to require changes pursuant to a prereview is limited to adding risk disclosures and FDA approval dates for new drugs.[168] The scope of FDA regulations as ceilings on corporate

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[160] Litigants have contested implied conflict preemption in claims involving prescription drugs. Schwartz et al., *supra* note 8, at 379. Field preemption might also be available in the DTC context with an eye to the FDA's "primary responsibility for [this] issue." HERRMANN & ALDEN, *supra* note 52, at 341.

[161] HERRMANN & ALDEN, *supra* note 52, at 318.

[162] *Id.*

[163] *Id.* at 318–19.

[164] *Compare* 21 U.S.C. § 352(n) (2012) *and* 21 U.S.C. § 353c (2012 & Supp. I 2013) *with* Wyeth v. Levine, 555 U.S. 555, 578–79 (2009) (explaining that preemption is not available by default and "manufacturers, not the FDA, bear primary responsibility for their drug labeling"); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (AM. LAW INST. 1998); Schwartz et al., *supra* note 8, at 386.

[165] Moore et al., *supra* note 2, at 3-14.

[166] HERRMANN & ALDEN, *supra* note 52, at 335.

[167] *Levine*, 555 U.S. at 590–91 (Thomas, J., concurring) (explaining that the Court's impossibility standard is so narrow that it is possible for federal and state law requirements to directly conflict with each other without being impossible to demonstrate compliance with both); HERRMANN & ALDEN, *supra* note 52, at 339.

[168] 21 U.S.C. § 353c(e).

conduct, and whether they would trigger a conflict, is unclear.[169] As for obstacle preemption and field preemption, it is difficult to defer to the FDA's decision-making process and regulatory goals when it does not have sufficient power to require changes to an advertisement before it reaches consumers[170] and it has not demonstrated a reliable capability of policing every DTC advertisement.[171] A lack of preemption gives rise to a liability nightmare in which varying standards of care for DTC advertisements emerge from fifty state tort regimes and federal regulatory provisions.[172]

III. PROPOSED SOLUTIONS DO TOO LITTLE OR GO TOO FAR

A reformulation of the FDA's oversight of DTC drug advertisements should account for both the public health interest in adequately informed consumers and pharmaceutical companies' right to communicate with prospective patients. Recent proposals, however, have not successfully balanced these considerations.

A. The FDA's "Limited Risks Plus Disclosure" Proposals Fall Short

On August 21, 2017, the FDA proposed to limit required disclosures to risks "that are severe (life-threatening), serious, or actionable, coupled with a disclosure to alert consumers that there are other product risks not included in the advertisement."[173] The proposal retains the fair balance requirement, even in instances when medications do not have severe, serious, or actionable risks.[174] Some commenters supported reform, but criticized the

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[169] *Levine*, 555 U.S. at 575; Schwartz et al., *supra* note 8, at 380–81. In *Wyeth v. Levine*, the Court withheld preemption because it identified a technicality in the FDA's regulations that allowed a manufacturer to strengthen a drug warning without prior approval from the FDA, even though such a change would still be subject to later review and approval by the FDA. *Levine*, 555 U.S. at 575.

[170] 21 U.S.C. § 353c; WEBER, *supra* note 12, at 180–81.

[171] Perry et al., *supra* note 12, at 768; WEBER, *supra* note 12, at 160.

[172] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (AM. LAW INST. 1998); Schwartz et al., *supra* note 8, at 380.

[173] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017). Severe risks are serious risks that are also life-threatening; serious risks may require hospitalization, cause prolonged disability or incapacity, cause congenital anomalies or birth defects, or otherwise jeopardize the patient or require surgical intervention; and actionable risks are those that a patient can identify and act upon to mitigate its effects. *Id.* In 2014, the FDA categorized risks in a similar "limited risks plus disclosure" approach as "serious and actionable." Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements, 79 Fed. Reg. 9,217, 9,218 (Feb. 18, 2014).

[174] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599. For medications

FDA's sudden recalibration of drug risk categories as confusing for the pharmaceutical industry, doctors, and consumers.[175] Others lamented that the proposal fell short of full transparency to patients and called for simultaneous audio and video disclosure of *all* important risks without any accompanying distractions.[176] Other critics insisted on a ban on all DTC advertising.[177]

Consumers and industry need the FDA to revolutionize its broadcast disclosure requirements. The FDA's current "limited risks plus disclosure" proposal and past iterations thereof fall short of fixing the current regulatory regime's tendency to allow or overlook commercials that generate consumer confusion about risk disclosures.[178] The FDA's 2017 proposal identifies hierarchical categories for risks that drug manufacturers must still disclose individually,[179] so it would not substantially change what drug commercials look and sound like.[180] Adding to the mix are the FDA's subsequent recommendations on describing benefits and risks, which "apply to DTC promotional materials . . . regardless of the medium in which they are

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that do not have severe, serious, or actionable risks, a major statement must still strike a balance in its communication of a drug's benefits and risks. *Id.*

[175] *See* PhRMA Comment Letter, *supra* note 82, at 8–9 (asserting that the "FDA did not acknowledge, address, or explain the change in its position" on required risk disclosures and how to categorize them). The new "severe" risk category is also inconsistent with the drug safety reporting terminology that the industry uses. *Id.* at 9; Eli Lilly & Co., Comment Letter on Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements 4 (Nov. 20, 2017), https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-2936-0053&attachmentNumber=1&contentType=pdf [http://perma.cc/Q9XV-VQ2L] (arguing that the FDA's new "severe" risk category is not defined in the regulations and "will face significant implementation challenges by industry as well as consistency issues").

[176] Public Citizen, Comment Letter on Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements 10–11 (Nov. 20, 2017), https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-2936-0054&attachmentNumber=1&contentType=pdf [http://perma.cc/K7UZ-YQ3X].

[177] *Id.* at 4–5.

[178] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599; Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements, 79 Fed. Reg. at 9,218.

[179] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599. In a comment, a consumer advocacy group proposed that the FDA require full disclosure of the important risks of a drug in DTC advertisements with emphasis on more serious risks. Public Citizen, *supra* note 176, at 10.

[180] *Compare* 21 C.F.R. § 202.1(e)(3)(iii) (2018) (requiring advertisements to "disclose each specific side effect and contraindication" of the advertised drugs) *with* Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599 (describing the "major statement" and "adequate provision" for risk disclosure before defining possible ways to categorize major side effects); *see also* Eli Lilly & Co., *supra* note 175, at 2; Public Citizen, *supra* note 176, at 1.

presented."[181] Research, however, shows that any interest in facilitating consumer comprehension and redirecting information exchanges between pharmaceutical companies and patients away from the broadcast platform is poorly met by detailed disclosure requirements for broadcast platforms.[182] Other proposed overhauls that leave the FDA's DTC regulations untouched do not go far enough either and fall victim to the same criticisms.[183]

Nor do the modified risk disclosures do enough for drug manufacturers' business and litigation interests to dissuade their First Amendment challenges. From a constitutional standpoint, given their similarity, the FDA's proposals suffer from the same concerns about *Central Hudson*'s fourth prong as does the existing framework.[184] These proposals' failure to effectively address the core concern—inability of the broadcast platform to adequately convey efficacy and risk information—likewise threatens to undermine the credibility of broadcast advertisements.[185] Those advertisements will not alleviate the pressure that evolving DTC practices stand to exert on the learned intermediary doctrine, since the basis of that pressure lies in the effect of the broadcasts on patients and doctor-patient relationships.[186]

The FDA's proposal also does little to improve the prospects of preemption and regulatory compliance in the DTC context because the contemplated risk disclosures leave the FDA's problematic regulatory framework intact.[187] As commenters pointed out, the FDA has not promulgated new

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[181] Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements; Draft Guidance for Industry, 83 Fed. Reg. 52,484, 52,485 (Oct. 17, 2018).

[182] *See supra* Section II.B.

[183] *See, e.g.*, Bennett et al., *supra* note 59, at 201–12 (advocating that drug manufacturers' speech be categorized on a spectrum of increasing FDA regulation, exempting noncommercial scientific exchanges from the FDA's scrutiny on one end, while subjecting communications that induce "an immediate commercial transaction involving the drug," including DTC advertisements, to the "existing regulatory framework"). Absent a change to DTC regulations in particular, current problems with consumer-facing advertisements would continue unabated.

[184] *See supra* Section I.C (explaining the fourth prong's requirement that a speech restriction be narrowly tailored to the underlying governmental interest).

[185] Commenters even argued that the broadcast platform is inherently incapable of adequately informing a consumer, because the viewer has a mere moment to comprehend highly scientific and condensed information before other programming commands his or her attention instead. Ass'n of Magazine Media, Comment Letter on Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements 10–11 (Nov. 20, 2017), https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-2936-0051&attachmentNumber=1&contentType=pdf [http://perma.cc/XS5P-93ZB].

[186] *See* AM. COLL. OF PHYSICIANS, *supra* note 3, at 9.

[187] *See supra* notes 80–82 and accompanying text (providing an overview of the FDA's lack of formal rulemaking and increasing reliance on non-binding guidance documents and other informal processes).

regulations for DTC broadcast advertisements pursuant to the FDA Amendments Act of 2007, instead issuing notices of proposed rulemaking or requests for comments (that it did not implement) and resorting to guidance documents.[188] Importantly, the pharmaceutical industry expressed concern about the FDA's unilateral and unsubstantiated reformulation of the risk categories, as compared to its 2014 proposal.[189] Such flexibility of the FDA's process to issue guidelines allows it to stay current, but this comes at the expense of full regulatory scrutiny, which compromises a regulatory compliance defense.[190] This proposal also fails to satisfy *Levine*'s high bar for preemption, which, in the absence of Congress's express statutory provision preempting state law, requires that it truly be impossible for a manufacturer to comply with both federal and state law.[191] Here, the FDA continues to lack codified authority to require anything other than additional risk disclosures and a new drug's FDA approval date in drug commercials before they reach the consumer, which leaves room for state law standards, and even other federal agencies, to require other disclosures.[192]

The FDA's proposal, therefore, does not adequately confront state law liability either. Given the potential for liability—due to the questionable prospects for preemption and unavailability of the regulatory compliance defense in the current DTC context, as well as increased pressure on the learned intermediary doctrine—it would be in the drug industry's best interest for the FDA to find another solution.

B. A Ban on DTC Advertisements Would Be Unconstitutional

Opponents of DTC drug advertisements would be unable to defend a ban on these ads from a constitutional challenge. One such opponent, the American College of Physicians (ACP), argues that the practice "undermines the patient-physician relationship" and "confuse[s] and misinform[s]" patients.[193] The American Medical Association,[194] as well as advocacy groups like

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[188] *See, e.g.*, Public Citizen, *supra* note 176, at 3–4.

[189] PhRMA Comment Letter, *supra* note 82, at 8–9. The industry was surprised to see that the FDA expanded the required risk disclosure from serious and actionable risks to severe, serious, or actionable risks, when the FDA's most recently concluded study of DTC advertisements examined serious and actionable risks only. *Id.*

[190] *See supra* notes 153–156 and accompanying text.

[191] *See supra* notes 164–169 and accompanying text.

[192] *See supra* notes 25–27, 168–169 and accompanying text.

[193] AM. COLL. OF PHYSICIANS, *supra* note 3, at 2.

[194] Press Release, Am. Med. Ass'n, *supra* note 19.

Public Citizen, similarly oppose DTC advertising practices as harmful to patients.[195] These organizations prefer that the practice be banned altogether.[196] Other critics support a limited ban on DTC broadcast advertisements in particular, while leaving other forms of drug promotion intact.[197] And yet other critics propose that drug manufacturers observe moratoria for new drugs "to permit physicians and the agency to assess whether the newly-sold drugs pose risks" that clinical trials might fail to uncover.[198]

Regardless of the legitimacy of such concerns, commercial speech jurisprudence suggests that neither a moratorium, nor an outright ban, would survive a First Amendment challenge.[199] *Central Hudson* protects DTC advertisements as commercial speech if the speech is lawful and is not misleading, and if a ban would exceed what is necessary to serve the government's interest of protecting patients.[200] The Supreme Court has expressed its preference for "the far less restrictive alternative" of simply requiring drug manufacturers to disclose a drug's risks instead of preventing manufacturers from advertising to patients at all.[201] Furthermore, the law already protects consumers from advertisements that unlawfully contravene the FDA's regulatory process, if manufacturers disregard the FDA's warnings about omissions from their ads[202] or advertise the drug for uses beyond the set of indications for which the FDA has already approved the drug.[203]

In essence, courts are "hostil[e] to categorical restraints denying consumers information about lawful products."[204] A regulation targeting DTC advertisements, or broadcasts in particular, should address concerns about consumer confusion

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[195] Public Citizen, *supra* note 176, at 4–5.

[196] AM. COLL. OF PHYSICIANS, *supra* note 3, at 2; Press Release, Am. Med. Ass'n, *supra* note 19; Public Citizen, *supra* note 176, at 4–5.

[197] Vladeck, *supra* note 51, at 284.

[198] Margaret Gilhooley, *Drug Regulation and the Constitution After* Western States, 37 U. RICH. L. REV. 901, 921 (2003); *see also* SUSAN THAUL, CONG. RESEARCH SERV., R40590, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS 32 (2009).

[199] Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002); *see* Margaret Gilhooley, *Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses*, 47 SAN DIEGO L. REV. 845, 848 (2010) (explaining that "the Court's rationale raises a constitutional question about the permissibility of a moratorium on DTC advertisements or other speech restrictions for drugs"); Mark I. Schwartz, *To Ban or Not to Ban—That Is the Question: The Constitutionality of a Moratorium on Consumer Drug Advertising*, 63 FOOD & DRUG L.J. 1, 18 (2008).

[200] *See supra* Section I.C.

[201] *W. States Med. Ctr.,* 535 U.S. at 376.

[202] 21 U.S.C. § 353c(e) (2012 & Supp. I 2013).

[203] 21 U.S.C. § 352(n) (2012); 21 C.F.R. § 202.1(e)(6)(i) (2018).

[204] Vladeck, *supra* note 51, at 287.

without blocking an entire channel of communication between the drug manufacturer and the consumer.

IV. DTC BROADCAST ADVERTISEMENTS AS LIMITED CALLS TO ACTION

Congress should expand the FDA's authority to regulate prescription drug claims and disclosures in DTC broadcast advertisements, and the FDA should promulgate implementing regulations, as follows: (1) permit drug manufacturers to identify the drug and the class of patients the drug would treat in a commercial, but otherwise disallow the mention of any other benefits of a drug; (2) determine consumer-friendly risk categories to organize safety information from the drug's label and identify the category names as the *sole* vocabulary for a commercial's risk disclosure;[205] and (3) retain the "adequate provision" requirement, directing the patient to various resources where the drug's approved labeling is available, including the drug's official website, "an operating toll-free telephone number," "print advertisements," and prescribing and dispensing healthcare professionals.[206] For the sake of argument, this note adopts the risk categorizations that the FDA recently proposed—severe, serious, and actionable.[207] When compared to the current framework for DTC drug advertisements, this proposal will yield *restricted* product claims[208] by limiting benefit information to a drug's intended treatment and balancing that with a warning about the applicable groups of drug risks.[209]

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[205] Similar to the FDA's attention to risk signals, this proposal suggests that in DTC broadcast advertisements, risk categorizations should strike a balance between generality and specificity; whatever that balance may be, the commercial's disclosure of the relevant risk categories should not include a list of the drug's specific risks. *See* Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,600 (Aug. 21, 2017); *cf.* Eli Lilly & Co., *supra* note 175, at 5–6 (requesting more specific risk categories than the three that the FDA proposed and showing how DTC commercials rely on risk information from product labeling).

[206] 21 C.F.R. § 202.1(e)(1); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2–3 (1999).

[207] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599.

[208] *See* Schwartz et al., *supra* note 8, at 344.

[209] The FDA does not allow drug manufacturers to group drug risks without permission from the FDA during the approval process or labeling review. 21 C.F.R. § 202.1(e)(3)(iii)(b). It is, therefore, imperative that the FDA codify certain risk groupings for DTC advertising purposes to satisfy this requirement.

A. What Viewers Will See and Hear

A DTC commercial in this framework for a drug ("X") that treats a condition ("Y") and has serious and actionable risks might look this:

> Have you been living with Y? This message is for you. X is FDA-approved to treat patients with Y. X is also associated with serious and actionable risks, so talk to your doctor about X and Y and see our website, www.X.com, for more information about X's benefits and risks.[210]

This format, upon codification, facilitates consumer understanding and nationwide drug advertising standards by simplifying the framework and cementing them as requirements, rather than recommendations in a guidance document.[211] The advertisements are also purposefully general when making an efficacy claim—that the drug treats a certain condition—and when describing the groups of risks that have been observed in patients using the drug. This generality will induce consumers to treat broadcast commercials as calls to action, not to buy a brand medication, but to trigger conversations with doctors and research on print and web platforms, where explanations of a drug's benefits and risks can be much more comprehensive.[212]

In the interest of both business and patients' rights, the FDA should utilize broadcast regulations to promote a shift to web and print advertisements. Print advertisements and online content are better vehicles for specific benefit and risk information, because they are flexible platforms that give patients an opportunity to review a drug's materials on their own time and at their own pace.[213] A regulation that strictly limits the content of a DTC broadcast advertisement and requires manufacturers to direct potential patients to consult more comprehensive platforms like a magazine or a drug's

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[210] This proposal lends itself well to a recent trend in drug advertising, in which manufacturers preface the launch of a new drug with a "disease awareness" campaign informing consumers about the condition that the new drug will treat, without naming the drug. *See* Schwartz & Woloshin, *supra* note 5, at 82. The launch of a commercial after the FDA's approval of a new drug, under this proposal, would preserve the drug industry's introduction of that drug as a possible solution to the ailment. Beth Snyder Bulik, *Awareness Is In: DTC Disease Campaigns Surge in the U.S.*, FIERCEPHARMA (Jan. 25, 2019, 12:25 PM), https://www.fiercepharma.com/marketing/did-you-know-dtc-disease-awareness-soars-u-s-spending-and-placement-up [https://perma.cc/3ZMW-HVFV].

[211] *See* Noah, *supra* note 52, at 97–98; *cf.* PhRMA Comment Letter, *supra* note 82, at 15–16 (recommending that any new risk categorizations be implemented across the entire prescription drug regulatory framework).

[212] *See* Ass'n of Magazine Media, *supra* note 185, at 10–11.

[213] *Id.*

website would facilitate that behavior.[214] It would also balance the manufacturer's profit interests as a business and the patient's interests in complete and accurate information, by allowing the manufacturer to make thorough claims and disclosures on appropriate platforms.

As to enforcement, this note is silent on whether Congress should also authorize the FDA to require changes further to prereview of drug advertisements because it may not be necessary in this proposed framework. This note rests instead on the text of the proposed restrictions as sufficiently clear to direct manufacturers to treat broadcast ads as distinctly limited vehicles, integrated into a comprehensive advertising campaign with print and web components. The question still remains whether the FDA can undertake an exhaustive role in regulating DTC advertisements. This note takes no position on how the FDA would afford the personnel and resources to review advertising campaigns in this framework, except to say that Congress should, at the same stroke, enable the FDA to fulfill its enhanced regulatory responsibilities.[215] So long as these commercials are as pervasive as they are today, the FDA must be able to consistently regulate them, rather than "merely scratching the surface in its efforts to improve the quality of consumer information."[216]

B. Drug Industry Buy-In: Commercial Speech and Products Liability in the Big Picture

Another consideration is whether the scope of this restriction on a drug manufacturer's DTC communications would survive a First Amendment challenge.[217] There are two answers to this challenge: (1) satisfy a *Central Hudson* analysis; or (2) persuade drug companies, especially if strict scrutiny ultimately governs, that this restriction is in the industry's best interest.[218]

Under *Central Hudson*, DTC advertisements are protected commercial speech because they are lawful and not

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[214] *See id.* Another concern is the fact that much of the targeted audience—consumers over 65 years of age, for example—may not be especially tech savvy and thus rely on broadcast advertisements. Kaufman, *supra* note 22. In that case, it becomes even more imperative that manufacturers refrain from overwhelming viewers with too much efficacy and risk information in a brief broadcast, and redirect older patients to medical professionals for that conversation.

[215] *See* Vladeck, *supra* note 51, at 287. Congress may be able to accomplish this by enhancing the FDA's regulatory authority or directing more resources to the agency. *Id.*

[216] Perry et al., *supra* note 12, at 768.

[217] *See* Schwartz, *supra* note 199, at 18.

[218] *See supra* note 59 and accompanying text.

inherently misleading. Thus, for any speech regulation to pass constitutional muster, the government must show that it has a valid interest in the FDA's authority to regulate DTC advertisements and that the corresponding regulation is no more restrictive than necessary.[219] The government interest in regulating DTC broadcast advertisements is valid: protecting lay consumers, as unsophisticated listeners, from a barrage of efficacy and risk information in a constrained medium,[220] in which the manufacturer does not even have a clear tort duty to warn the viewer.[221] This interest, put another way, is to force consumers to rely on more comprehensive platforms, like print, web, and doctor's offices, for drug information.

While the FDA's pending proposal may claim the same governmental interest, the restricted product claims in this framework are better tailored to this interest.[222] The difficulty of measuring the statutorily required fair balance of benefits and risks in a broadcast grows as the volume of information increases; recent studies show poor consumer retention of risk information when a commercial discloses too many risks, while consumer retention improves when less information is presented or important information is emphasized.[223] Here, the required balanced disclosure would comprise the drug's approved use and clearly defined risk categories.[224] Systematizing the messages and vocabulary in these advertisements does not exceed the government's interest here, and even falls in line with the pharmaceutical industry's own expressed interests in consistency.[225]

To be clear, this restriction would not ban a company from saying that a drug is effective.[226] A rule that shifts claims and disclosures away from constrained broadcast platforms to other platforms undeniably restricts broadcast communications, but actually serves to encourage more speech on more flexible

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[219] *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 566 (1980); *see also supra* Section I.C.

[220] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017); Friedman & Gould, *supra* note 4, at 106; Ass'n of Magazine Media, *supra* note 185, at 10–11; *see also supra* Sections I.C & II.B.

[221] *See supra* Section II.C.1.

[222] Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. at 39,599.

[223] Betts et al., *supra* note 17, at 957; Sivanathan & Kakkar, *supra* note 17, at 797.

[224] *See* 21 C.F.R. § 202.1(e)(5) (2018).

[225] *See* Eli Lilly & Co., *supra* note 175, at 2–3.

[226] As mentioned before, the Supreme Court does not look favorably on outright bans on commercial speech. *See supra* note 199 and accompanying text.

platforms.[227] The broadcast itself would serve as a testament to the drug's efficacy, since a company still would only be able to advertise a drug for a specific use if its approval and labeling explicitly indicate that the drug has satisfactorily demonstrated efficacy.[228] The broadcast then fulfills its purpose as a call to action in a multifaceted advertising campaign, by directing the viewer to more reliable sources of information, like the drug's website, print advertisements, or an actual doctor.[229] In this way, the restriction is not excessive, but rather, is tailored to define appropriate vehicles for substantive pharmaceutical company messages in a comprehensive campaign.[230]

If the Supreme Court dissolves the distinction between commercial and non-commercial speech,[231] it is not clear that this proposal will survive strict scrutiny analysis. It will, at the very least, intrigue drug companies looking to the future of products liability theories as the market evolves.[232] First, it would bring the FDA's DTC advertising regulations closer to satisfying *Levine*'s high bar for implied conflict preemption.[233] The codified restrictions on all permissible content in DTC broadcast ads would not only set floors, but they would also function as ceilings that would enable the FDA to require changes to noncompliant ads.[234] Each component establishes a requisite floor for advertising practices, while a court would be able to construe broadcast restrictions as a simultaneous ceiling on a drug manufacturer's permissible communications in this context.[235] These floors and ceilings would also lend themselves to a regulatory compliance defense, working together to enforce

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[227] *Cf.* Vladeck, *supra* note 51, at 284–85 (describing how a ban limited to broadcast DTC advertisements would still allow drug companies to "reach consumers with print ads that, presumably, are more informative than brief broadcast ads").

[228] *Cf.* 21 C.F.R. § 202.1(e)(3), (6)(i) (limiting a drug manufacturer's product claims to what the FDA already approved in the labeling).

[229] *Cf.* Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017) (requiring disclosure that advertisement does not convey all of a drug's risks and adequate provision directing patients to printed or web materials).

[230] *See* Ass'n of Magazine Media, *supra* note 185, at 6–7 (explaining how "advertising is more effective the more channels that are used" and when different formats complement each other).

[231] *See supra* note 59 and accompanying text.

[232] Of course, this leaves *any* regulatory solution in the DTC sphere vulnerable to any single manufacturer who endeavors to abolish the regime altogether. Since the Supreme Court has not yet ruled as much, a regulatory framework that would survive strict scrutiny is beyond the scope of this note.

[233] *See* Wyeth v. Levine, 555 U.S. 555, 574–75 (2009); *see also supra* Section II.C.3.

[234] *See* Schwartz et al., *supra* note 8, at 380.

[235] *See Levine*, 555 U.S. at 575. By extension, depending on the language of Congress's authorizing statute, this expanded regulatory power could also be construed as implied field preemption, leaving no room for state law standards of conduct in this context. *See* HERRMANN & ALDEN, *supra* note 52, at 318–19.

national standards of conduct that drug manufacturers could rely on to plan their advertising campaigns before dissemination.[236]

Regardless of which solution the FDA pursues, consumer access to the internet and social media, together with the constraints of managed care, urgent care, and telemedicine on the doctor-patient relationship, will put pressure on the learned intermediary doctrine.[237] This framework recognizes the importance of the prescribing physician and minimizes any perceived fiduciary relationship between the drug manufacturer and the patient, by requiring the manufacturer to convey that it is the doctor who assesses the patient and decides on a course of treatment. Most cases have emphasized the centrality of the learned intermediary—a patient's physician as the ultimate arbiter of the patient's access to any advertised medications—in withstanding ongoing pressure to reject the doctrine.[238] Should current market forces, however, be enough to reject the learned intermediary doctrine, the advantages of bolstered regulatory compliance and preemption defenses here exceed those of the FDA's other options.[239] Combined with drug manufacturers' interests in the credibility that FDA regulations afford their advertisements, the improved viability of these litigation doctrines may facilitate a First Amendment ceasefire between the pharmaceutical industry and the FDA.

CONCLUSION

The FDA's limited regulation of DTC prescription drug advertisements has yielded commercials overflowing with benefit and risk information that often is difficult for consumers to comprehend.[240] Commercials should not hasten a patient's insistence on getting (or stopping) a particular prescription. Congress and the FDA must confront pressure to promote effective advertising of a drug's benefits and risks, especially considering current regulatory constraints and inherently

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[236] *See* Tobias, *supra* note 86, at 1030 (explaining a court's observation that a presumption of regulatory compliance could be overcome "when the FDA imposed no warning strictures").

[237] Yang & Chen, *supra* note 112, at 50; *see supra* notes 131–134 and accompanying text.

[238] *See supra* note 113 and accompanying text.

[239] Arnold, *supra* note 115 (demonstrating the resilience, with some exceptions, of the learned intermediary doctrine as the field of medicine and DTC advertising practices evolve); *see supra* Section III.A.

[240] *See supra* Sections II.A–B.

limited broadcast platforms, as well as consumers' web access and social media use.[241]

A reform should balance policy and legal considerations that affect patients, doctors, drug manufacturers, and the FDA. Restricted product claims offer a balance that other proposals do not. As limited calls to action, these commercials will provide just enough information to catch the attention of targeted patients and prompt them to inquire further, on their own time and volition. This approach not only informs patients, but also provides nationwide floors and ceilings for DTC broadcast practices, while preserving a manufacturer's right to communicate with consumers.

Andrew Andrzejewski[†]

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[241] *See* Friedman & Gould, *supra* note 4 at 106; Yang & Chen, *supra* note 112, at 50.

[†] J.D. Candidate, Brooklyn Law School, 2019; B.S.F.S., Georgetown University, 2009. Thank you to Allison Cunneen, Alexander Mendelson, Chloe Gordils, Briana Stapleton, Anne Conroy, Gabriella Conte, Elyssa Abuhoff, the entire *Brooklyn Law Review* team, and everyone who let me bounce ideas off of them, for your help, guidance, and diligence as I developed this note. Thank you to my Mom, my Dad, and Eva for so many years of love, support, and encouragement. Thank you to Ben for your love and patience as I push myself harder every day. Thank you as well to Jacky for your friendship. You all have my love and eternal gratitude.