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Advertising Medicine: Selling the Cure

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ABSTRACT

Although most countries forbid advertising medicine to patients, "direct-to-consumer advertising" has flourished in the United States over the past century. Research shows that the practice prompts inappropriate prescriptions and disadvantages generic competitors, leading to adverse drug reactions and increased prescription drug spending.

Nevertheless, a comprehensive regulatory system for direct-to-consumer advertising continues to escape the grasp of policymakers. Regulatory authority has bounced between the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA), where primary jurisdiction now resides. Since the FDA assumed responsibility, the agency's only major regulatory initiative has been to minimize disclosure requirements for advertisements. Enforcement of violations has been similarly lackluster. This Article examines the history of medical advertising and the consequences of insufficient regulation, highlighting the need for a new regulatory model.

Rather than leaving responsibility with the FDA or simply transferring it back to the FTC, this Article proposes a coordinated regulatory effort. A coordinated approach to oversight of prescription drug advertising should enable more effective regulation, drawing on the expertise of each agency. In this partnership, the FTC would reprise its past role as monitor and enforcer of prescription drug advertising rules, while the FDA would leverage its scientific expertise to assist in evaluating compliance. By combining the resources and capacities of both agencies, this model offers the potential to fill the problematic gaps in the current regulation of direct-to-consumer advertising.

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TABLE OF CONTENTS

INTRODUCTION

Do you suffer from a sour stomach? What about spinal weakness or other female complaints?[1] Have you been afflicted with internal slime fever?[2] Decades before emergence of the images of talking stomachs[3] or couples in separate bathtubs[4] that are characteristic of today's pharmaceutical advertisements, drug-makers aggressively marketed cures for a whole host of illnesses, real and invented. With vibrant names like Hamlin's Wizard Oil and Dr. Kilmer's Swamp Root, such "patent medicines" tended to keep their actual ingredients—often alcohol or opium—a closely guarded secret.[5] All the while, however, their advertisements were disseminated widely in newspapers, pamphlets, trading cards—even the sides of buildings.[6]

Many decades, laws, and regulations later, prescription drugs continue to be promoted extensively to consumers today, a practice known as "direct-to-consumer advertising," which this Article will refer to as, simply, "advertising."[7] The United States occupies a lonely outpost in allowing unfettered direct-to-

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[1] *See* Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 664 (2006) (describing Lydia Pinkham's Vegetable Compound, a descendant of which is still marketed today).

[2] *See Curious Collections of Fort Stanwix National Monument: Dr. Kilmer's Medicine Bottle*, NAT'L PARK SERV., https://perma.cc/HNU5-W9PW.

[3] *See* GERALD POSNER, PHARMA: GREED, LIES, AND THE POISONING OF AMERICA 508 (2020) (describing the gamut of television advertising gimmicks).

[4] Beth Snyder Bulik, *My Bathtub or Yours? How a Panned Cialis Ad Became Promotional Gold*, FIERCE PHARMA (May 27, 2015), https://perma.cc/3NB5-SEMZ.

[5] *See* GRAHAM DUTFIELD, THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY, 1880-2020, at 166 (2020) (distinguishing patented ethical medications from the secret recipes of "patent medicines"); *History of Patent Medicine*, HAGLEY, https://perma.cc/ACQ6-Q7MN (explaining that so-called "patent medicines" in the 19th century were elixirs that did not hold patents, were often similar among competitors, and generally consisted of vegetable extracts and alcohol).

[6] *See History of Patent Medicine: Advertising and Branding*, HAGLEY, https://perma.cc/57HL-GEC4 (describing printed advertisements, trading cards and broadsides as patent medication marketing materials).

[7] Direct-to-consumer advertising began to flourish in 1997, when the FDA relaxed certain regulatory disclosure requirements, *see infra* notes 81-82 and accompanying text. The practice now exists alongside a separate practice known as "detailing," in which pharmaceutical company representatives make direct contact with physicians to provide more information on a particular drug and emphasize its benefits. Like direct-to-consumer advertising, detailing has been shown to drive inappropriate prescriptions and higher health costs. *See* Melissa N. Hoffman, *Pharmaceutical Detailing Is Not for Everyone: Side Effects May Include Sub-Optimal Prescribing Decisions, Compromised Patient Health, and Increased Prescription Drug Spending*, 33 J. LEGAL MED. 381 (2012); *see also* Ram Bala & Pradeep Bhardwaj*, Detailing vs. Direct-to-Consumer Advertising in the Prescription Pharmaceutical Industry,* 56 MGMT. SCI. 148 (2010).

consumer advertising. The United States and New Zealand are the only nations that permit medical advertising to include product claims.[8] Canada allows advertising to reference either the product or the medical condition, but not to make claims about how effective the product is, and most countries completely forbid advertising medicine to patients.[9] Looking across the pond to Europe, European Union nations voted twenty-two to five in 2008 to reject a proposal allowing even limited advertising directly to patients.[10]

When prescription drugs first replaced "patent" medications in the mid-20th century, however, direct-to-consumer advertising was seldom employed. In fact, many drug-makers actively opposed direct-to-consumer advertising until the 1990s, preferring to market to physicians.[11] Now, however, the average American television viewer can expect to watch more than sixteen hours of televised prescription drug advertisements annually,[12] on top of exposure to advertisements in magazines and on the Internet.

Although supporters of direct-to-consumer advertising contend that the practice provides an important educational resource to patients,[13] research highlights the breadth of its negative consequences. Among these, marketing a drug directly to consumers boosts drug prices,[14] raises health care spending, and increases adverse patient outcomes.[15] The practice also enables brand companies to disadvantage generic competitors, inhibiting price-lowering generic uptake.

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[8] C. Lee Ventola, *Direct-To-Consumer Pharmaceutical Marketing: Therapeutic or Toxic?*, 36 PHARM. & THERAPEUTICS 669 (2011).

[9] *Id.*; Steven G. Morgan, *Direct-to-Consumer Advertising and Expenditures on Prescription Drugs: A Comparison of Experiences in the United States and Canada,* 1 OPEN MED. 37 (2007); *see also* Ann Silversides, *Abramson: Direct-to-Consumer Advertising Will Erode Health Care,* 178 CANADIAN MED. ASS'N J. 1126 (2008).

[10] Ventola, s*upra* note 8, at 669; *see also* G. Humphreys, *Direct-to-Consumer Advertising Under Fire,* 87 BULL. WORLD HEALTH ORG. 576, 577 (2009).

[11] Donohue, *supra* note 1, at 677-78; POSNER, *supra* note 3, at 501-03. *But see* Jeremy A. Greene & David Herzberg, *Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century*, 100 AM. J. PUB. HEALTH 793 (2010) (describing how, although refraining from direct-to-consumer drug advertising, drug-makers in the mid-20th century engaged in "institutional advertising" to promote their company or implicitly promote a certain product).

[12] Dominic L. Frosch et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANN. FAM. MED. 6, 6 (2007).

[13] Ventola, *supra* note 8, at 672.

[14] Dhaval Dave & Henry Saffer, *Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand*, 79 S. ECON. J. 97, 97 (2012).

[15] *See, e.g.*, Guy David, Sara Markowitz & Seth Richards-Shubik, *The Effects of Pharmaceutical Marketing and Promotion on Adverse Drug Events and Regulation*, 2 AM. ECON. J.: ECON. POL'Y 1, 1 (2010) (associating direct-to-consumer advertising with greater adverse drug reactions).

As consumer advertising has flourished, federal regulation has withered. Over the past century, regulatory authority for prescription drug advertising has bounced between the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA), where primary jurisdiction now resides. As with any solution that addresses only part of the problem, the current regulatory regime falls short of the mark. The FDA tends to focus narrowly on the technical details of issues such as side effects rather than addressing the broader questions of medical advertising. In theory, the FDA requires that prescription drug advertisements communicate a "fair balance" of benefits and risks.[16] In practice, however, research suggests that drug companies routinely fail to convey a balanced portrait of their product.[17] The 1997 loosening of televised advertising disclosure requirements only serves to tip the scales further from a fair balance. In the fifty years since the FDA assumed responsibility for prescription drug advertising, the only major update to the regulatory regime has effectively minimized the amount of risk information manufacturers must disclose.[18]

FDA enforcement of prescription drug advertising violations is similarly lackluster. The agency relies principally on so-called "untitled letters" and warning letters to sanction noncompliant advertisers,[19] a relatively toothless measure that often fails to rectify the damage caused by misleading advertisements. A record of the FDA's enforcement actions, moreover, suggests that the agency is underequipped for the task: Recent years have witnessed a precipitous drop in the number of warning letters issued—with 80% fewer letters issued in 2016 than 2010, for example—even as direct-to-consumer drug advertising spending continues its growth.[20] It is certainly possible that companies have become expert at staying carefully within

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[16] *See Prescription Drug Advertising: Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Jun. 19, 2015), https://perma.cc/YW9B-BB3K.

[17] *See, e.g.*, Frosch, *supra* note 12, at 12.

[18] *See infra* Section III.A.

[19] *See* Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 429-30 (2002) (describing the FDA's use of untitled and warning letters).

[20] Yam B. Limbu, Christopher McKinley & Valerio Temperini, *A Longitudinal Examination of FDA Warning and Untitled Letters Issued to Pharmaceutical Companies for Violations in Drug Promotion Standards*, 53 J. CONSUMER AFFS. 3, 9 (2019). Meanwhile, prescription drug advertising spending has mushroomed in recent years. *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://perma.cc/T8G4-CTQ5 (documenting a 65% increase in televised drug advertisements between 2012 and 2016). *See also infra* Section III.B.1.i (discussing evidence of ongoing regulatory violations by advertisers).

appropriate lines such that the need for regulatory response has plummeted, even as the volume of advertising has increased. Research suggests the contrary, however.[21]

Considerable ink has been spilled over the years contemplating how to design prescription drug advertising oversight at the FDA or debating whether that agency or the FTC should have sole responsibility for prescription drug advertising. A cogent regulatory regime for direct-to-consumer advertising, however, has continued to escape the grasp of policymakers. Rather than continue to allow the FDA to try—and fail—to shoulder the burden alone, this Article proposes a coordinated regulatory effort between the two agencies, headed by the FTC.

Drawing on the expertise of each agency, a coordinated approach to prescription drug advertising oversight should enable more effective regulation. In outlining such a partnership, this Article also advocates more broadly for a departure from the siloed model of regulation, in which an agency monitors its bailiwick in relative isolation. Rather, because the impact of practices like prescription drug advertising often extends beyond a lone agency's confines, it becomes sensible to harmonize regulatory efforts and leave the silo behind.

This Article proceeds as follows. Part I tours the history of pharmaceutical promotion efforts, tracing the path from nostrum newspaper pullout to primetime television commercial. Part II reviews the consequences of direct-to-consumer advertising for outcomes such as prescription drug usage and health care spending, illustrating the harms wrought by the practice. Part III follows the tortuous development of modern prescription drug regulations, passed between the FTC and FDA as policymakers struggled to adapt to evolving marketing tactics. Part IV outlines an alternative regulatory regime with the two agencies working together: The FTC should re-enter the field so that it can play a significant role as monitor and enforcer of prescription drug advertising rules, while the FDA leverages its scientific expertise to assist in evaluating compliance.

I. A BRIEF HISTORY OF PHARMACEUTICAL MARKETING

Pharmaceutical marketing has had three historical phases. In the 19th and early 20th centuries, the "patent medicine" industry flourished with the help of

[21] *See infra* text accompanying notes 186-189.

widespread and exuberant marketing campaigns.[22] Following passage of the Food, Drug & Cosmetic Act of 1938 and other legislation—measures that moved many drugs behind the pharmacy counter—drug companies largely shifted their attention to physician marketing, although not at the expense of inventive direct-to-consumer ploys. More recently, the rise of health care consumerism and the FDA's 1997 decision to simplify broadcast advertisement disclosure requirements for drug-makers heralded the modern era of direct-to-consumer advertising.[23]

A. Patent, but not Patented: Marketing "The People's Remedy"

More than a century ago—before prescriptions, dosage regulation, and proof of safety were commonplace—consumers purchased what were generally known as "patent medicines." These ostensible cure-alls were sometimes dubbed "nostrums," a Latin word that meant "our remedy," speaking to their popular appeal.[24] Some are still marketed: Coca-Cola and tonic water were originally "patent medicines", though the modern formulations omit key ingredients, like cocaine and quinine.[25]

Patent medicines were hawked through extensive and outlandish marketing.[26] Advertisements trumpeted cures for myriad afflictions, often with the help of memorable illustrations.[27] An advertisement for Hunt's Remedy ("cures dropsy and all diseases of the kidneys, bladder and liver"), for instance, shows a healthy young man wielding a bottle of Hunt's, arm cocked back to strike down his skeleton assailant.[28] So pervasive were these advertisements that, in 1900, they accounted for half of all newspaper revenue.[29]

Without any regulations requiring safety information or even factual claims, early patent medication advertisements rarely disclosed risks or even ingredients.[30] Manufacturers took pains to protect the secrecy of their

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[22] *See generally* James Harvey Young, *Proprietary Advertising and the Wheeler-Lea Act*, *in* THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN 20TH CENTURY AMERICA 296, 296 (1967).
[23] *See* Donohue, *supra* note 1, at 680-85.
[24] *Id.*
[25] *Id.*
[26] *See generally History of Patent Medicine*, *supra* note 5.
[27] *See, e.g.*, *id.*; Allison C. Meier, *15 Curious Quack Remedies from the Age of Patent Medicine*, MENTAL FLOSS (Sept. 15, 2016), https://perma.cc/ZL3C-BALG.
[28] Meier, *supra* note 27.
[29] POSNER, *supra* note 3, at 30.
[30] Donohue, *supra* note 1, at 664 ("[Patent medicine] advertisements routinely made

formulations, many of which were simply vegetable extract or herbs with alcohol.[31] Consequently, the term "patent medicine" is a misnomer: Many "patent medicines" were not patent*ed* because to receive a patent would require disclosure of their contents.[32]

While critics accused the "patent medicine" industry of peddling snake oil to unwitting consumers,[33] not all medications were phony. Ethical medications tended to be patent-protected, with their chemical formulation publicly accessible through the U.S. Patent & Trademark Office; early examples of ethical medications still used today include aspirin and morphine.[34] The legitimacy of these medications extended to their marketing: Ethical medications were not promoted directly to consumers and were available only through physician prescription, whereas "patent medicines" were generally self-administered by patients.[35]

Ultimately, the marketing prowess of the "patent medicine" industry was its own undoing. By the early 20th century, a popular and legislative backlash against "patent medicines" contributed to the decline of self-medication and direct-to-consumer advertising and brought most drugs behind the pharmacy counter. Public outrage about the fraudulence of "patent medicine" claims led to the 1906 Pure Food and Drugs Act, which required manufacturers to disclose certain substances in their labels and prohibited mislabeling.[36] But the Act's shortcomings were soon exposed by tragedy. In the 1930s, dozens of children

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exaggerated claims about the effectiveness of their products and seldom disclosed their ingredients or risks.").

[31] *History of Patent Medicine*, *supra* note 5; Meier, *supra* note 27. In fact, alcohol was so common to "patent medicine" that Prohibition more effectively hamstrung the industry than early 20th century policies like the Pure Food & Drug Act. *See* POSNER, *supra* note 3, at 38.

[32] *See History of Patent Medicine*, *supra* note 5. Patent medications drew their name from the "patents of royal favor" that were granted to producers of medicine for the royal family in England. The "patent medicine" industry flourished in England, exporting products to the United States as early as the 18th century.

[33] *See, e.g.*, JAMES HARVEY YOUNG, *The Foolmaster Who Fooled Them*, *in* AMERICAN HEALTH QUACKERY: COLLECTED ESSAYS OF JAMES HARVEY YOUNG 32, 33-38 (1992); Frank Billings, *The Secret Nostrum Evil*, 3 CAL. STATE J. MED. 379, 379 (1905).

[34] Donohue, *supra* note 1, at 664.

[35] *Id*. at 665; DUTFIELD, *supra* note 5, at 166.

[36] Pure Food & Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768. For background on the Act, see POSNER, *supra* note 3, at 27-28. The impact of this statute, however, was largely blunted by the ruling in U.S. v. Johnson, 221 U.S. 488 (1911), which decided that the mislabeling provision did not bar companies from making misleading therapeutic claims. The subsequent legislative response—codified in the 1912 Sherley Amendments to the Pure Food & Drug Act—required the government to show that drug-makers intended to defraud consumers, a difficult bar to clear. *See* Donohue, *supra* note 1, at 666.

died after taking "Elixir Sulfanilamide," a sweetened cough syrup mixture.[37] Because existing regulations required only accurate labeling and not safety verification, the elixir manufacturer could be cited only for falsely marketing an "elixir," which, by statutory definition, needed to contain alcohol.[38] The 1938 Food, Drug & Cosmetic Act accordingly mandated safety testing for new drugs, pre-marketing approval by the FDA, and new labeling requirements that included directions for use.[39] The Wheeler-Lea Act concomitantly amended the FTC Act to prohibit the false advertising of products including drugs.[40]

The FDA used its power to regulate drug labeling under the 1938 Food, Drug & Cosmetic Act to designate certain drugs, such as sulfanilamide and narcotics, as prescription-only, partially undercutting the lucrative tide of self-medication that buoyed "patent medicine" makers.[41] Over the subsequent decade, the FDA deemed more than twenty drugs sufficiently dangerous to require a physician's prescription, and a definition of prescription-only drugs was codified in the 1951 Durham Humphrey Amendments.[42]

The resulting regulatory regime redirected consumer drug spending from "patent medicines" to prescription drugs. Drug sales grew more than seven-fold in the twenty years following the 1938 Food, Drug & Cosmetic Act, a surge driven almost exclusively by spending on prescription drugs.[43] "Patent medicines"—which by this point could be more accurately described as proprietary formulations—continued to be prolifically promoted, especially with the advent of television broadcasting.[44] But the greater number of drugs requiring a prescription meant that physicians, not patients, effectively made most purchasing decisions.

B. The Doctor Is In: Direct-to-Physician Marketing

With the rise of prescription requirements, drug-makers developed direct-to-physician marketing, which was poorly regulated by government yet richly

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[37] *See* Julian G. West, *The Accidental Poison That Founded the Modern FDA*, ATLANTIC (Jan. 16, 2018), https://perma.cc/A37X-MGZA.
[38] POSNER, *supra* note 3, at 48.
[39] *See generally* Federal Food, Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
[40] Wheeler-Lea Act of 1938, Pub. L. No. 75-447, 52 Stat. 111.
[41] Harry M. Marks, *Public Health Then and Now: Revisiting "The Origins of Compulsory Drug Prescriptions"*, 85 AM. J. PUB. HEALTH 109, 110-11 (1995).
[42] 1951 Food, Drug & Cosmetic Act Amendments, Pub. L. No. 82-215, 65 Stat. 648.
[43] Donohue, *supra* note 1, at 668.
[44] *See* Harvey Young, *supra* note 22, at 307.

remunerative for industry. Pharmaceutical efforts to "educate" physicians about drug products concentrated in two areas: physician detailing and medical journal articles.[45]

Physician detailing arose in the 1950s, as drug companies began to deploy sales representatives, known as "detail men," to promote drug products to doctors, face-to-face.[46] In what became an industry exemplar of direct-to-physician marketing, Pfizer, then mainly a chemical supplier, increased its detailing corps from eight personnel to 2,000 during the 1950s to promote its broad-spectrum antibiotic, Terramycin.[47] With frequent office calls and direct mailers,[48] Pfizer sales representatives aggressively courted physicians of all specialties to persuade them to prescribe Terramycin for a vast range of afflictions.[49] These efforts paid dividends: Eventually, Terramycin was approved to treat almost forty different conditions, and American antibiotic consumption quintupled, with Terramycin leading the way.[50] Terramycin sales, in fact, catapulted Pfizer to the status of highest-grossing drug-maker in the world.[51]

Pfizer's Terramycin marketing campaign was also groundbreaking in its use of medical journals as a promotional platform. Pfizer inundated publications like the prestigious Journal of the American Medical Association (JAMA) with advertisements touting its antibiotic, a strategy that became standard across the industry.[52] By the 1960s, drug advertising comprised 40% of the American Medical Association's revenue,[53] just as patent medication advertisements, ironically, bankrolled the publication at the turn of the century.[54]

The sheer volume of medical journal advertising likely also owed to lax regulation. The Wheeler-Lea Act of 1938 loosened standards explicitly for

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[45] *See generally* POSNER, *supra* note 3.

[46] *See generally* Scott H. Podolsky, David Herzberg & Jeremy A. Greene, *Preying on Prescribers (and Their Patients) — Pharmaceutical Marketing, Iatrogenic Epidemics, and the Sackler Legacy*, 380 NEW ENG. J. MED. 1785 (2019).

[47] *Id.*; *see also* POSNER, *supra* note 3, at 116-17.

[48] Direct mailers could be regulated by the FDA, in contrast to other forms of advertising like medical journals, which the FDA could not reach prior to the 1962 Kefauver Amendments. *See* Donohue, *supra* note 1, at 670.

[49] Podolsky et al., *supra* note 46, at 1786; *cf.* Carl Elliott, *The Drug Pushers*, ATLANTIC (Apr. 2006), https://perma.cc/38R9-KBKM (describing the modern continuation of physician detailing).

[50] Podolsky et al., *supra* note 46, at 1786. Blockbuster antibiotic sales, in turn, helped generate widespread antibiotic resistance, a problem ongoing today.

[51] POSNER, *supra* note 3, at 117.

[52] POSNER, *supra* note 3, at 115; Donohue, *supra* note 1, at 668.

[53] POSNER, *supra* note 3, at 115.

[54] *Id.* at 18.

physician-directed promotions—such as medical journal advertisements—on the theory that physicians would not be unduly swayed by misleading claims.[55] As a result, manufacturers had significant license to exaggerate claims about their drug to physicians, so long as they disclosed ingredients and refrained from outright falsehood.[56] For instance, Pfizer advertisements highlighted the alleged molecular complexity of its antibiotic to imply that the drug was more innovative than peer antibiotics;[57] others vastly understated clinical evidence of side effects.[58] Some advertisements blatantly conflicted with scholarship published in medical journals.[59] Nor was it unheard of for journal editors to be on the payrolls of pharmaceutical marketers.[60] In short, the notion of an infallible physician audience came to appear misguided as a basis for advertising regulation.

Although the dominance of prescription drugs caused manufacturers to largely refrain from direct-to-consumer advertising during this time, some remarkable marketing ploys did promote drug products to the laity.[61] Drug-makers contracted savvy marketers, like Arthur Sackler, architect of the Terramycin campaign (and patriarch of the now-infamous Purdue Pharma Sacklers), to send pre-written articles to popular magazines like *Time*, highlighting a new drug while ostensibly reporting an interesting story.[62] One such article described how exotic zoo animals were calmed by the new tranquilizer Librium (while another piece remarked on a similar effect in "psychopathic" prisoners).[63] Being "news" rather than advertisements, these

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[55] Milton Handler, *The Control of False Advertising under the Wheeler-Lea Act*, 6 L. CONTEMP. PROB. 91, 102 (1939).

[56] *Id.*

[57] POSNER, *supra* note 3, at 115-16.

[58] *See, e.g.*, Donohue, *supra* note 1, at 670 (describing one example of an antidiabetic drug advertisement that boasted "an almost complete absence of unfavorable side effects," despite 27% of patients in one trial experiencing serious side effects like jaundice).

[59] *See, e.g.*, POSNER, *supra* note 3, at 124-25 (describing one medical journal that published the articles favorably reviewing drugs with the highest sales in order to boost the number of journal reprints).

[60] *See, e.g.*, *id.* at 121-22, 124-25 (noting that the FDA's Division of Antibiotics chief received a six-figure salary from pharmaceutical marketing agencies to edit an antibiotics publication that reviewed efficacy studies of novel antibiotics).

[61] *But see* Greene & Herzberg, *supra* note 11, at 794-97 (noting that direct-to-consumer advertising by pharmaceutical companies, albeit in less explicit forms, was relatively common even during the height of ethical marketing to physicians). Moreover, patent drug-makers were also marketing directly to consumers via television at this time. *See* Harvey Young, *supra* note 22, at 307-08.

[62] POSNER, *supra* note **Error! Bookmark not defined.**, at 184-85.

[63] *Id.*

sensational publications skirted regulatory scrutiny, allowing drug-makers to market to both the doctor and the patients reading in the waiting room.[64]

C. Changing the Channel: The Return of Direct-to-Consumer Advertising

Eventually, direct-to-consumer advertising became a key component of prescription drug marketing as well. After obtaining jurisdiction over prescription drug advertising in 1962, the FDA assumed a permissive posture toward direct-to-consumer promotion.[65] The development of patient advocacy and health care consumerism movements beginning in the 1970s also served to increase patient influence in the prescribing process.[66] As a result, brand recognition among consumers in addition to physicians became valuable to drug companies.[67]

The first direct-to-consumer drug advertisement aired on American television in 1981.[68] The FDA's prescription advertising regulations of 1969 had included no specific guidelines for direct-to-consumer advertising,[69] and, following that first TV ad, the agency proposed a voluntary moratorium in 1982 while it weighed policy.[70] An FDA study found that consumers were unlikely to correctly interpret a medication's risk-benefit balance from a television advertisement.[71] Physician and consumer groups and the pharmaceutical industry came out against direct-to-consumer advertising.[72] Among the complaints levied were that direct-to-consumer advertising would generate higher drug prices and unnecessary prescriptions, and would erode physician authority.[73] Nevertheless, the FDA lifted the moratorium in 1985, stipulating

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[64] *See id.* at 185-86 (marketing agencies contracted by drug-makers sent complementary magazines stocked with their promotional material for display in the doctor's waiting room, where they could be perused by patients).

[65] *See infra* Part III.A (providing a more detailed timeline of prescription drug advertising regulation).

[66] *See generally* Donohue, *supra* note 1, at 673-74, 680-83.

[67] *See id.* at 680 (explaining the value of brand recognition as many companies began to market their older prescription drugs as over-the-counter drugs following patent expiry).

[68] *See* POSNER, *supra* note 3, at 501 (noting that, ironically, the advertisement was for a generic version of Motrin).

[69] *See* Palumbo & Mullins, *supra* note 19, at 427. *See also infra* Part III.A (providing a more detailed timeline of prescription drug advertising regulation).

[70] Palumbo & Mullins, *supra* note 19, at 424.

[71] *Id.*

[72] *See* Donohue, *supra* note 1, at 677-78; POSNER, *supra* note 3, at 501-03.

[73] POSNER, *supra* note 3, at 501-03.

that advertisements to consumers must meet the same standards as those to physicians.[74]

Over the next decade, spending on direct-to-consumer advertising increased industry-wide. The increase was due to FDA approval, the ascendancy of patient-centered medicine and patient involvement in clinical decisions, and the industry's belief that the increased profitability would more than offset any "loss of goodwill" from doctors.[75] Direct-to-consumer spending grew nearly four-fold between 1980 and 1990, and continued to accelerate, growing seven-fold between 1990 and 1995.[76] The transition of more drugs to over-the-counter status after their patent expired also encouraged companies to market prescription drugs directly to consumers: Once over-the-counter, medication is selected purely through consumer preference.[77]

Ambiguities in the FDA regulatory regime, however, did circumscribe the growth of direct-to-consumer advertising in the 1980s and 1990s, particularly on television. The 1969 regulations required that prescription drug product claim advertisements, which name both a drug and what it treats, communicate a brief summary of a drug's risks, side effects, and other label information, or else make "adequate provision" to convey that information separately from the advertisement.[78] Given that the FDA left little guidance about how to fulfill the "adequate provision" requirement and that properly conveying label information would consume much of a television advertisement time slot, drug-makers largely refrained from televised product claim advertisements.[79] Rather, drug-makers tended to limit their televised marketing to help-seeking advertisements, which name a condition but not a drug, or reminder advertisements, which name a drug but not the condition it treats.[80]

This changed in 1997 when the FDA issued draft guidance (finalized in 1999) that eased requirements for televised product claim advertisements, a move that triggered a spending boom in televised direct-to-consumer advertising.

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[74] Palumbo & Mullins, *supra* note 19, at 424.

[75] *See* Donohue, *supra* note 1, at 681-83 (describing the shift toward patient-centered medicine, the corresponding emphasis on "the patient's participation" in clinical decision-making, and the erosion of the paternalistic model of medical care thanks to the availability of online medical information).

[76] Ventola, *supra* note 8, at 670.

[77] Donohue, *supra* note 1, at 680.

[78] *See* Ventola, *supra* note 8, at 670 (outlining the 1969 FDA final regulations).

[79] *See* POSNER, *supra* note 3, at 499. For print advertisements, which were less constrained by space, the 1969 brief summary requirement was less limiting.

[80] Donohue, *supra* note 1, at 684.

Since 1997, direct-to-consumer advertisement spending for prescription drugs has ballooned. The pharmaceutical industry spent $9.6 billion marketing directly to consumers in 2016, up from $2.1 billion in 1997.[81] This staggering growth is concentrated in television and, increasingly, Internet advertisements.[82] Almost 65% more prescription drug advertisements aired in 2016 than in 2012.[83]

Prescription drug advertisements today fall into one of three categories: product claim, reminder, and help-seeking.[84] The most prevalent type is the product claim advertisement, so-called because, in addition to the drug's name and the indication it is approved to treat, it may contain claims about a drug's safety or efficacy.[85] A product claim advertisement is required to communicate a "fair balance" of relevant risks and benefits, and must provide a "brief summary" of side effects and other label information; for televised advertisements, a product claim advertisement may simply include a "major statement" of risks instead of a lengthier summary.[86] A reminder advertisement may list a drug's name and dosage, but it cannot give information about what it treats; the fair balance and brief summary requirements do not pertain to reminder advertisements, as they refrain from making any product claims.[87] Help-seeking advertisements, conversely, provide information about a condition but not a specific drug, although they may include a drug company's logo and website.[88] Unlike product claim and reminder advertisements, which

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[81] Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 JAMA 80, 82 (2019).

[82] Despite the rise of Internet prescription drug advertising, television remains king. Advertising spending in both media have nevertheless experienced exponential growth in recent decades. *See id.* at 82-83 fig. 2 (comparing 72,000 television advertisements in 1997 with the 663,000 aired in 2016, and no Internet spending in 1997 with approximately $500 million in 2016); U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-380, PRESCRIPTION DRUGS: MEDICARE SPENDING ON DRUGS WITH DIRECT-TO-CONSUMER ADVERTISING 13-14 (2021) (noting that drug-makers spent just $603 million on Internet advertising between 2016-2018, compared to $13.4 billion on television, but that more unique drugs advertised on the Internet than on television); Ventola, *supra* note 8, at 671 (noting that Internet prescription drug advertising spending garners an impressive 5:1 return on investment from its highly targeted audience).

[83] Kaufman, *supra* note 20.

[84] *Id.* at 669 (describing each in detail).

[85] *Id.*

[86] *Id.* at 670. In 2004, print advertisement requirements were also relaxed to permit a "simplified brief statement." *Id.*

[87] *Id.* at 669. However, reminder advertisements are not permitted for drug products with black box warning labels. *See Prescription Drug Advertising: Questions and Answers*, *supra* note 16.

[88] *See Correct Help-Seeking Ad*, U.S. FOOD & DRUG ADMIN. (Dec. 23, 2015),

are regulated by the FDA, help-seeking advertisements fall under the jurisdiction of the FTC because they do not include specific prescription drug information.[89]

Notwithstanding their direct-to-consumer advertising, drug-makers have continued their detailing and other physician-focused promotion efforts. Indeed, research suggests that physician detailing, dollar for dollar, generates more new drug sales compared to direct-to-consumer advertising.[90] But some physician-directed promotion campaigns have improperly boosted drug sales through illicit kickbacks or have exacerbated prescription drug abuse. With sales representatives financially incentivized to induce doctors to write more prescriptions, examples abound of illegal payments to physicians, often camouflaged as educational talks, consultancies, or lavish meals.[91] Perhaps the most infamous physician-directed marketing scheme was conducted by Purdue Pharma—owned and operated by the Sackler family—whose highly addictive OxyContin painkiller caused thousands of overdose deaths.[92] In addition to dispensing kickbacks, the company explicitly induced high-prescribing physicians to prescribe the painkiller in cases that were unsafe or medically

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https://perma.cc/2T84-E6H2. *But see* Elisabeth Rosenthal, *Ask Your Doctor if This Ad Is Right for You*, N.Y. TIMES (Feb. 27, 2016), https://perma.cc/6LJT-8T8V (noting that including this information in a help-seeking advertisement can nevertheless point consumers to promotional information about a specific prescription drug).

[89] *Correct Help-Seeking Ad*, *supra* note 88. One exception is that if help-seeking and reminder ads are aired in close proximity to one another, then the advertisements must comply with FDA regulations. *See* U.S. FOOD & DRUG ADMIN., "HELP-SEEKING" AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS: GUIDANCE FOR INDUSTRY 6-7 (2004). *See also infra* Part III (exploring the regulatory split in greater depth).

[90] *See, e.g.*, Julie M. Donohue & Ernst R. Berndt, *Effects of Direct-to-Consumer Advertising on Medication Choice: The Case of Antidepressants*, 23 J. PUB. POL'Y MKTG. 115, 122 (2004) (finding that an increase in detailing spending increases antidepressant prescriptions by a much greater magnitude than an equivalent increase in direct-to-consumer advertising spending).

[91] *See, e.g.*, Press Release Number 19-928, U.S. Dep't of Just., Mallinckrodt Agrees to Pay Over $15 Million to Resolve Alleged False Claims Act Liability for "Wining and Dining" Doctors (Sep. 4, 2019), https://perma.cc/7DS9-QT6L (detailing how drug-maker Mallinckrodt paid $15 million to settle claims that the company illicitly paid physicians kickbacks in the form of "lavish dinners and entertainment" to prescribe their multiple sclerosis drug Acthar Gel); Jeremy Pelofsky & Maureen Bavdek, *Factbox: Pfizer Settlement for Drug Promotion, Compliance*, REUTERS (2019), https://perma.cc/A3XF-PN45 (describing a Pfizer settlement of over $2 billion for allegations that it, among other offenses, paid out kickbacks for physicians to prescribe 13 different drugs).

[92] *See generally* Patrick Radden Keefe, *The Family that Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), https://perma.cc/23LA-562D; POSNER, *supra* note 3, at 609-10. The patriarch of the Sackler family was none other than Arthur Sackler, who engineered Pfizer's Terramycin marketing campaign in the 1950s and applied aggressive "Madison Avenue"-style marketing techniques to pharmaceuticals.

unnecessary, actions that served to perpetuate the ongoing opioid crisis.[93] For these offenses, the company paid more than $8 billion, an amount that included a larger criminal penalty than any previously paid by a drug-maker.[94]

Concerns about physician-directed marketing helped spur passage of the Physicians Payment Sunshine Act, which requires that all payments by drug manufacturers to physicians be publicly disclosed.[95] Many hospitals also have restricted sales representative access to physicians, consequently reducing prescriptions of detailed drugs and off-label prescriptions (i.e., prescriptions for an unapproved indication).[96] Thus, unlike direct-to-consumer advertising, physician detailing is now more stringently regulated than in past decades.[97] That tighter regulation may help explain why detail spending has stalled relative to the direct-to-consumer advertising surge.

In short, the pendulum of pharmaceutical marketing has swung from consumer-oriented to physician-oriented advertising and back again. Despite the reams of legislative and regulatory changes enacted in the interim, direct-to-consumer advertising is no less prevalent today than during the era of so-called "patent" medicines.[98] Although the prescription drugs marketed today are a far cry from the dangerous nostrums of yesteryear, as Section II will demonstrate the direct-to-consumer marketing of prescription drugs can have detrimental consequences nonetheless.

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[93] Keefe, *supra* note 92; Press Release Number 20-1136, U.S. Dep't of Just., Justice Department Announces Global Resolution of Criminal and Civil investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), https://perma.cc/YC75-VAXM.

[94] Press Release Number 20-1136, *supra* note 93.

[95] *See* 42 U.S.C. § 1320a-7h. The Physicians Payment Sunshine Act was enacted as part of the Patient Protection and Affordable Care Act.

[96] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 JAMA 1785, 1785 (2017) (finding that greater detailing regulation in medical centers translated to fewer prescriptions of detailed drugs); Ian Larkin et al., *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 HEALTH AFF. 1014, 1014 (2014) (finding that off-label prescriptions for antidepressants and antipsychotics decreased after detailing restrictions were implemented); *cf.* Jonathan D. Rockoff, *Drug Reps Soften Their Sales Pitches*, WALL ST. J. (Jan. 10, 2012), https://perma.cc/R2NY-6L9K (noting that drug-makers have reduced the intensity of detailing efforts in the wake of increased regulation).

[97] *See infra* Part II for a discussion of drug safety crises, such as Vioxx, and other perils associated with direct-to-consumer advertising.

[98] *See infra* Part II.

II. BUYER BEWARE: THE PERILS OF DIRECT-TO-CONSUMER ADVERTISING

Although proponents of direct-to-consumer advertising highlight its utility as an informational source, research illustrates that the practice drives more inappropriate prescriptions, adverse drug reactions, and prescription drug spending. Direct-to-consumer advertising can also help brand drug-makers erode generic competition and target specific groups of consumers to create demand for expensive brand drugs.

Direct-to-consumer advertising increases prescription drug spending both by boosting advertised drug prices and by expanding the utilization of advertised drugs. On one side, advertising spending causes the price of an advertised drug to rise.[99] Direct-to-consumer advertising also improves the sales of advertised drugs.[100] Other studies have found, similarly, that direct-to-consumer advertising spending translates to greater patient utilization of an advertised drug.[101] These price and sales effects are especially pronounced for spending on televised drug advertising compared to print advertisements.[102] These effects, in fact, are not limited to patients: Physicians exposed to more televised direct-to-consumer advertisements tend to write more prescriptions for the drugs advertised.[103]

However, the ability of direct-to-consumer advertising to grow prescriptions may also speak to its value as an informational resource. The

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[99] Dave & Saffer, *supra* note 14, at 97.

[100] *Id.*; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-07-54, PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 14-15 (2006) (providing a review of literature demonstrating that direct-to-consumer advertising increases sales of advertised drugs).

[101] Abby Alpert et al., *Prescription Drug Advertising and Drug Utilization: The Role of Medicare* 35 (Nat'l Bureau of Econ. Rsch., Working Paper No. 21714, 2015) (finding an increase in patient utilization of advertised drugs consistent with increases in direct-to-consumer advertising in a given geographic area); Hsieh-Yen Chang et al., *Effect of Direct-to-Consumer Advertising (DTCA) on Statin Use in the United States*, 55 MED. CARE 759, 759 (2017) (patient viewership of statin advertisements was associated with an uptick in prescriptions); Matthew P. Gray et al., *Impact of Direct-to-Consumer Advertising During the Super Bowl on Drug Utilization*, 16 RSCH. SOC. & ADM. PHARMACY 1136, 1136 (2020) (drugs advertised during the Super Bowl football game experienced large utilization increases in the immediate aftermath); Bradley T. Shapiro, *Promoting Wellness or Waste? Evidence from Antidepressant Advertising*, 14 AM. ECON. J.: MICROECON. 439, 439 (finding that an increase in antidepressant advertising led to a growth in new prescriptions).

[102] Dave & Saffer, *supra* note 14, at 97, 122.

[103] Tongil Kim, *Direct-to-Consumer Advertising for Doctors? Uncovering the Effect of Pharmaceutical Advertising on Health Care Providers' Prescribing Behavior* 1 (Naveen Jindal Sch. of Mgmt., Working Paper, 2020) (on file with author).

practice has been shown to increase physician visits[104] and improve patient compliance for certain drugs,[105] outcomes with positive public health effects.[106] Similarly, other research has linked the direct-to-consumer advertising of antidepressants to reduced work absenteeism, speaking to the unintended positive effects that may stem from advertising.[107] Moreover, advertising can expand usage across a therapeutic category, driving sales of more affordable generic drugs in addition to expensive brands.[108]

On the other hand, direct-to-consumer advertising also helps cement the advantages enjoyed by brand drugs, boosting unnecessary spending in the process. Direct-to-consumer advertising is overwhelmingly applied to promote brand drugs.[109] Most generic drug-makers, in contrast, secure too thin a profit margin to afford advertising.[110] Attempts to mandate the inclusion of drug cost

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[104] *See, e.g.*, Toshiaki Iizuka & Ginger Zhe Jin, *The Effect of Prescription Drug Advertising on Doctor Visits*, 14 J. ECON. & MGMT. STRATEGY 701, 701 (2005) (finding every $28 increase in direct-to-consumer advertising after 1997 leads to one additional doctor visit within 12 months); W. David Bradford et al., *How Direct-To-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior*, 25 HEALTH AFF. 1371, 1371 (2006) (finding that direct-to-consumer advertising for osteoarthritis drugs Vioxx and Celebrex increased how many osteoarthritis patients physicians saw monthly).

[105] John E. Calfee, Clifford Wilson & Randolph Stempski, *Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs*, 45 J. L. & ECON. 673, 673 (2002) ("[T]elevision advertising increased the proportion of cholesterol patients who had been successfully treated, which suggests that advertising reinforces compliance with drug therapy.").

[106] *Cf.* Ventola, *supra* note 8, at 672-74 (outlining affirmative arguments for direct-to-consumer advertising including that advertising can empower patients and improve the patient-physician relationship). *But see* Bradford et al., *supra* note 104, at 1376 (noting that direct-to-consumer advertising drove physician visits and patient utilization of Vioxx, a medication eventually pulled off the market for safety risks it posed to patients); *see also infra* text accompanying notes 129-132 (discussing the Vioxx safety scandal).

[107] Shapiro, *supra* note 101, at 1. *Cf.* TI Tongil Kim & Diwas Singh KC, *Can Viagra Advertising Make More Babies? Direct-to-Consumer Advertising on Public Health Outcomes*, 57 J. MKTG. RSCH. 599, 612 (2020) (associating direct-to-consumer advertising for erectile dysfunction medication with an increased birth rate—an outcome of perhaps subjective utility).

[108] *See* Meredith B. Rosenthal et al., *Demand Effects of Recent Changes in Prescription Drug Promotion, in* FRONTIERS IN HEALTH POLICY RESEARCH 1, 1 (David M. Cutler & Alan M. Garber eds., 2003) (between 1996-1999, direct-to-consumer advertising did more to expand the sales of an entire class of drugs as opposed to expanding the market shares of individual drugs within a given class); Bradley T. Shapiro, *Positive Spillovers and Free Riding in Advertising of Prescription Pharmaceuticals: The Case of Antidepressants*, 126 J. POL. ECON. 381, 434 (2018) (describing antidepressant advertising as a "proverbial tide that lifts all ships," benefitting low-cost generics in addition to brands).

[109] Dave & Saffer, *supra* note 14, at 97 ("promotion of prescription drugs is generally limited to patented drugs"); Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 680 (2007) (noting that generic drugs are typically not promoted).

[110] Carolyn Y. Johnson, *The Generic Drug Industry Has Brought Huge Cost Savings. That May*

information in advertisements, meanwhile, have proved unsuccessful.[111] Moreover, because physicians are more likely to prescribe a drug when asked for it by name, direct-to-consumer advertising can serve to funnel patients toward brand drugs instead of cheaper, therapeutically equivalent generic products.[112] The widespread usage of brand drugs instead of generics, in turn, inflates prescription drug spending.[113]

In other instances, direct-to-consumer advertising can empower brand drug companies to explicitly disadvantage prospective generic competitors. For example, in 2021, the FDA warned Amgen about an advertisement that, by misrepresenting the results of a clinical study, implied their brand bone marrow stimulant to be safer than its cheaper biosimilar competitors.[114] Although the FDA ordered Amgen to explain "any plan for discontinuing use of such communications,"[115] a patient or physician that viewed the offending advertisement may nevertheless shape medication choice accordingly, unaware of the advertisement's error. The agency, moreover, did not mandate corrective advertising.[116] The biologics market is especially ripe for abusive advertising of this kind; because few biosimilars are interchangeable (i.e.,

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Be Changing., WASH. POST (Aug. 1, 2017), https://perma.cc/4ZPR-T4W9 (describing problems posed by the low profit margins typical of the generic drug industry).

[111] *See, e.g.*, Merck & Co. v. U.S. Dep't of Health & Hum. Servs., 962 F.3d 531 (D.C. Cir. 2020) (affirming district court rulings that struck down an HHS rule requiring drug-makers to disclose the wholesale acquisition cost of a drug in its televised advertisements).

[112] Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1998 (2005) (55% of patients with adjustment disorder who made a brand-specific request received an antidepressant prescription, versus just 39% who made a general drug request); KATHRYN J. AIKIN, JOHN L. SWASY & AMIE C BRAMAN, PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS 91 (2004) (noting that in one survey, patients who asked about a specific prescription drug were more likely to receive the requested drug, less likely to receive no prescription, and less likely to receive a recommendation for a different prescription drug).

[113] *See* Mariana P. Socal, Ge Bai & Gerald F. Anderson, *Factors Associated with Prescriptions for Branded Medications in the Medicare Part D Program*, 4 JAMA NETWORK OPEN, at 1 (Mar. 2021) (finding that patient requests for branded drugs when their generic equivalents were also available cost Medicare $673 million in 2017).

[114] *See* FDA Untitled Letter, RE: BLA 125031 Neulasta (July 7, 2021) [hereinafter Neulasta Untitled Letter] ("The above misleading claims and presentations are particularly concerning from a public health perspective because they could undermine confidence not just in Neulasta delivered via PFS but also in FDA-licensed biosimilar pegfilgrastim products, *which are only delivered via PFS*.") (emphasis added); Ed Silverman, *FDA Scolds Amgen over a Misleading Ad that Could Deter Use of Biosimilar Versions of Its Drug*, STAT NEWS (July 14, 2021), https://perma.cc/YQ7S-ZQ4X (noting that biosimilars are the generic equivalent of large-molecule biologic drugs).

[115] Neulasta Untitled Letter, *supra* note 114, at 4.

[116] *See id.* (noting that requested actions do not mention corrective advertising).

automatically substitutable) with their reference biologics, greater discretion exists for physicians and patients over which medication to prescribe or use.[117]

Direct-to-consumer advertising, similarly, can enable a brand company's "product hop." A product hop occurs when a brand drug company launches a new version of a drug (usually as the original drug's patents and monopoly period near expiration), then shifts the market toward the new, patent-protected version of the drug before generic competition for the original version can gain a foothold.[118] When brand companies keep the original version of their drug on the market, direct-to-consumer advertising is an important means of transitioning consumers and physicians to the new version. One product hop engineered by AstraZeneca (then Astra) in the heartburn drug market exemplifies the utility of advertising as a means of differentiating and re-casting similar drug products.[119] As its heartburn drug Prilosec neared its patent expiration cliff in 2001, AstraZeneca launched the slightly different—yet clinically indistinguishable—Nexium, which it protected with a new complement of patents, then aggressively promoted.[120] Despite their almost identical efficacy, the drug-maker presented Nexium as a stronger sequel to

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[117] Because slight differences can exist between biologics and their biosimilars, only two biosimilars—as of 2021—have been approved as interchangeable with their reference biologic. Press Release, U.S. Food & Drug Admin., FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira (Oct. 18, 2021), https://perma.cc/82F4-BPU9. As a result, automatic substitution laws, which require interchangeability, fail to assist biosimilar penetration in most biologic markets.

[118] For a primer on product hopping, *see generally* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 69-71 (2017) [hereinafter DRUG WARS]. A product hop may be a "hard" switch, in which the drug company completely removes the old version of the drug from the market, or a "soft" switch, in which the old product remains on the market but is cannibalized by the new product. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 170 (2016). Soft hops, thus, benefit particularly from advertising that can inspire consumers to switch to a new version of a drug product. Moreover, soft product hops may be the more prevalent, as some recent hard product hops have been cited as antitrust violations. *See, e.g.*, New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (affirming a district court injunction that prevented a drug-maker from executing a hard product hop on its Alzheimer's drug, Namenda).

[119] *See* DRUG WARS, *supra* note 118, at 71-74. By boosting the sales of drugs with minimal clinical improvement, direct-to-consumer marketing helps enable the increasing paucity of true "breakthrough" drugs. *See* DUTFIELD, *supra* note 5, at 396-97 (linking the incremental patenting and evergreening of today's pharmaceutical industry to its marketing-based business model). As an example of this phenomenon, a recent Congressional report found that AbbVie's R&D decrease over time corresponded to an increase in its direct-to-consumer advertising spending for Humira, as it replaced research efforts with marketing. *See* STAFF OF H.R. COMM. ON OVERSIGHT & REFORM, 117TH CONG., DRUG PRICING INVESTIGATION: ABBVIE – HUMIRA AND IMBRUVICA 43-44 fig. 15 (Comm. Print 2021), https://perma.cc/74XW-YGEG.

[120] DRUG WARS, *supra* note 118, at 72-74.

Prilosec, the iconic "purple pill," which it rebranded as over-the-counter and advertised with its own celebrity spokespeople.[121] As a result, despite the availability of cheaper Prilosec generic products, Nexium's $6 billion in 2013 sales equaled Prilosec's 2001 sales—a sign of a successful product hop.[122]

Direct-to-consumer advertising also raises concerns about how it drives improper or extraneous drug prescriptions. Research demonstrates that direct-to-consumer advertising increases the number of inappropriate prescriptions for certain medications.[123] Adverse reactions to a given drug, in turn, also increase when they are marketed directly to consumers.[124] Many direct-to-consumer advertisements promote off-label (i.e., unapproved) usages for the drug; one study of five diabetic medications found that 13% of advertisements mentioned off-label usages, sometimes highlighting multiple unapproved usages per medication.[125] Moreover, although advocates assert that advertising educates patients about afflictions for which they may not have otherwise sought help,[126] the practice is also fundamental to "disease mongering," encouraging prescriptions in many cases that are not medically necessary.[127]

Predictably, not all direct-to-consumer advertising campaigns are created equal; some instances of misleading direct-to-consumer marketing can be acutely harmful. In recent decades, for example, the manufacturers of several blockbuster drugs have been tagged for misleadingly marketing their efficacy

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[121] *Id.*

[122] *Id.*

[123] Michele M. Spence et al., *Direct-to-Consumer Advertising of COX-2 Inhibitors: Effect on Appropriateness of Prescribing*, 62 MED. CARE RSCH. & REV. 544, 554-55 (2005) (finding that direct-to-consumer advertising caused more patients to be inappropriately prescribed dangerous COX-2 inhibitors (e.g., Vioxx) instead of NSAID pain medications).

[124] *See* David et al., *supra* note 15, at 1 (finding that promotion increases adverse drug reactions for certain conditions).

[125] Kristina Klara, Jeanie Kim & Joseph S. Ross, *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-Label Promotion and Adherence to FDA Guidelines*, 33 J. GEN. INTERNAL MED. 651, 651 (2018).

[126] *See* Ventola, *supra* note 8, at 672.

[127] For a general description of disease mongering, see DUTFIELD, *supra* note 5, at 31-34 (using the term "pharmaceuticalisation" to describe the process of marketing an affliction alongside its treatments, employing Ritalin and Viagra as examples). Certain drugs may be especially susceptible to disease mongering, depending on the disease they treat. *See, e.g.*, Rosenthal, *supra* note 88 (describing how discretionary medications, such as certain irritable bowel syndrome drugs, frequently feature in direct-to-consumer advertisements); Frosch et al., *supra* note 12, at 10 ("By ambiguously defining who might need or benefit from the products, DTCA implicitly focuses on convincing people that they may be at risk for a wide array of health conditions that product consumption might ameliorate, rather than providing education about who may truly benefit from treatment.").

or safety risk profiles directly to consumers.[128] When the safety risks of a drug are not properly conveyed, direct-to-consumer advertising can severely amplify drug-related health crises. For example, after promoting Vioxx into a multi-billion dollar drug, Merck was forced to pull the drug in 2004 after a study showed it increased the risk of heart attacks and strokes—a fact Merck had known for years as it marketed Vioxx directly to consumers.[129] Research subsequently attributed 38,000 deaths to Vioxx use, a number that may have been amplified in part by the success of Merck's promotional output for the drug.[130] In 2007, Merck settled thousands of outstanding lawsuits with a $4.85 billion payout, the drug industry's largest ever settlement at the time.[131] In the wake of the Vioxx crisis, the FDA briefly considered a moratorium on direct-to-consumer advertisements, only to settle for minor restrictions on the practice.[132]

The abusive potential of direct-to-consumer advertising may increase with the capacity of drug-makers to target specific groups of prospective patients.[133] For example, drug companies have boosted their televised advertising spending in areas with a higher concentration of elderly individuals, who tend to

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[128] *See, e.g.*, *Celebrex Ads Misleading, Says FDA*, ASSOCIATED PRESS (Jan. 12, 2005), https://perma.cc/K4LL-3EKT; Tracy Staton, *Bristol-Myers to Pay $19.5 Million in Abilify Off-Label Marketing Settlement*, FIERCE PHARMA (Dec. 14, 2016), https://perma.cc/JKJ2-Q2E6 (describing how, in addition to off-label marketing of Abilify, Bristol-Myers Squibb allegedly minimized safety risks and misrepresented clinical study data).

[129] *See* Snigdha Prakash & Vikki Valentine, *Timeline: The Rise and Fall of Vioxx*, NPR (Nov. 10, 2007), https://perma.cc/RN39-BA9S; Harlan Krumholz et al., *What Have We Learnt From Vioxx?*, 334 BRIT. MED. J. 120, 120-23 (2007) (describing how Merck concealed the cardiovascular risks of Vioxx for several years while it sold on the market, even pressuring physicians who raised concerns about the drug through their hospital department chairs).

[130] Prakash & Valentine, *supra* note 129 (citing research showing 38,000 deaths from the use of Vioxx); Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749, 751-52 (2006) (describing Vioxx's late arrival to the COX-2 inhibitor market, after which Merck overtook its competitors through its prolific—and misleading—marketing).

[131] Prakash & Valentine, *supra* note 129.

[132] *See* POSNER, *supra* note 3, at 510-11 (for instance, erectile dysfunction advertisements could only be aired between 10 PM and 6 AM).

[133] *See, e.g.*, *id.* at 241-47 (describing how amphetamines and anti-anxiety medicines in the 1960s was marketed expressly toward women to correct the uniquely female "unstable emotional equilibrium"); *cf.* Jennifer Mongiovi et al., *Characteristics of Medication Advertisements Found in US Women's Fashion Magazines*, 7 HEALTH PROMOTION PERSP. 28, 31 (2017) (showing that direct-to-consumer advertising in magazines tended to rely on either emotional or rational appeals depending on the racial or ethnic group that predominated the magazine's readership); Joe Hernandez, *Johnson & Johnson Targeted Black Women with Products Linked to Cancer, Lawsuit Says*, NPR (July 29, 2021), https://perma.cc/X3BB-LK8C (summarizing a 2021 lawsuit alleging that Johnson & Johnson targeted Black women in their marketing of a cancer-causing talcum powder).

consume more prescription drugs.[134] Similarly, news programs and television dramas—which have higher elderly viewership—attract more drug advertising spending than other programs.[135] These targeted marketing tactics may be validated, for example, by evidence that elderly drug utilization is more strongly associated with increases in advertising spending than drug utilization of younger patients is associated with increases in such spending.[136] Targeted marketing ploys ought to highlight concerns about inappropriate or unnecessary prescriptions rather than alleviate them.

Television programming might allow a drug-maker to broadly solicit a certain demographic, but the rise of "e-direct-to-consumer advertising" over the Internet enables much greater precision.[137] For example, a predisposition to certain medical conditions could be extrapolated from the patient's internet footprint (e.g., Amazon order history), prompting a drug-maker to bombard the patient with online advertisements for a drug.[138] To circumvent risk disclosure

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[134] *See* Alpert et al., *supra* note 101, at 3 ("[T]here was a large relative increase in advertising exposure immediately following the introduction of Part D in geographic areas with a high share of elderly compared to areas with a low elderly share."); *see also* Christina J. Charlesworth et al., *Polypharmacy Among Adults Aged 65 Years and Older in the United States: 1988–2010*, 70 J. GERONTOLOGY: SERIES A 989, 989 (2015) (noting that as of 2010, 39% of adults 65 and older take 5 or more medications, up from just 12.8% in 1988).

[135] Kaufman, *supra* note 20 (noting that viewers of dramas and news shows are more likely to be exposed to prescription drug advertising); John Consoli, *Median Age for Primetime Viewing Is Up? Not a Problem for Advertisers in Some Mass-Reach Shows*, NEXTTV (Nov. 2, 2012), https://perma.cc/KC7Z-GJVF (noting that TV dramas tend to skew older in median viewer age); A.J. Katz, *Here's the Median Age of the Typical Cable News Viewer*, AD WEEK (Jan. 19, 2018, 5:25 PM), https://perma.cc/PDN7-382S (noting that as of 2017, median viewer age for cable news shows all exceeded 60 years).

[136] *See, e.g.*, Robin Feldman, *Physicians Treating Alzheimer's Disease Patients Should Be Aware that Televised Direct-to-Consumer Advertising Links More Strongly to Drug Utilization in Older Patients*, 81 J. ALZHEIMER'S DISEASE 1169, 1174-75 (2021) (finding that, for certain drugs, increases in advertising spending were associated with significantly stronger drug utilization among seniors as opposed to younger patients, suggesting that direct-to-consumer advertising for some drugs may bear more influence on the drug choices of older adults).

[137] *Cf.* Ventola, *supra* note 8, at 671 (noting the increase in direct-to-consumer advertising spending on the Internet and its superior return on investment compared to other advertising forms).

[138] *See* Nitasha Tiku, *Facebook Has a Prescription: More Pharmaceutical Ads*, WASH. POST (Mar. 4, 2020), https://perma.cc/B9XP-43LD (describing the ability of drug companies to reach social media users likely to have a relevant condition); *cf.* Hyosun Kim, *Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters*, 4 INT'L J. HEALTH POL'Y & MGMT. 813, 813 (2015) (describing regulatory challenges endemic to social media prescription drug advertising and the frequent failure of drug websites to communicate risk information). The prevalence of off-label prescriptions for certain drugs may compound the danger posed by e-direct-to-consumer advertising.

and fair balance requirements, a savvy e-marketer could direct reminder advertisements—which do not require a mention of risks or side effects—to a patient with an online profile suggestive of a certain affliction.[139] Targeted drug marketing via the Internet, in short, threatens to further defang efforts to police direct-to-consumer advertising.

III. DROPPING THE BATON: ATTEMPTS TO REGULATE PRESCRIPTION DRUG ADVERTISING

For the better part of a century, policymakers and regulators have struggled to achieve a cogent regulatory regime for direct-to-consumer advertising. The FTC and FDA have passed regulatory responsibility for direct-to-consumer advertising between one another, yet the only significant update to its regulation in the past fifty years served to largely eviscerate the "fair balance" doctrine core to regulating advertising content. Although the FTC today oversees the advertising of almost all products, the FDA retains responsibility for prescription drug advertising, which it polices primarily with warning letters. Even relying on these relatively lax measures, FDA enforcement actions have waned during the recent decades' surge of direct-to-consumer advertising.

Imagine the above example but with patients who suffer from a condition that is commonly treated by prescribing a drug off-label. Such an example is described below by Nutt and Keating: AstraZeneca might target advertisements for Seroquel—an anti-psychotic that physicians also prescribe for insomnia—toward consumers whose online activity points to insomnia. Even if the advertisement does not explicitly mention insomnia, it could use imagery to suggest a claim of sleep relief; at the least, information about Seroquel's usages is only an Internet search away. A positive advertisement for Seroquel in general could also persuade a consumer familiar with both Seroquel's insomnia usage and its possible adverse effects to ask her doctor about a prescription. In fact, thousands of patients died in the last decade using Seroquel off-label while AstraZeneca promoted its off-label usages to physicians; a cunning direct-to-consumer advertising campaign could have exacerbated this harm. *See* Amy Ellis Nutt & Dan Keating, *One of America's Most Popular Drugs — First Aimed at Schizophrenia — Reveals the Issues of 'Off-Label' Use*, WASH. POST (Mar. 30, 2018), https://perma.cc/WJX7-5FRG (describing safety risks associated with off-label Seroquel); *cf.* Klara et al., *supra* note 125, at 651 (finding that off-label indications are commonly marketed for diabetes drugs).

[139] *See* Ventola, *supra* note 8, at 669 (noting that reminder advertisements are impermissible for drugs with black box warnings, like Seroquel, that signal a potential for safety concerns or abuse). *See Prescription Drug Advertising: Questions and Answers*, *supra* note 16.

A. Regulatory History

Following the elixir sulfanilamide disaster,[140] Congress in 1938 passed both the Federal Food, Drug & Cosmetic Act and the Wheeler-Lea Act to bolster consumer protections. The Food, Drug & Cosmetic Act tasked the FDA with regulating drug safety and labeling;[141] the Wheeler-Lea Act assigned the FTC to oversee advertising of all drugs, in addition to food and cosmetics.[142] The decision to locate drug advertising with the FTC rather than the FDA aligned with the FTC's task of preventing unfair or deceptive business practices, but the choice was also the product of lobbying by the drug industry, which preferred the FTC's cease-and-desist orders to the FDA's seizure powers.[143] As a result of the legislation, the FDA could regulate direct mailers to physicians, but did not regulate advertisements placed in medical journals.[144]

The adjacent roles of the FTC and FDA did not inspire interagency cooperation in regulating drugs. The two agencies, which relied on different standards to evaluate misleading advertisements, frequently diverged as to what information they allowed in the labels and advertisements of the same drug.[145] Sometimes, the FTC failed to communicate to the FDA which violations it would pursue or enforce, and vice versa.[146] Beyond simply failing to harmonize with the FTC, the FDA actively sought to expand its labeling responsibilities to include separately distributed brochures, which drug manufactures had used to evade FDA's reach.[147] The FTC, meanwhile, slackened its drug advertising enforcement efforts, issuing zero complaints in

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[140] *See* West, *supra* note 37.

[141] Federal Food, Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[142] Wheeler-Lea Act of 1938, Pub. L. No. 75-447, § 4, 52 Stat. 111.

[143] *See* Palumbo & Mullins, *supra* note 19, at 426. *See infra* Part IV (noting that the FTC Act is a civil rather than criminal statute, in contrast to the Food, Drug & Cosmetic Act, although the FDA now tends to employ weaker enforcement measures than the FTC against advertising infractions).

[144] Donohue, *supra* note 1, at 670.

[145] *See* Harvey Young, *supra* note 22, at 302-03.

[146] *Id.*

[147] *See* Terry S. Coleman, *Origins of the Prohibition Against Off-Label Promotion*, 69 FOOD & DRUG L.J. 161, 179-80 (2014) (discussing United States v. Research Laboratories, Inc., 126 F.2d. 42 (9th Cir. 1942)). In *Research Laboratories*, the Ninth Circuit ruled that most printed labeling information was also advertising, thereby allowing the FDA—charged with regulating labeling but not advertising—to take action under the Food, Drug & Cosmetic Act. Behind this ruling was a typographical error: When advertising was deleted from the final version of the Food, Drug & Cosmetic Act of 1938 (Congress instead granted advertising regulation to the FTC in the Wheeler-Lea Act), the Food, Drug & Cosmetic Act was not appropriately amended to distinguish advertising and labeling, which are treated as mutually exclusive. *See* Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301-392.

1950, for instance, and rarely verifying whether companies complied with cease-and-desist orders.[148] Moreover, as prescription drugs began to attract the brunt of drug spending, medical journal advertisements—which were largely exempted from the Wheeler-Lea regulations—supplanted other advertising forms.[149] Thus, the FTC regulatory regime, even to the extent it was enforced, soon failed to address a meaningful subset of drug promotion.

To resolve their dissonant regulatory approaches, the FDA and FTC signed a "Memorandum of Understanding" in 1954 that granted the FDA oversight over both prescription drug labeling and advertising.[150] Consequently, prescription drugs became the lone exception to the division of labor between the two agencies. To this day, the FDA oversees the labeling of products including food, cosmetics, medical devices, and even over-the-counter drugs, while the FTC regulates the advertising of these products.[151] Thus, if the product requires a doctor's prescription, FDA has all authority. If it is not within the prescription realm, FDA has authority over labeling while the FTC has authority over advertising. Initially, shifting prescription drug advertising responsibility to the FDA may have helped invigorate regulation of drug marketing, just as congressional pressure on the FTC to clean up the non-prescription medicine industry spurred increased action.[152] Soon after the 1954 Working Agreement between the FTC and the FDA,[153] the FTC began to crack down on non-prescription medication advertisements.[154]

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[148] Harvey Young, *supra* note 22, at 305.

[149] *See supra* text accompanying notes 55-60 (describing the evolution of pharmaceutical marketing practices).

[150] Palumbo & Mullins, *supra* note 19, at 427-28 (noting that the Memorandum of Understanding between the two agencies was subsequently amended in 1968 & 1971 to reflect final FDA authority over prescription drug advertising following the 1962 Kefauver Amendments).

[151] *See* Donohue, *supra* note 1, at 667 (noting that the 1951 Durham Humphrey Amendments distinguished drugs as prescription or over-the-counter, as well as successfully promoted the use of prescriptions over more dangerous "self-medication" using over-the-counter drugs). *See generally* Anne V. Maher & Lesley Fair, *The FTC's Regulation of Advertising*, 65 FOOD & DRUG L.J. 589, 589 (2010) (outlining the respective jurisdictions of the FTC and FDA, and noting that to this day the FTC retains control over over-the-counter advertising, even if the same drug was previously a prescription drug, e.g., Prilosec).

[152] Harvey Young, *supra* note 22, at 310-11.

[153] At the beginning of the Working Agreement Between the FTC and the FDA in 1954, the FTC had sole "jurisdiction over all drug advertising," while the FDA had sole "jurisdiction over all drug labelling." Palumbo & Mullins, *supra* note 19, at 427-28. Jurisdiction over prescription drug advertising was shifted to the FDA in 1962. *Id*.

[154] *See* Harvey Young, *supra* note 22, at 310-11 (describing the FTC's stricter advertising regulation in "the drug and cosmetic field," resulting in an increase in complaints issued

The Kefauver-Harris Amendments to the Food, Drug & Cosmetic Act, passed in 1962, codified the new regulatory regime, formally transferring prescription drug advertising oversight to the FDA.[155] Catalyzed by the highly publicized spate of thalidomide birth defects, [156] the Kefauver-Harris Amendments required manufacturers to report serious side effects once a drug reached the market and required drugs be proven not just safe, but also effective prior to marketing.[157] Advertisements, in turn, needed to represent the drug's effectiveness in addition to its side effects and risks.[158] On this new authority, the FDA promulgated a fuller set of advertising regulations in 1969, which remain the basis of prescription drug regulation to this day.[159] The two core tenets of the 1969 guidelines were that advertisements include (1) a "brief summary" of side effects, warnings, and indications and (2) present a "fair balance" of clinically relevant risks and benefits.[160]

Reflecting the FDA's focus on advertising to physicians at the time, the 1969 regulations neglect to explicitly address direct-to-consumer advertising. [161] However, the agency specified that for radio, telephone, and television advertisements, a brief summary of all "side effects and contraindications" must be included, unless "adequate provision" was made to disseminate the labeling information. [162] As Part I discusses in detail, the ambiguity of this requirement hamstrung televised advertising until the 1997 Draft Guidance clarified that an "adequate provision" could be made simply by including, for example, a phone number or website URL.[163]

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against advertisers). Non-prescription drugs had taken a backseat to prescription drugs at this point, following passage of the Durham Humphrey Amendments which had expanded the category of prescription drugs. *See* Donohue, *supra* note 1, at 668 ("By 1969, prescription drugs made up 83 percent of consumer spending on pharmaceuticals."); *see also supra* note 42 and accompanying text (describing passage of the Durham Humphrey Amendments).

[155] Drug Amendments of 1962, 76 Stat. 780 (1962), 21 U.S.C. §§ 131; *see also* Palumbo & Mullins, *supra* note 19, at 428; Donohue, *supra* note 1, at 670.

[156] *See* Chanapa Tantibanchachai, *US Regulatory Response to Thalidomide (1950-2000)*, EMBRYO PROJECT ENCYC. (Apr. 1, 2014), https://perma.cc/ZU53-QY2S (describing how the more than 10,000 birth defects in Europe caused by thalidomide, then a morning sickness treatment, catalyzed the passage of the Kefauver-Harris Amendments).

[157] 76 Stat. 780 (1962), 21 U.S.C. § 102.

[158] 76 Stat. 780 (1962), 21 U.S.C. § 352(n).

[159] Donohue, *supra* note 1, at 671.

[160] *Id.*

[161] *Id.*

[162] *Id.*

[163] Ventola, *supra* note 8, at 670.

Just as the Wheeler-Lea Act failed to anticipate the role of medical journals and physician-centered advertising, the Kefauver-Harris Amendments and subsequent 1969 regulations have been outstripped by direct-to-consumer advertising. In easing the "adequate provision" stipulation, the FDA also undermined the "fair balance" required of advertisements, permitting advertisers to simply include a major statement of risks.[164] Rather than conveying a fair balance, in fact, studies show that contemporary prescription drug advertisements are overwhelmingly positive, especially in their affect and use of imagery.[165] Positive affect and distraction feature particularly during the presentation of drug risk information.[166] Similarly, although direct-to-consumer advertising drives online searches for drug information, such online information tends to be promotional rather than informative,[167] a finding that suggests the failure of the 1997 draft guidance to ensure the communication of balanced information. The profound transformation of pharmaceutical marketing efforts since 1969, moreover, has not corresponded to a meaningful change in the FDA's regulation or enforcement of prescription drug advertising.

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[164] *Id.*

[165] *See* Janelle Applequist & Jennifer Gerard Ball, *An Updated Analysis of Direct-to-Consumer Television Advertisements for Prescription Drugs*, 16 ANNALS FAM. MED. 211, 211 (2018) (finding that 94% of sampled advertisements included positive emotional appeals while only 16% included information about risk factors or prevalence); *see also* Paul Biegler & Patrick Vargas, *Ban the Sunset? Nonpropositional Content and Regulation of Pharmaceutical Advertising*, 13 AM. J. BIOETHICS 3, 3-6, 12 (2013) (contending that positive imagery in direct-to-consumer advertising promotes positive attitudes about prescription drugs in viewers, independent of material factors like the drug's risk-benefit profile); *cf.* Ed Silverman, *Music in Drug Ads Makes it Easier for the Public to Tune Out Side Effects, Advocates Argue*, STAT NEWS (Aug. 3, 2020), https://perma.cc/Y4QZ-327R (arguing that the prevalence of upbeat music in televised drug ads poses a distraction to risk and side effect communication).

[166] Jesse King, Leslie Koppenhafer & Robert Madrigal, *Look, Puppies! A Visual Content Analysis of Required Risk Statements Embedded in Direct-to-Consumer Pharmaceutical Advertising*, 40 J. PUB. POL'Y & MKTG. 45, 45 (2021) ("[T]he major risk statements of DTCAs feature more positive imagery, visually complex imagery, and motion than other portions of the ads."); *see also* Helen W. Sullivan et al., *Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study*, 36 J. PUB. POL'Y & MKTG. 236, 242 (2017) (finding that even when advertisements communicate risk information through audio and visible text, the presence of distracting elements reduces viewer retention of drug risks).

[167] *See* Matthew Chesnes & Ginger Zhe Jin, *Direct-to-Consumer Advertising and Online Search* 3-4 (Nat'l Bureau of Econ. Rsch., Working Paper No. 22582, 2016) ("Clicks (both organic and paid) on promotional websites are more strongly associated with DTCA compared to clicks on informational websites.").

B. Modern Regulations

1. The FDA

In the wake of the Kefauver-Harris Amendments and post-1997 televised spending boom, the FDA alone is responsible for minding an increasingly busy store. The Office of Prescription Drug Promotion (OPDP), the FDA office tasked with drug advertising oversight, is supplemented by the "Bad Ad" program, allowing health care professionals to report potentially false or misleading advertisements to the agency.[168] Most promotional materials are required to be submitted to the FDA for review only after the materials are disseminated to the public.[169] Although manufacturers have the option to submit their marketing materials to the FDA for approval prior to release of the materials, the agency does not require pre-approval for drug advertisements, with limited exceptions.[170] As of 2016, the FDA reviewed just 41% of key marketing materials (e.g., risk disclosures) before the market launch of a new drug or new drug indication.[171]

The FDA regulates direct-to-consumer advertising primarily by issuing letters to offending companies and invoking the threat of more serious actions. First, the FDA issues a Notice of Violation, otherwise known as an untitled letter, to a noncompliant drug-maker, which specifies how a certain advertisement

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[168] *The Bad Ad Program*, U.S. FOOD & DRUG ADMIN. (Jan. 5, 2021), https://perma.cc/Y62G-SHRS. The OPDP was established in 2011 to replace the Division of Drug Marketing, Advertising and Communication (DDMAC), a change that was intended to bolster the FDA's prescription drug regulation efforts by expanding the number of staff working specifically on direct-to-consumer advertising (as distinct from physician promotion). *See* Alan G. Mink & Kelley Coleman Nduom, *DDMAC Loses a Letter but Gains a New Name and More Prominence*, LEXOLOGY (Oct. 26, 2011), https://perma.cc/ZK2M-638D.

[169] Prescription drug promotional materials for accelerated approval products must be submitted before dissemination. *See* U.S. FOOD & DRUG ADMIN., PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC AND NON-ELECTRONIC FORMAT—PROMOTIONAL LABELING AND ADVERTISING MATERIALS FOR HUMAN PRESCRIPTION DRUGS: GUIDANCE FOR INDUSTRY 6-8 (2022). Meanwhile, promotional materials for other prescription drugs must be submitted at the time of dissemination, although producers may submit materials before dissemination for FDA advisory comment. *Id.*

[170] *Id.*; *see, e.g.*, 21 C.F.R. § 314.550 (2022) (stating that applicants for accelerated approval of new drugs for serious or life-threatening illnesses must submit advertisements and other promotional materials to FDA for consideration before their dissemination); 21 C.F.R. § 314.640 (2022) (stating the same for applicants for approval of new drugs when human efficacy studies are not ethical or feasible).

[171] Schwartz & Woloshin, *supra* note 81, at 85.

misrepresents safety risks or efficacy.[172] The FDA can also issue a warning letter, ordering the company to respond to the agency by a certain deadline.[173] In some instances, a warning letter may also require a company to issue corrective advertising, but this is a relatively rare stipulation.[174] If letters fall short of bringing a non-compliant advertiser into line, the FDA has statutory authority to deliver a civil penalty of $250,000 for false or misleading advertising.[175] The FDA also can collaborate with the Department of Justice to pursue an injunction against an advertiser in court, but this option is also rarely exercised.[176]

i. Shortfalls of FDA Prescription Drug Advertising Regulation

The FDA regulation of prescription drug advertising disappoints both in its relaxation of the fair balance doctrine and the subsequent decline in its enforcement activity. The 1997 guidelines upset the risk-benefit balance that the 1969 FDA advertising regulations set forth. Of the three advertisement types—product claims, help-seeking, and reminder—only product claims require any mention of drug risks, a stipulation that can be satisfied with a relatively limited disclosure (i.e., a major statement and a URL).[177] Moreover, rather than trigger more active regulation, the uptick of contemporary television and Internet advertisements has coincided with a notable drop-off in FDA enforcement actions.

A look at FDA actions against non-compliant prescription drug advertisers in recent years reveals an anemic enforcement regime. Foremost, in recent years the FDA has decreasingly dispensed untitled and warning letters to drug-makers: in 2020, the agency issued just five total letters (untitled and warning),

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[172] SUSAN THAUL, CONG. RSCH. SERV., R40590, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS 15 (2009); *see, e.g.*, Neulasta Untitled Letter, *supra* note 114.

[173] *See e.g.*, Letter from The Office of Prescription Drug Promotion, U.S. Food & Drug Admin., to Vincent J. Angotti, Chief Executive Officer, AcelRX Pharmaceuticals (Feb. 11, 2021), https://perma.cc/739N-G34M.

[174] *See, e.g.*, *id.*; ABIGAIL CAPLOVITZ, TURNING MEDICINE INTO SNAKE OIL: HOW PHARMACEUTICAL MARKETERS PUT PATIENTS AT RISK 15 (2006) (noting that only 23% of all warning letters issued as of 2006 call for corrective advertisements).

[175] 21 U.S.C. § 333(g).

[176] THAUL, *supra* note 172, at 15 ("Very few such cases have actually come to court.").

[177] *See* Ventola, *supra* note 8, at 669-70. Reminder ads are covered by the FTC, not the FDA, because they do not expressly mention a prescription drug.

compared to twenty-one in 2008, despite the dramatic surge of drug advertising that occurred during the same period.[178]

The FDA also has been slower to issue a letter than in years past, blunting the utility of the measure by allowing consumers and physicians to view misleading advertising dozens of times before requesting that it be rescinded.[179] Also casting doubt on the efficacy of letters is how rarely the letters call for corrective advertising.[180] Meanwhile, the frequency with which certain drug-makers have received letters in years past suggests that such warning letters do little to discourage recidivism.[181] In addition, many recipients of warning letters in recent years are smaller pharmaceutical companies that may lack regulatory expertise.[182] In this regard, FDA regulatory letters may disproportionately address blunders by naïve actors instead of curbing willfully bad behavior by sophisticated players.

Nor is it possible that the FDA has compensated for this drop-off in letter output by employing stronger enforcement actions. Statutory language requires that the Agency send untitled and warning letters first, as a prerequisite for the injunctions or civil penalties that the agency can levy against a drug-maker.[183] Moreover, although FDA may rely on the threat of more serious actions to deter noncompliance,[184] the agency may not be able to plausibly imply that it will employ a measure (e.g., a civil penalty) that it has seldom or never before used.[185] Of course, minimal enforcement activity may also indicate compliant prescription drug advertising. One could certainly hypothesize that companies have become expert at staying carefully within appropriate lines such that the need for regulatory response has plummeted,

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[178] *Compare* THAUL, *supra* note 172, at 15 (noting that the FDA issued twenty-one untitled and warning letters in 2008), *with* Silverman, *supra* note 114 (noting that the FDA sent just six total letters in 2020).

[179] *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 100, at 21 (describing how a 2002 policy change that required all regulatory letters to undergo legal review caused a sharp increase in the amount of time needed to issue an untitled or warning letter).

[180] CAPLOVITZ, *supra* note 174, at 15.

[181] *See id.* at 16 (noting that many companies received multiple letters over a five-year period, with some receiving multiple letters regarding advertisements for the same drug).

[182] *See* Silverman, *supra* note 114.

[183] 21 U.S.C. § 333(g)(2) (2007).

[184] *See* THAUL, *supra* note 172, at 15 ("FDA believes that the threat of such [injunction] makes the warning letter a powerful tool in its regulatory arsenal.").

[185] Even if the FDA penalized a drug-maker, the $250,000 fine is paltry compared to blockbuster drug sales or even the cost of a primetime ad spot. In fact, the company may well determine that the extra sales earned through a noncompliant advertisement outweighs the cost of an FDA fine, factoring in the time required to issue letters and further actions.

even as the volume of advertising has increased. Contemporary research, however, detects widespread violations of FDA regulations as companies underplay drug risks,[186] overstate efficacy,[187] or promote unapproved indications.[188] And, of course, recent episodes from the opioid saga also suggest otherwise.[189] In other words, there is no reason to believe that the FDA's waning enforcement activity has stemmed from a dearth of advertising violations.

Instead, there is reason to believe the FDA is overburdened. In addition to the staggering growth of prescription drug marketing since the passage of the Kefauver Amendments in 1962, the FDA also has added medical devices, tobacco products, and dietary supplements to its purview.[190] Consequently, just as the agency has slackened its prescription drug advertising oversight, other commentators have noted similar regulatory shortcomings in various other areas of FDA regulation.[191]

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[186] *See, e.g.*, Applequist & Ball, *supra* note 165, at 215 (finding that drug advertisements rarely convey a fair balance of risks and benefits when accounting for the affect and imagery of advertisements).

[187] *See, e.g.*, Cole Wayant et al., *Evaluation of Selective Outcome Reporting Bias in Efficacy Endpoints in Print and Television Advertisements for Oncology Drugs*, 35 J. GEN. INTERNAL MED. 2853, 2855 (2020) (finding that oncology drug advertisements tend to cherry-pick statistically significant studies or inappropriately use immature endpoints (i.e., those analyzed before the study has accrued enough patient data) to support a given drug's efficacy).

[188] *See, e.g.*, Klara et al., *supra* note 125, at 651 (finding that off-label indications are commonly marketed for diabetes drugs).

[189] Jonathan H. Marks, *Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation*, 17 J. BIOETHICAL INQUIRY 173, 204 (2020) (describing advocacy ads in the Washington Post as late as 2018 that originally acknowledge public health risks from opioids "even when taken as prescribed" and then later removed the words "even when taken as prescribed").

[190] *See Milestones in U.S. Food and Drug Law,* U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://perma.cc/Y8GC-UNC2s (describing the Medical Device Amendments (1976), Family Smoking and Tobacco Control Act (2009), and Dietary Supplement Health and Education Act (1994)).

[191] *See, e.g.*, Diane E. Hoffman & Jack Schwartz, *Stopping Deceptive Health Claims: The Need for a Private Right of Action Under Federal Law*, 42 AM. J.L. & MED. 53, 69-70 (2016) (describing the FDA's failure to keep pace with food labeling violations); Nicholas Florko, *FDA Misses Deadline for Deciding Which E-Cigarette Products Should Be Removed from the Market*, STAT NEWS (Sept. 9, 2021), https://perma.cc/B734-WUBQ (stating that in 2021, the FDA missed a court-imposed deadline to rule on which e-cigarette products should be removed from marketing, citing its inability to review e-cigarette marketing applications in time).

As a general matter, the FDA does not require that prescription drug advertisements undergo review before their dissemination.[192] The upshot of limited pre-screening is that any misleading advertisements are still viewed by millions, if only for a few weeks or—considering the FDA's lagging response time—months. It may take no more than one advertisement illicitly disparaging a brand drug's generic equivalent to convince a patient to demand the brand in the future, as is the patient's prerogative. This danger is especially salient considering the rarity with which corrective advertising measures are mandated by the FDA.

ii. Learned Intermediary Doctrine

Beyond FDA shortcomings, another important enabler of direct-to-consumer advertising is the learned intermediary doctrine, which protects pharmaceutical companies from product harm claims so long as they communicate drug risks to physicians (i.e., the learned intermediary).[193] In other words, most courts have ruled that even if a drug-maker advertises a drug directly to consumers, the drug-maker is insulated from liability simply by informing physicians of risks.[194] Although some states have interpreted the learned intermediary doctrine differently when drug-makers engage in direct-

[192] *See Office of Prescription Drug Promotion Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN. (July 29, 2021), https://perma.cc/AV2U-J524 (explaining that pre-approval of promotional materials is not required except in rare instances such as part of a compliance action or for accelerated approval products).

[193] *See generally* Joshua E. Perry, Anthony D. Cox & Dena Cox, *Direct-to-Consumer Advertisements and The Informed Patient: A Legal, Ethical and Content Analysis*, 50 AM. BUS. L.J. 729, 746 (2013).

[194] Even if a drug-maker inadequately communicates drug risks to physicians, the learned intermediary doctrine may still insulate the drug-maker if the physician independently knows about the risks of that drug. *See* Dean v. Eli Lilly & Co., 387 F. App'x 28, 30 (2d Cir. 2010) (finding learned intermediary doctrine applied because the doctor had actual knowledge of the alleged warning); Sita v. Danek Medical, Inc., 43 F. Supp. 2d 245 (E.D.N.Y. 1999) (finding learned intermediary doctrine applied because physician was already aware of the drug's risk), *reprinted in* Marisa A. Trasatti & Lindsey N. Lanzendorfer, *Defending Products Liability Suits Involving Off-Label Use: Does the Learned Intermediary Doctrine Apply?*, SEMMES (2011).

to-consumer advertising,[195] every state accepts that the rule protects drug-makers from liability claims stemming from prescription drug-related injury.[196]

By preventing product harm claims against drug-makers, the learned intermediary doctrine in its current form cripples another means of deterring improper direct-to-consumer advertising. The protections afforded by the learned intermediary doctrine may be understood as a holdover from the era of paternalistic medicine, in which physicians alone and not patients contributed to prescribing decisions.[197] Today, however, drug-makers are allowed to have their cake and eat it too, as they drive increased or improper patient usage with direct-to-consumer advertising but continue to be protected by the physician writing the prescription. The validity of the learned intermediary doctrine in the case of drugs promoted heavily to consumers may be called into question by research showing that physicians, too, can be swayed by direct-to-consumer advertisements.[198] The learned intermediary doctrine, rather, should not apply when drugs are advertised directly to consumers.

2. The FTC

The FTC's regulatory procedures are somewhat more comprehensive than those of the FDA, and distinctly more standardized. The FTC is responsible for regulating advertisements for all products other than prescription drugs, including over-the-counter drugs, as well as for regulating a limited category of advertisements for prescription drugs known as "help-seeking" ads.[199] In contrast to the FDA, the FTC generally does not enumerate distinct regulations for each product, applying instead similar standards to evaluate all

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[195] *Compare* Perez v. Wyeth Laboratories Inc., 161 N.J. 1, 21-22, 24 (N.J. 1999) (holding that direct-to-consumer advertising negates the learned intermediary doctrine, but also that the drug-maker in this instance fulfilled its duty to warn by complying with FDA advertising regulations), *with* Dean, 387 F. App'x at 30 (holding that the learned intermediary doctrine protected the drug-maker even when it failed to warn physicians about a drug's risk because the prescribing physician was already independently aware of the risk).

[196] *See* Trasatti & Lanzendorfer, *supra* note 194, at 5-6. West Virginia, the one state whose highest court rejected the learned intermediary doctrine, passed a law in 2016 codifying the learned intermediary protection for drug-makers. *See* Eric Hudson, *West Virginia Legislature Adopts Learned Intermediary Rule by Statute*, AM. BAR ASS'N (Feb. 29, 2016), https://perma.cc/YGP5-KCVK.

[197] *See* Perry et al., *supra* note 193, at 745.

[198] *See* Kim, *supra* note 103, at 1.

[199] Maher & Fair, *supra* note 151, at 589.

advertisements.[200] Specifically, the FTC evaluates whether an advertisement is false or misleading, a focus taken from the FTC Act's Section 12 prohibition on false advertisements for food, drugs, devices, services and cosmetics.[201]

In determining whether an advertisement is deceptive (i.e., false or misleading), the FTC employs a three-step test.[202] First, the agency evaluates what claims an advertisement makes (or fails to make). Second, like the FDA,[203] the FTC asks whether the claim or omission is likely to be misleading to a reasonable consumer. Finally, if the first two conditions are satisfied, then the FTC decides whether the misleading claims were material or, in other words, whether they would influence the consumer to purchase the product in question.[204] The FTC does not examine individual claims in a vacuum; instead it evaluates the "net impression" conveyed by an advertisement.[205] Within this three-step framework, the agency requires the support of at least one randomized control trial for any health-related claim made by an advertisement.[206]

Section 5 of the FTC Act prohibits actions that are not deceptive but nevertheless constitute "unfair methods of competition," a clause that the agency has historically employed to regulate advertising, although not in recent

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[200] *But cf.* The FTC does promulgate specific guidelines for certain products that might be susceptible to spurious promotional claims (e.g., jewelry, wool, "Made in the USA" products). *See Advertising and Marketing on the Internet: Rules of the Road*, FED. TRADE COMM'N (Dec. 2000), https://perma.cc/6W3T-FQ2J (offering compliance guidance for marketing specific products on the Internet).

[201] 15 U.S.C. § 52(a). A false advertisement is defined as one that is misleading in a material aspect. *See* 15 U.S.C. § 55(a)(1); *see also* Maher & Fair, *supra* note 151, at 591.

[202] This test is outlined in the FTC Policy Statement on Deception appended to the Commission's administrative proceedings against Cliffdale Associates. *See* Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984), *cited with authority in* Kraft, Inc. v. F.T.C., 970 F.2d 314 (7th Cir. 1992).

[203] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION 5-6 (2009) ("The reasonable consumer standard used by FDA in evaluating promotional materials is similar to the FTC standard").

[204] *See, e.g.*, Kraft, Inc. v. F.T.C., 970 F.2d. 311, 322-24 (7th Cir. 1992) (evaluating the materiality of advertised claims about calcium content in cheese); Thompson Med. Co., Inc. v. F.T.C., 791 F.2d. 189, 197 (D.C. Cir. 1986) (dismissing plaintiff's argument that misleading claims about the presence of aspirin in an over-the-counter cream are not material); F.T.C. v. Roca Labs, Inc., 345 F.Supp.3d. 1375, 1386 (M.D. Fla. 2018) (listing ways by which the FTC can demonstrate the materiality of misleading claims).

[205] *See generally* Maher & Fair, *supra* note 151, at 595, 597; *see, e.g.*, *Kraft*, 970 F.2d at 314; POM Wonderful, LLC v. F.T.C., 777 F.3d. 478, 493 (D.C. Cir. 2015) ("The Commission concluded that the use of one or two adjectives does not alter the net impression.") (internal quotation omitted). The FDA also uses a "net impression" standard to evaluate risk statements. *See* U.S. FOOD & DRUG ADMIN., *supra* note 203, at 4-5.

[206] *POM Wonderful*, 777 F.3d. at 493-94.

decades.[207] To some extent, some examples of unfair advertising are made redundant by measures taken against deceptive advertising. For example, in 1977, the FTC ruled that making an affirmative product claim without a reasonable basis for doing so constituted a Section 5 unfair violation,[208] an offense that the FTC in recent years has classified as deceptive.[209] Similarly, before the Wheeler-Lea Act explicitly outlawed false advertising, the FTC used the prohibition on "unfair methods of competition" to combat the marketing of "patent" medicines, which often featured hyperbole if not outright falsehoods.[210]

The FTC has invoked its authority over unfair practices in past attempts to expand its regulation of advertising. For example, the FTC cited unfairness to justify a proposed—but never passed—rule in the 1970s that would have limited permissible advertising content for food and over-the-counter products to the information specified in their FDA-approved labels.[211] Similarly, the FTC's ill-fated attempt to ban advertising to children in the late 1970s under the unfairness doctrine—a controversy known as "KidVid"—initiated sufficient Congressional backlash to effectively limit the FTC to policing advertisements on the basis of being deceptive, not unfair.[212] Thereafter, the FTC raised the unfairness threshold to actions that cause substantial injury, are not outweighed by possible consumer benefits, and cannot be reasonably avoided.[213] Thus, although difficult to demonstrate under the current FTC

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[207] 15 U.S.C. § 45(a). *See generally* Luke Herrine, *The Folklore of Unfairness*, 96 N.Y.U. L. REV. 431 (2021) (describing the history of the FTC's unfairness doctrine); Maher & Fair, *supra* note 151, at 601-02 (distinguishing between deceptive and unfairness standards in the context of modern FTC enforcement).

[208] *See In re* Pfizer Inc., 81 F.T.C. 23 (1972) ("[T]he making of an affirmative product claim in advertising is unfair to consumers unless there is a reasonable basis for making that claim.").

[209] *See, e.g.*, *POM Wonderful*, 777 F.3d. at 501 ("In finding petitioners liable for deceptive ads, the Commission determined that petitioners' efficacy and establishment claims were misleading because they were unsubstantiated by RCTs [randomized controlled trials].")

[210] *See* Herrine, *supra* note 207, at 523.

[211] *See id.* at 440.

[212] *See id.* at 484-91, 502-09 (describing KidVid and the ensuing fallout, during which Congress withheld funding from the agency until the bill was restricted to address only deceptive advertising). In 1980, the FTC released a Policy Statement on Unfairness, adding "substantial" consumer injury and a "costs and benefits" analysis as conditions to qualifying an act as unfair. *See* Fed. Trade Comm'n, Policy Statement on Unfairness (Dec. 17, 1980), https://perma.cc/3NT4-RAHA.

[213] *See In re* Int'l Harvester Co., 104 F.T.C. 949 (1984) ("In 1980 we prepared a formal policy statement describing our jurisdiction over unfair practices. . . . An actionable consumer injury must be: (1) substantial; (2) not outweighed by any offsetting consumer or competitive benefits that the practice produces; and (3) one which consumers could not reasonably have avoided."); *see also* Maher & Fair, *supra* note 151, at 601-02.

framework, unfairness may offer a complementary means of expanding FTC advertisement oversight in the future. Moreover, the more standardized FTC test for deceptive advertising is already preferable to the more ad hoc and woefully underenforced FDA approach.

In summary, prescription drug advertising has seen generally inadequate regulation and is in need of regulatory restructuring. The FDA's failure to enforce prescription drug advertising regulations is exacerbated by an industry-wide surge in promotional spending. Since the agency took control of prescription drug advertising in 1969, the FDA has neglected to adequately respond to evolving promotional forms, effectively gutting the fair balance doctrine to accommodate televised advertising in 1997. The learned intermediary doctrine, moreover, insulates drug-makers from product harm liability, further enabling misleading or off-label marketing directly to consumers. Meanwhile, the FTC's extensive experience with advertising makes the agency a viable contender to help reinvigorate oversight. Its existing regulatory doctrines and practices are already a step above those of the FDA, and its past use of the unfairness doctrine offers a model for stronger future regulation.

3. Advertising Regulation Case Studies: FTC & FDA

The FDA and FTC exhibit distinct yet complementary focuses in their respective actions against non-compliant advertisers. The FDA marshals highly technical expertise to interrogate the clinical studies and other evidence that substantiate drug advertisements, while the FTC more holistically evaluates advertised messages, accounting for implied and unspoken claims alongside explicit statements. The following case studies help illustrate the nuances between each agency's approach to addressing improper advertising, highlighting the utility of both skillsets in concert.

i. FTC: Doan's Pain Relief (Novartis)

In 1998, the FTC filed a complaint against Novartis, alleging that advertisements for its over-the-counter Doan's pain reliever violated the prohibitions on deceptive advertising found in Sections 5 and 12 of the FTC Act.[214] The FTC alleged that Novartis, without adequate substantiation, implied

[214] Novartis Corp. v. F.T.C., 223 F.3d. 783, 785-86 (D.C. Cir. 2000); Majority Opinion of the Commission at 4, Novartis Corp. et al., No. 9279 (F.T.C. 1999).

Doan's to be superior to its competitors in relieving backache. An administrative law judge agreed in 1999 that Novartis engaged in deceptive advertising, a decision that led a panel of FTC commissioners to order corrective advertising.[215]

Doan's held a minor share of the sizable backache analgesic market, which Novartis sought to expand with a marketing campaign that would distinguish Doan's from its competitors.[216] Crucially, Doan's relied on a different—but not more efficacious—active ingredient than its competitors.[217]

At issue was not whether Doan's was better at relieving back pain than other painkillers (it was not), but whether Novartis promoted that claim, however subtly, in its advertisements. Specifically, Novartis highlighted its "special" and "unique" ingredient that "other pain relievers don't have."[218] Novartis also—often in the same advertisement—marketed Doan's as "made for back pain," or as "the back specialist," attempting to translate the distinctness of Doan's active ingredient to an exceptional ability to treat back pain.[219] Although it was true that Doan's had a unique active ingredient and was marketed especially for back pain, the FTC determined that the combination of these statements expressly conveyed the superior efficacy of Doan's to other analgesics, a claim that lacked corroboration.[220] Similarly, another advertisement featured a person bending over further after ingesting Doan's, which the FTC found to imply superior efficacy through the visual content of the advertisement if not explicitly in words.[221]

To amend the misleading claims advanced by Novartis' marketing, the FTC required the manufacturer to include an explicit disclaimer in future advertisements: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain."[222] The FTC order required Novartis to spend an equivalent amount on its corrective advertising as it spent on the misleading Doan's advertisements.[223]

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[215] *Novartis*, 223 F.3d. at 785-86. The administrative law judge had found that Novartis' claims lacked adequate substantiation, but the judge declined to order corrective advertising. The Commissioners upheld the decision on inadequate substantiation, but reversed on the remedial portion of the opinion and ordered corrective advertising. *See id.*

[216] Majority Opinion of the Commission, *supra* note 214, at 3.

[217] *Id.* at 2.

[218] *Id.* at 7.

[219] *Id.*

[220] *Id.* at 8.

[221] *Id.* at 7.

[222] *Novartis*, 223 F.3d. at 786.

[223] *Id*.

The FTC's corrective advertising mandate served to counteract Novartis' subtly and implicitly misleading promotional efforts.

ii. FDA: Neulasta (Amgen)

In 2021, the FDA sent an untitled regulatory letter to Amgen, citing an animated banner advertisement[224] that promoted the on-body injector form of Neulasta (pegfilgrastim), Amgen's febrile neutropenia treatment, as being false or misleading.[225] Febrile neutropenia is a potential side effect of cancer therapy that is characterized by fever and a sub-normal count of the type of white blood cells that fight infection.[226] The advertisement highlighted the results of an Amgen study that found a 31% higher incidence of febrile neutropenia in patients administered Neulasta via a pre-filled syringe compared to those administered Neulasta through a wearable on-body injector (Neulasta Onpro).[227] The advertisement, in short, conveyed the message that the on-body injector was a more effective and less risky delivery method for Neulasta.[228]

Notably, biosimilar versions of pegfilgrastim are available only in the form of a pre-filled syringe, not an on-body injector.[229] Amgen launched Neulasta Onpro in 2015, the same year it lost market exclusivity on pegfilgrastim. However, because the Onpro delivery mechanism remains patent-protected, biosimilar versions of pegfilgrastim can be administered only via pre-filled syringe.[230] As of 2020, Amgen had successfully converted 58% of the pegfilgrastim market to Neulasta Onpro, which allows patients to receive their necessary follow-up dose at home, rather than returning to the hospital after undergoing chemotherapy.[231]

The FDA derived its false or misleading determination about the advertisement from the shortcomings of the cited study, which the agency

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[224] Animated banner advertisements are common to prescription drug promotion on the Internet and social media.

[225] Neulasta Untitled Letter, *supra* note 114, at 2.

[226] *See NCI Dictionary of Cancer Terms: Febrile Neutropenia*, NAT'L CANCER INST., https://perma.cc/3ETH-RZYN; Krish Patel & Howard (Jack) West, *Febrile Neutropenia*, 3 JAMA ONCOLOGY 1751 (2017).

[227] U.S. Food & Drug Admin., BLA 125031 Neulasta Promotional Material (2021).

[228] Neulasta Untitled Letter, *supra* note 114, at 1.

[229] *Id.*

[230] Isha Bangia, *Drug Delivery Devices Help Originator Companies Retain Market Share*, AJMC CTR. FOR BIOSIMILARS (Sept. 19, 2020), https://perma.cc/T5XG-8KQ8.

[231] *Id.* Biosimilar versions of Neulasta, consequently, have enjoyed limited market penetration thus far, having captured less than 25% of the market as of 2019.

found to "preclude" Amgen from making the advertised conclusion.[232] The FDA elaborated on several flaws in Amgen's study. First, the algorithm used to retrospectively identify patients for the study was "unvalidated . . . with unknown performance characteristics," raising concerns about the size and composition of the study population.[233] Second, the study design neglected to control for potential comorbidities or risk factors between the two groups, failing to ensure that the two study groups were appropriately balanced.[234] As a result, the study may have been compromised by selection bias, a salient concern considering that the incidence of febrile neutropenia in either group was low (1.7% of pre-filled syringe patients vs. 1.3% of Onpro patients).[235] In other words, even though 31% *more* pre-filled syringe patients experienced febrile neutropenia relative to Onpro patients, that difference amounts to only a 0.4% higher incidence in absolute terms.[236] The slim margins that characterize the study results leave open the possibility that its conclusion can be entirely explained by selection bias (i.e., an unbalanced or uncontrolled study population).[237] As a result, the FDA's letter ordered Amgen to submit a plan of action to discontinue the advertisement and any related promotional materials.[238]

The scientific and technical expertise of the FDA is on display in its citation of the Neulasta advertisement. In contrast to the FTC prosecution of Novartis, whose Doan's advertisements subtly mislead viewers with unsubstantiated claims, the FDA explicitly faulted the empirical basis of Amgen's advertised claims. The FTC investigation, that is, focused on components of the advertisement itself, such as voiceovers and on-screen graphics; the FDA, by contrast, scrutinized the statistics and experimental design supporting the message of the Neulasta advertisement.

The distinct approach with which each agency evaluates drug advertisements does not need to signify a discordant regulatory regime; rather, each agency's complementary expertise ought to be coordinated to improve the regulation of prescription drug advertisements. The FDA, on the one hand,

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[232] Neulasta Untitled Letter, *supra* note 114, at 2.
[233] *Id.* at 3.
[234] *Id.*
[235] *Id.* The 1.7% febrile neutropenia incidence in pre-filled syringe patients represents a 31% higher incidence of febrile neutropenia compared or relative to the 1.3% febrile neutropenia incidence in Onpro patients.
[236] *Id.*
[237] *Id.*
[238] *Id.* at 4.

offers invaluable scientific expertise. Although a viewer may have no difficulty interpreting the conclusion of Amgen's Neulasta study, for example, the average consumer may be unlikely or unable to evaluate the study itself, much less detect its limitations. By verifying the underlying science, the FDA can inspire consumer confidence in the empirical claims featured in advertisements. On the other hand, the FTC's attention to *how* claims are communicated to consumers, such as through televised graphics or a combination of implicit statements, offers an important deterrent against spurious advertising tactics.

IV. COORDINATING THE REGULATORY APPROACH

The United States is practically alone in failing to restrict the harms brought by direct-to-consumer advertising: Only New Zealand, of all other nations, also allows the practice. Having experimented with this regime, one could argue that it is time to move on, and that banning direct-to-consumer advertising would best serve patients and payors alike. Once unleashed, however, it is difficult to put the demons back in Pandora's Box, and one would be hard pressed to imagine Congress taking such a dramatic step.

Absent a ban on direct-to-consumer advertising, regulation of the practice requires a more concerted and coordinated process, one that speaks to the strengths of both agencies and features interaction and cooperation between the two. The Section below envisions a coordinated process in which the FTC has the ball, along with an assist from the FDA. But the agencies would do better to go further, allowing their expertise to dictate what each regulates. Returning principal control of prescription drug advertising to the FTC, while employing the FDA in an advisory role, best capitalizes on the agencies' respective strengths.

As regulators re-organize their efforts, other measures, such as circumscribing the learned intermediary doctrine and eliminating the direct-to-consumer advertising tax deduction, may be enacted with the stroke of a pen. If the United States insists on going its own way, then we must invest in the oversight necessary to protect the public. This would require not just changing laws and regulations, but also providing adequate additional funding to ensure that those laws and regulations can be properly enforced.

A. Agencies Can Play Nicely

The FTC and the FDA have been able to coordinate in areas outside of prescription medicine. In the case of food, cosmetics, dietary supplements, and over-the-counter drugs, the FDA regulates labeling information and the FTC handles advertising.[239] With these non-prescription products, a more fluid border operates between the two agencies, as each agency exchanges expertise with the other: The FTC advises the FDA on advertising or marketing issues[240] and often refers to FDA-approved materials to evaluate a product's advertising claims.[241] Conversely, the FTC accepts FDA labeling materials as a reasonable basis for health claims made in advertisements.[242] For food advertising, moreover, the FTC only permits the advertising of nutrient content descriptions that are also approved by the FDA for food labels, with limited exceptions.[243]

An FDA-FTC partnership to regulate prescription drug advertising is far from unprecedented. Several examples of interagency collaboration exist, as agencies seek to avoid duplicative labor and benefit from shared expertise. Often, the same agency collaborates with several others as it regulates different areas of its purview. The Departments of Defense, for one, collaborates with Homeland Security for cybersecurity, and with the Environmental Protection Agency (EPA) for watershed protection and mitigation purposes.[244] The EPA, in turn, also works with the Department of Energy to evaluate energy efficiency claims.[245]

The FTC and FDA are no strangers to interagency agreements. Along with their past Memoranda of Understanding (MOUs) for prescription drug

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[239] Maher & Fair, *supra* note 151, at 589.

[240] *Id.* at 602; *see, e.g.*, Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission, In the Matter of Request for Comment on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion, Docket No. 2004D-0042 (May 10, 2004), https://perma.cc/9KC4-CGTF.

[241] Maher & Fair, *supra* note 151, at 602; *see, e.g.*, *In re* Thompson Med. Co., Inc., 104 F.T.C. 648 (1984) (noting that the FTC elected to require two clinical trial studies to evaluate efficacy claims based on the FDA's requirement that two clinical trial studies substantiate efficacy claims for labeling purposes).

[242] Maher & Fair, *supra* note 151, at 603.

[243] *Id.* at 603-04 (describing the FTC's Food Policy Statement).

[244] Specifically, the Army Corps of Engineers, a component of the Department of Defense, collaborates with the EPA. For additional examples of inter-regulatory collaboration, *see* FREDERICK M. KAISER, CONG. RSCH. SERV., R41803, INTERAGENCY COLLABORATIVE ARRANGEMENTS AND ACTIVITIES: TYPES, RATIONALES, CONSIDERATIONS (2011).

[245] Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1162 (2012).

advertising,[246] both agencies split oversight of other portions of their regulatory jurisdiction with different agencies. For example, the FDA cooperates with the U.S. Department of Agriculture to ensure food safety, signing MOUs to clarify the regulation of dairy exports and catfish, for instance.[247] The FTC, meanwhile, shares responsibility for merger oversight with the Department of Justice, allocating responsibility based on the industry of the prospective merger.[248]

1. Who Has the Ball?

In any coordinated activity, someone needs to take the lead. As any football player can tell you, two quarterbacks cannot have the ball at the same time. Considering the agencies' respective strengths, effectively regulating prescription drug advertising would benefit from a coordinative venture led by the FTC, as opposed to a collaborative, equal partnership between the two agencies.[249]

In choosing between the agencies to find a quarterback, the FTC is best suited to lead the effort. First, prescription drug advertising is better aligned with the other duties of the FTC, which already regulates the advertising of over-the-counter drugs and help-seeking advertisements for prescription drugs.[250] The experience gained from regulating direct-to-consumer advertising in myriad contexts provides the background for effective regulation of direct-to-consumer advertising in the prescription drug realm.

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[246] *See* Palumbo & Mullins, *supra* note 19, at 427-28 (noting MOUs signed in 1954, 1968 and 1971 addressing prescription drug advertising regulation).

[247] *See* U.S. FOOD & DRUG ADMIN., MOU 225-20-017, MEMORANDUM OF UNDERSTANDING BETWEEN THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THE U.S. DEPARTMENT OF AGRICULTURE'S AGRICULTURAL MARKETING SERVICE AND FOREIGN AGRICULTURAL SERVICE RELATED TO THE EXPORT OF MILK AND MILK PRODUCTS (2020) (coordinating the exportation of dairy from the United States); U.S. FOOD & DRUG ADMIN., MOU 225-14-009, MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD SAFETY AND INSPECTION SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE AND THE FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (2014) (transferring the oversight of catfish from the FDA to the USDA's Food Safety and Inspection Service).

[248] *See* Merger Review, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-and-competition/merger-review. Note that the split in subject matter is sometimes abstruse. One agency traditionally covers truck companies while the other's jurisdiction included automobile makers, for instance, and attempts to formally divide merger review along subject matter lines in 2002 failed. *See* Yochi J. Dreazen & John R. Wilke, *Justice Department, FTC Deal Dividing Merger Reviews Collapses*, WALL ST. J. (May 21, 2002), https://perma.cc/Y5EM-WWEJ.

[249] *See generally* KAISER, *supra* note 244, at 6 (distinguishing regulatory coordination from collaboration).

[250] *See supra* part III.B.2.

Second, the FTC has more vigorously enforced advertising violations compared to the FDA in recent years, which may translate to improved deterrence of noncompliant prescription drug advertisers. While FDA regulatory efforts are concentrated mainly in advisory letters, the FTC implements a wider gamut of penalties, including corrective advertising, permanent injunctions, and civil penalties.[251] Commentators have also noted that between the two agencies, the FTC more actively prosecutes deceptive health claims,[252] positioning the FTC well to step into the prescription drug arena.

As an aside, if the impetus moves to the FTC, the agency might have the potential to harness additional enforcement measures that would bolster its regulation of prescription drug advertising. In most cases, the FTC can bring civil penalties against a company only after the company violates a consent decree or cease-and-desist order.[253] However, the COVID-19 Consumer Protection Bill, passed in 2020, allows the FTC to levy civil penalties for a first deceptive act or practice relating to COVID-19 treatments or cures (e.g., misleading advertising) for the extent of the public health emergency.[254] Congress could choose to grant the same first-offense civil penalty powers to the agency to prosecute misleading marketing for drugs with a black box warning, indicating a significant potential for abuse or safety risk (e.g., opioid painkillers). After all, among the hard lessons taught by opioid crisis, it is clear how profoundly prescription drug marketing can bear on public health.[255]

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[251] *See, e.g.*, Novartis Corp. v. F.T.C., 223 F.3d 783, 788-89 (D.C. Cir. 2000) (denying Novartis' appeal of FTC-mandated corrective advertising); Stipulated Ord. for Permanent Injunction and Monetary Judgment, F.T.C. v. NeuroMetrix, Inc. (D. Mass. 2020) (No. 20-cv-10428-FDS) (granting permanent injunction against marketing misleading claims of pain relief and order to pay $4 million to the FTC); Decision and Ord., United States v. NBTY, Inc. (E.D.N.Y. 2005) (No. CV-05-4793) (granting $2 million civil penalty for violating terms of an FTC order by making deceptive health claims for a diet program). *See generally* LESLEY FAIR, FED. TRADE COMM'N, FEDERAL TRADE COMMISSION ADVERTISING ENFORCEMENT (2019) (outlining the gamut of FTC enforcement tools and providing numerous examples of each). The FTC also pursues legal actions in conjunction with the Department of Justice, which may strengthen deterrence. *See, e.g.*, Complaint for Civ. Penalties, Permanent Injunction and Other Relief, United States v. Nepute (E.D. Mo. 2021) (No. 4:21-cv-00437) (complaint submitted by the DOJ Consumer Protection Branch and the FTC following continued deceptive advertising violations).

[252] Hoffman & Schwartz, *supra* note 191, at 70.

[253] *See* FAIR, *supra* note 251, at 10; *see, e.g.*, *NBTY*, No. CV-05-4793, at 1.

[254] COVID-19 Consumer Protection Act of the 2021 Consolidated Appropriations Act § 1401, Pub. L. No. 116-260, 134 Stat. 1182, 15 U.S.C. § 45(a). *See generally* Kristi Wolff, *ICYMI: The FTC Has Civil Penalty Authority Relative to COVID-Related Advertising*, JD SUPRA (Feb. 4, 2021), https://perma.cc/FUT8-VS9E.

[255] *See generally* Keefe, *supra* note 92.

Advertising regulation also belongs with the FTC because false advertising is a competition issue, another area of FTC concern.[256] One need only revisit Amgen's Neulasta advertisement—which incorrectly implied that their drug was safer than a biosimilar competitor—to begin to imagine how false advertising can impact competition in drug markets.[257] In fact, the FTC and FDA released a joint statement in 2020 pledging to combat anticompetitive behavior in the biologics market, a missive that, although short on specifics, acknowledges that misleading advertising can impede competition in drug markets.[258] To deter anticompetitive advertising, future instances of false advertising that directly disadvantage competition ought to automatically trigger conduct-based remedies, such as corrective advertising or consumer education campaigns.[259]

Handing prescription drug advertising to the FTC would also enable the agency to evaluate both permissible and misleading advertising campaigns alike as part of an investigation into anticompetitive behavior like product hopping.[260] To this end, a broader application of the FTC's unfairness standard could sanction advertising campaigns that support other anticompetitive practices. Finally, prescription drug advertising regulation could complement the FTC's heightened attention to pharmaceutical consolidation.[261] For example, advertising spending could be used as a proxy to gauge the market

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[256] *See* Michael A. Carrier & Rebecca Tushnet, *An Antitrust Framework for False Advertising*, 106 IOWA L. REV. 1841 (2021) (describing problems posed for functional markets by false advertising and proposing a rebuttable presumption that false advertising by monopolists violates antitrust law); *cf.* California Dental Ass'n v. F.T.C., 526 U.S. 756, 786 (1999) (Breyer, J., concurring in part and dissenting in part) ("We must also ask whether, despite their anticompetitive tendencies, these restrictions [on false and misleading advertising] might be justified by other procompetitive tendencies or redeeming virtues.").

[257] *See* Silverman, *supra* note 114.

[258] U.S. FOOD & DRUG ADMIN. & FED. TRADE COMM'N, JOINT STATEMENT OF THE FOOD & DRUG ADMINISTRATION AND THE FEDERAL TRADE COMMISSION REGARDING A COLLABORATION TO ADVANCE COMPETITION IN THE BIOLOGIC MARKETPLACE 5-6 (2020).

[259] *See* FAIR, *supra* note 251, at 2-5 (describing various examples of past conduct-based remedies).

[260] *See, e.g.*, DRUG WARS, *supra* note 118, at 69-71 (describing the Prilosec-Nexium product hop).

[261] *See* Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), https://perma.cc/P4CY-SN5G (announcing an international working group meant to bolster oversight and new policy regarding pharmaceutical consolidation).

power of drug-makers, helping inform whether the agency approves mergers or mandates product divestitures.[262]

2. The Model

As noted above, the proposed model envisions a coordinated process in which the FTC has the ball, along with an assist from the FDA. Specifically, FTC regulators—preserving the FDA fair balance doctrine and major statement requirement—could gauge whether prescription drug advertisements reasonably convey a fair balance of risks and benefits, include off-label indications and properly communicate risk disclosures (i.e., proper use of voiceovers, font size, etc.). The FTC would direct questions about specific safety or efficacy claims to the FDA's Office of Prescription Drug Promotion (OPDP), whose scientific expertise equips the group for a more thorough investigation and verification of such claims.[263] The pathways established between the two agencies could provide mechanisms so that the FDA could choose to raise its own concerns with the FTC in relation to particular direct-to-consumer advertising safety and efficacy claims.

In practice, this regulatory transition could be enacted through an amendment to the FTC Act or the Food, Drug & Cosmetic Act, or through a Memorandum of Understanding. [264] Given that prescription drug advertisements under FDA purview must clear a higher bar than simply being not "false or misleading," the FTC ought to adapt the FDA's "fair balance" doctrine to its own regulatory regime in order to avoid further loosening advertising standards during the regulatory transition. For prescription drug advertisements in particular, the FTC could layer on the "fair balance" doctrine to supplement the "net effect" and "reasonable consumer" standards it uses to evaluate deceptive advertising. The FDA would remain integral to this new paradigm, moreover, by helping the FTC evaluate specific safety and efficacy claims made in advertisements.

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[262] *Cf.* Robin Feldman, Brent D. Fulton, Jamie R. Godwin & Richard M. Scheffler, *Challenges with Defining Pharmaceutical Markets and Potential Remedies to Screen for Industry Consolidation,* 47 J. HEALTH POL., POL'Y & L. 583 (2022) (highlighting the shortcomings of the Herfindahl-Hirschman Index, the measure currently used by the FTC to evaluate pharmaceutical industry concentration levels).

[263] *See, e.g.*, Neulasta Untitled Letter, *supra* note 114, at 3 (describing in detail the limitations of a clinical study used by Amgen to substantiate their advertised claims).

[264] The FTC and FDA have in the past used Memoranda of Understanding as a means of delineating their jurisdiction over prescription drug advertising. *See* Palumbo & Mullins, *supra* note 19, at 427-28.

B. Other Proposals

Short of completely banning direct-to-consumer advertising, re-structuring regulation under an FTC-led venture is perhaps the most significant step policymakers can pursue at this time to improve consumer protection and limit extraneous drug spending. To supplement the regulatory re-organization, moreover, other legislative measures can also meaningfully deter direct-to-consumer advertising.

For example, at the federal level, lawmakers should rescind the tax deduction that drug manufacturers currently receive for direct-to-consumer advertising expenditures.[265] At the very least, drug-makers, not taxpayers, should foot the bill for prescription drug advertisements. Furthermore, boosting regulatory resources—whether through industry user fees or, perhaps, a tax levied on advertising spending—remains a necessary step to ensuring effective regulation, irrespective of the agency at the helm. Increased funding may provide the resources to enable more stringent regulations, such as a mandatory pre-review of advertisements.[266]

At the state level, legislatures should establish an exception to the learned intermediary doctrine for direct-to-consumer advertising.[267] As a result, if a drug-maker markets a drug product directly to consumers, then it would no longer be shielded from possible product harm liability by the learned intermediary doctrine for that drug. This would especially deter the marketing of dangerous drugs or the use of advertisements that suggest off-label usage.

Finally, Congress could amend the FTC Act to allow private actors to also submit claims against deceptive marketing in order to improve deterrence of misleading advertising. At present, under Section 5 of the FTC Act, only the FTC may bring an action against a company for unfair or deceptive practices.[268]

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[265] *See* THAUL, *supra* note 172, at 32-33. A number of unenacted legislative measures have sought to end the tax deduction for direct-to-consumer advertising. *See, e.g.*, End Taxpayer Subsidies for Drug Ads Act, H.R. 8399, 116th Cong. (2020).

[266] *See id.* at 13 (noting that the 2007 FD&C Amendments authorized additional funds for FDA pre-review of advertisements via increased user fees, but these funds were never appropriated).

[267] *See supra* text accompanying notes 193-198 (describing the learned intermediary doctrine and its relationship to direct-to-consumer advertising).

[268] Pub. L. No. 63-203, 38 Stat. 717; 15 U.S.C. § 45(a)(1). Many states have unfair or deceptive practices laws allowing private plaintiffs to bring an action for unfair or deceptive acts or practices, but state standards are misaligned and frequently outdated with respect to the standards applied by the FTC. Matthew W. Sawchak & Troy D. Shelton, *Exposing the Fault Lines Under State UDAP Statutes*, 81 ANTITRUST L.J. 903 (2017); *cf.* Hoffman & Schwartz, *supra*

But some commentators have proposed permitting certain non-federal actors, such as state attorney generals and consumer protection organizations to also take up legal action under the statute, in the same manner that Congress has permitted for other consumer protection statutes.[269] This "limited private right of action" would serve to help relieve the regulatory burden on the FTC as it prosecutes misconduct over a wide range of issues.[270]

CONCLUSION

From "patent medicines" a century ago to modern blockbuster drugs, advertising directly to consumers has harmed consumers by driving unnecessary prescriptions, extraneous drug spending, and full-blown safety crises. The practice can also privilege brand companies to undermine generic competitors and improperly promote dangerous unapproved usages of a drug. It should not come as a surprise that all but two countries (the United States and New Zealand) have outlawed direct-to-consumer advertising altogether.

Direct-to-consumer advertising, which has enjoyed staggering growth in spending during recent decades, benefits from an ineffective regulatory regime. Passed between the FDA and FTC, the regulation of direct-to-consumer advertising deviates from the normal division of labor between the two agencies, leaving the area severely unsupervised. Regulation of the direct-to-consumer advertising should return to the FTC, with a coordinated assist from the FDA. Other measures such as eliminating the direct-to-consumer tax deduction and restricting the learned intermediary doctrine would also contribute to meaningful regulatory progress.

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note 191, at 78-80 (describing the failure of state unfair or deceptive acts or practices statutes to deter false health claims).

[269] *See* Hoffman & Schwartz, *supra* note 191, at 81-83 (noting statutes for which Congress has permitted private rights of action).

[270] *See id.* at 82. Limiting the private right of action, rather than providing a full private right of action, avoids opening the floodgates to reams of spurious litigation from a wide range of private actors seeking to benefit from a quick settlement.