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Commentary

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[Editor's Note: Mark Behrens co-chairs Shook, Hardy & Bacon L.L.P.'s Washington, DC-based Public Policy Group. Cary Silverman is a partner in the group. Any commentary or opinions do not reflect the opinions of Shook, Hardy & Bacon L.L.P. or LexisNexis® Mealey Publications™. *Responses are welcome.]*

Introduction

U.S. Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr., a longtime critic of prescription drug advertising, has vowed to ban direct-to-consumer (DTC) ads.[1] He has found allies on the Hill. Senator Bernie Sanders introduced the End Prescription Drug Ads Now Act with fellow independent Senator Angus King in June.[2] Representatives Jerrold Nadler (D-NY), Maxine Dexter (D-OR), and Illhan Omar (D-MN) joined the bandwagon last month, introducing an identical bill in the House of Representatives.[3] These proposals are both bad policy and unconstitutional.

Direct-to-Consumer Pharmaceutical Ads

Pharmaceutical advertisements educate people about products that can improve – even save – their lives. Senator Sanders calls them "absurd,"[4] since some ads may feature smiling middle-aged folks cruising in convertibles, happy tail-wagging dogs, and people enjoying life while the narrator explains how the medication can help a serious medical condition and the drug's side effects.

Regardless of how one feels about DTC ads, there are checks in place that protect the public.

All prescription drug advertising, whether it is in print, on the radio, or on television, must contain a "fair balance" of information about drug risks as compared with information about drug benefits.[5] Television advertisements, in particular, must include information relating to the major side effects and contraindications of the advertised drugs, known as a "major statement," in the audio or audio and visual parts of the presentation, as well as a brief summary of all necessary information related to side effects and contraindications.[6] Federal regulations require that information to be presented to viewers in consumer-friendly language, at the same pace as the rest of the audio information presented in the advertisement, and in text that is displayed in a sufficient size and for a sufficient duration that it can be easily read.[7] Prescription drug ads also must be submitted to the U.S. Food and Drug Administration (FDA) when they first appear so the agency can ensure that advertisements meet these and other requirements.[8]

If an ad for a medication overstates the product's benefits, downplays risks, or makes unsupported claims, the FDA can tell the manufacturer to stop running an ad or seek corrections. The FDA's Office of Prescription Drug Promotion does so through issuing warning letters and "untitled letters" to pharmaceutical companies.[9] In addition, the FDA has long had a "Bad Ad" program that encourages healthcare providers to report pharmaceutical ads that they view as misleading to the agency.[10]

Aside from these regulatory safeguards on advertising, there is also another key factor that protects the pub-

lic. A viewer whose interest is peaked by a prescription drug advertisement cannot walk into a pharmacy and immediately purchase the product. He or she must first speak with a doctor, who will make a learned assessment as to whether that patient would benefit from the medication based on that person's specific medical history and health needs.

Lawsuit Advertising Targeting Medications

Now, compare the advertisements marketing pharmaceuticals to television commercials and social media ads that recruit people for lawsuits targeting such products.

Lawsuit ads are often highly misleading. The ads are all about risks. The public is typically told that the product causes horrific injuries, sometimes based on dubious science. The ads do not inform viewers that a side effect may be extremely rare or that doctors carefully consider that risk when prescribing the drug to patients, for example. There is also no acknowledgment that the FDA approved the product as safe and effective, that it remains approved, or that the medication may have significant benefits for many patients. Any disclaimers typically flash at the conclusion of the advertisement in tiny print and are read at lightning speed.

The aim of lawsuit advertisers is not to impart objective health information, as some of the ads suggest. Rather, they use fearmongering tactics to generate as many "leads" for lawsuits as possible, regardless of the public health consequences. In some instances, lawyers and lead generators have spent over $100 million on ads targeting a single medication.[11]

Studies repeatedly show that lawsuit ads can put public health at risk.[12] Viewers may stop taking a medication or avoid a treatment that is medically necessary. Misleading lawsuit ads have led elderly people to stop prescribed blood thinners with dire consequences.[13] They have resulted in people at risk of HIV not taking preventative medications.[14] They have caused viewers to mistakenly believe the FDA has recalled products, when it has not.[15] Doctors have testified before Congress on the real-life harm that deceptive lawsuit advertising has caused.[16]

State judiciaries or bar authorities cannot be relied upon to address such concerns. While disciplinary rules prohibit attorneys from making a false or misleading communications "about the lawyer or the lawyer's services"[17] (such as promises of favorable results, representing themselves as "experts," or not disclosing fees), attorney regulators are less equipped to evaluate misleading claims, tactics, or imbalance in drug lawsuit ads. The FDA has this expertise, which it uses when reviewing pharmaceutical advertising. In addition, many lawsuit advertisements aired on television are sponsored by nonlawyer marketing companies, known as "lead generators," who are not subject to the attorney disciplinary system. And the people harmed by misleading lawsuit ads often have no remedy through filing an attorney complaint (most of which arise from disputes between clients and their attorneys). Those who are influenced by the lawsuit ads to stop taking a prescribed drug or not seek treatment may not all file lawsuits; their injuries are a "side effect" of a system that places recruiting plaintiffs above public health.

Yet, there is no federal oversight of misleading drug lawsuit ads, aside from the Federal Trade Commission acknowledging the problem and sending a warning shot across the bow of some advertisers several years ago.[18]

The First Amendment Protects Truthful, But Not Misleading, Advertising

Proponents of the End Prescription Drug Ads Now Act argue that most other countries do not permit direct-to-consumer pharmaceutical advertising. There is another type of advertising rarely seen abroad – advertisement for legal services. In the United States, the First Amendment protects *truthful* advertising about products and services and does not permit banning ads simply because the government disfavors the speaker or the message.[19]

The United States Supreme Court has repeatedly reaffirmed this principle, including in the context of prescription drugs.[20] It has struck down bans and other restrictions on truthful speech that rest on the "offensive assumption that people will respond 'irrationally' to the truth" or that "seek to keep people in the dark for what the government perceives to be their own good."[21]

The Problematic Approach of the Federal Legislation and RFK Proposals

The End Prescription Drug Ads Now Act makes no distinction between truthful and misleading advertising. Rather, it would deem a prescription drug "mis-

branded," subjecting the company to penalties, if it engages in any form of promotional communication targeting consumers.

RFK Jr.'s floated Plans B and C fare no better. He is reportedly weighing measures that would make pharmaceutical ads prohibitively expensive by requiring even more disclaimers and single out pharmaceutical companies by not allowing them to deduct advertising costs as business expenses for tax purposes.[22] These options are also constitutionally suspect, as they clearly target a particular message and messenger.

A Growing Number of States Are Acting

While the federal government has largely taken a hands-off approach to lawsuit advertisements targeting pharmaceuticals, seven states have enacted legislation to stop the most obviously deceptive practices in these ads, such as introducing TV commercials as "medical alerts," flashing the FDA logo, or suggesting a product has been recalled when it has not.[23] These laws also require lawsuit ads to warn viewers not to stop taking a prescribed drug without first speaking with their doctor.

A federal appellate court has upheld these safeguards as targeting misleading speech and requiring "the sort of health and safety warnings that have long been considered permissible."[24]

Conclusion

RJK Jr. and his allies in Congress say they are seeking to ban DTC ads to protect the public. If so, their focus is misplaced. Rather than attack *truthful*, balanced advertisements that inform viewers about available medications, they should seek stronger federal oversight of *misleading* pharmaceutical lawsuit ads.

Endnotes

1. David Lim & Lauran Gardner, *Can RFK Jr. Ban Pharma TV Ads?*, Politico, Mar. 25, 2025, https://www.politico.com/newsletters/prescription-pulse/2025/03/25/can-rfk-jr-ban-pharma-tv-ads-00246067.

2. S. 2068, 119th Cong., 1st Sess.

3. H.R. 4065, 119th Cong., 1st Sess.

4. Bernie Sanders, Press Release, *Sanders, King Introduce Bill to Ban Prescription Drug Ads*, June 12, 2025, https://www.sanders.senate.gov/press-releases/news-sanders-king-introduce-bill-to-ban-prescription-drug-ads/.

5. 21 C.F.R. § 202.1(e)(5)(ii).

6. 21 C.F.R. § 202.1(e)(1)(i).

7. 21 C.F.R. § 202.1(e)(1)(ii).

8. 21 C.F.R. § 314.81(b)(3)(i).

9. *See* U.S. Food & Drug Admin., Office of Prescription Drug Promotion (OPDP), https://www.fda.gov/about-fda/cder-offices-and-divisions/office-prescription-drug-promotion-opdp (providing links to issued warning letters and untitled letters).

10. *See* U.S. Food & Drug Admin., *The Bad Ad Program*, https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program.

11. Roy Strom, *Camp Lejeune Ads Surge Amid 'Wild West' of Legal Finance, Tech*, Bloomberg L., Jan. 30, 2023, https://news.bloomberglaw.com/business-and-practice/camp-lejeune-ads-surge-amid-wild-west-of-legal-finance-tech (reporting $122 million spent on advertising for Xarelto lawsuits).

12. *See generally* Jesse King & Elizabeth Tippett, *Drug Injury Advertising*, 18 Yale J. of Health Pol'y, L. & Ethics 114 (2019).

13. Mohamed Mohamoud, et al., *Discontinuation of Direct Oral Anticoagulants in Response to Attorney Advertisements: Data From the FDA Adverse Event Reporting System*, Annals of Pharmacotherapy, vol. 53, issue 9, at 962-63 (Sept. 2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC8919214/pdf/nihms-1786330.pdf.

14. Pedro A. Serrano, et al., *Effect of Truvada Lawsuit Advertising on Preexposure Prophylaxis Attitudes and Decisions Among Sexual and Gender Minority Youth and Young Adults at Risk for HIV*, 35 AIDS 131-39 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC7718403/pdf/nihms-1647974.pdf.

15. Christopher F. Tenggardjaja, et al., *Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery*, 85 Urology 326, 327 (2015), https://pubmed.ncbi.nlm.nih.gov/25623677/.

16. Examining Ethical Responsibilities Regarding Attorney Advertising, Hearing Before the Subcommittee on the Constitution and Civil Justice of the Committee on the Judiciary, House of Representatives, 115th Cong., Serial No. 115-22, June 23, 2017.

17. ABA Model Rule of Prof. Conduct 7.1.

18. Fed. Trade Comm'n, Press Release, *FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits*, Sept. 24, 2019, https://www.ftc.gov/news-events/news/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits.

19. *Bates v. State Bar of Arizona*, 433 U.S. 350, 383-84 (1977).

20. *See Sorrell v. IMS Health, Inc*., 564 U.S. 552, 564 (2011), *Thompson v. Western States Med. Ctr.*; 535 U.S. 357, 374-75 (2002); *Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. 748, 769-71 (1976).

21. *Western States,* 535 U.S. at 375 (quoting *Liquormart, Inc. v. Rhode Island*, 517 U. S. 484, 503 (1996)).

22. Liam Reilly & Tami Luhby, *RFK Jr. Wants to Crack Down on Drug Ads. That Could Cripple Some Broadcasters*, CNN, June 18, 2025, https://www.cnn.com/2025/06/17/media/drug-ads-broadcasters-rfk.

23. Fla. H.B. 1205 (2023) (codified at Fla. Stat. § 501.139); Ind. H.B. 1125 (2021) (codified at Ind. Code § 24-5-26.5); Kan. S.B. 150 (2022) (codified at Kan. Stat. Ann. § 50-6,144); La. S.B. 378 (2022) (codified at La. Rev. Stat. § 62:3221); Tenn. S.B. 352 (2019) (codified at Tenn. Code §§ 47-18-5601 et seq.); Tex. S.B. 1189 (2019) (codified at Tex. Gov't Code §§ 81.151 et seq.); W. Va. Comm. Sub. S.B. 136 (2020) (codified at W. Va. Code Ann. §§ 47-28-1 et seq.).

24. *Recht v. Morrissey,* 32 F.4th 398 (4th Cir. 2022), *cert. denied,* 143 S. Ct. 527 (U.S. 2022). The Supreme Court has upheld restrictions on misleading attorney advertising. *See, e.g.*, *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 650 (1985) (upholding disciplinary action for attorney in Dalkon Shield mass tort litigation whose ads did not inform clients that they would be liable for costs, even if their claims were unsuccessful); *see also Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 464-65 (1978) (upholding state rules prohibiting lawyers from soliciting people in person or by phone when they are injured or distressed). ■

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