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FDA's Inadequate Interests for Ending Drug Advertising "Adequate Provision" Protections

Don't let the government hide behind sensible sounding professions of advancing citizen health-and-safety.

by Zac Morgan

Just over eighty years ago, Justice Robert Jackson observed that "[i]t is not often in this country that we now meet with direct and candid efforts to stop speaking or publication as such. Modern inroads on these rights come from associating the speaking with some other factor which the state may regulate so as to bring the whole within official control."[1] When it comes to regulating pharmaceutical marketing, such is the same as it ever was.

Everybody concedes that the distribution of prescription drugs may be regulated. That's what the word "prescription" is doing in the term "prescription drugs." A doctor's scrip isn't issued out of the goodness of her heart. The law insists that she (a member of a heavily regulated profession) ensure a valid medical reason for her patient to get access to (also highly regulated) pharmaceutical products. Nobody's interested in breaking that system, which directly promotes the health and safety of American citizens.

The constitutional problem comes when the government works to apply that health-and-safety interest one step up the chain, to control the free flow of information about safe and legal prescription drugs. Despite moving from regulating conduct (may a patient have access to a drug) to regulating speech (how companies may talk about the drug), state actors can be expected to invoke public health-and-safety all the same. In doing so, the government thinks it will obtain maximum deference from the regulated community and any reviewing tribunal. Nobody, after all, wants to stand in the way of protecting the public from harm.

True to form, Health and Human Services Secretary Robert F. Kennedy, Jr. claimed his self-described "crackdown" on direct-to-consumer (DTC) pharmaceutical ads is designed to ensure commercials carry "critical safety facts" (who could be against those?) to help "break the cycle of overmedicalization that drives America's chronic disease epidemic."[2] Should the FDA continue this crackdown by deleting the so-called adequate provision rule for DTC ads,[3] expect the Secretary to return to this line.

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[1] *Thomas v. Collins*, 323 U.S. 516, 547 (1945) (Jackson, J., concurring).

[2] FDA, *FDA Launches Crackdown on Deceptive Drug Advertising* (Sept. 9, 2025), https://perma.cc/5PVW-ELTN.

[3] Foley Hoag, *FDA Proposes to Eliminate "Adequate Provision" for Broadcast Prescription Drug Advertising* (July 7, 2026), https://perma.cc/7L8K-9AGV.

Zac Morgan is a Senior Litigation Counsel at Washington Legal Foundation.

The Food, Drug, and Cosmetic Act (FDCA) forces companies to attach remarkably lengthy disclosures about potential side effects and contraindications when promoting a prescription drug.[4] But limning out *all* risks, even relatively minute ones and even in "brief summary,"[5] would capture virtually the entire content of a 30-second spot.

In the late 1990s, realizing that getting information about life-altering or symptom-mitigating drugs to those suffering from malady and illness is beneficial, FDA clarified how an ad could ensure "adequate provision . . . for dissemination of the approved or permitted product labeling in connection with the broadcast presentation."[6] "That's what the 'ask your doctor for more information about this drug' is doing in these ads—a prescribing authority can give the full low-down if prompted."[7] This doesn't mean that ads can avoid talking about downsides entirely—the "adequate provision" doesn't oust the rule that DTC ads communicate "information relating to the *major* side effects and contraindications," the so-called major statement. [8] It just ensures that the voiceover or text statement isn't functionally endless.

FDA wants to ax this safe harbor. To do so, the agency would have to pass through two gates. It must first identify a particularly important state interest at hand and then show that mandating speech-quelching disclaimers will "directly advance" that interest.[9] Eliminating the adequate provision would certainly fail at that second step, since the practical effect would be to drive vital commercial information off the airwaves rather than merely contextualizing it.[10]

But FDA shouldn't be given a free pass on the first step. Sure, the federal government may profess deep concern and a compelling interest in preserving and protecting health-and-safety. But letting that claim go sans scrutiny allows FDA to start on third base and act as though it hit a triple. As then-Judge Gorsuch wrote in a different First Amendment context, courts should look askance at such generalized and expansive claims of government-doing-good:

> At some great height, after all, almost any state action might be said to touch on "one or another of the fundamental concerns of government: public health and safety, public peace and order, defense, revenue," and measuring a highly particularized and individual interest "directly against one of these rarified values inevitably makes the individual interest appear the less significant."[11]

In short, failing to rigorously check a government's asserted interest unfairly rigs review and privileges state concerns that the caselaw insists are "subordinate," not superior, to a claimant's First

[4] 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(1).

[5] *Id.*

[6] 21 C.F.R. § 202.1(e)(1)(i)(B); FDA, 1999 Guidance for Industry, *Consumer-Directed Broadcast Advertisements* (Aug. 1999), https://perma.cc/JK7W-CM83.

[7] Zac Morgan, *Regulation of Consumer Drug Ads: Legislative Dos and Don'ts*, 41 WLF Legal Backgrounder 4 (Mar. 31, 2026).

[8] 21 C.F.R. § 202.1(e)(1)(i)(A) (emphasis supplied).

[9] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564–66 (1980).

[10] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

[11] *Yellowbear v. Lampert*, 741 F.3d 48, 57 (10th Cir. 2014). (quoting J. Morris Clark, *Guidelines for the Free Exercise Clause*, 83 Harv. L. Rev. 327, 330–31 (1969)).

Amendment rights.[12]

So let's run the state interest in ending the adequate provision through its paces. FDA will hawk a health-and-safety interest, but that's an incomplete answer at best. The public health is more than properly served by the sum of the major statement and the adequate provision. It's more accurate to say that the agency has an informational interest in listing out every possible side effect and contraindication—even if that information is readily available off-screen and via a gatekeeping physician. That sort of vague "right to know" can't be "sufficiently important to justify" burdening protected speech,[13] since it seeks a permission slip for the "prophylaxis-upon-prophylaxis approach to regulating expression"[14] that's strongly disfavored under any type of First Amendment review.[15]

If FDA wants to try ending the adequate provision while preaching a general health-and-safety interest, litigants seeking to vindicate their constitutional freedoms should take then-Judge Gorsuch's advice to heart. Don't concede a sensible sounding governmental interest; reveal what such airy talk conceals.[16]

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[12] *Buckley v. Valeo*, 424 U.S. 1, 64 (1976) (per curiam) (describing the exacting scrutiny test used for compulsory disclosures of any sort, tense altered); *cf. Ams. for Prosperity Found. v. Bonta*, 594 U.S. 595, 608 (2021) (Roberts, C.J., controlling) ("Regardless of the type of association, compelled disclosure requirements are reviewed under exacting scrutiny").

[13] *See Calzone v. Summers*, 942 F.3d 415, 424–25 (8th Cir. 2019) (en banc) (finding government's sweeping transparency interest flunks exacting scrutiny, internal quotation marks omitted); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996) ("[C]onsumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement").

[14] *See FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 479 (2007) (Roberts, C.J., controlling). While *Wisconsin Right to Life* is a strict scrutiny case, that principle reaches beyond blatant speech prohibitions. *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 190 (2024) (First Amendment ensures that the government may not "do indirectly" what it "is barred from doing directly").

[15] *McCutcheon v. FEC*, 572 U.S. 185, 218 (2014) (Roberts, C.J., controlling) (In every "First Amendment context, fit matters").

[16] "A 'consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.' That reality has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011) (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977)).