Legal Backgrounder

Vol. 40 No. 16

December 8, 2025



Proscriptions for Prescription Drug Ads Can't Surmount First Amendment Hurdles

by Zac Morgan

The Food and Drug Administration (FDA) has begun a self-described "crackdown" on direct-to-consumer (DTC) pharmaceutical advertising. It has sent warning letters to hundreds of companies, vaguely suggesting that their ads may be "misleading" and therefore illegal.¹ And rumors continue to circulate in Washington that the Department of Health and Human Services (HHS) may issue new rules, regulations, or guidance expanding on the compelled disclaimer requirements of the Food, Drug, and Cosmetic Act (FDCA). The apparent goal: "mak[e] broadcast ads much longer and prohibitively expensive."²

As anyone who even casually watches television knows, pharmaceutical advertisements must disclose contraindications and potential side effects. The FDCA itself does not limn this demand in great detail, providing that in the case of prescription drug ads, the communication must "stat[e] the name of the drug and its conditions of use," and that a "brief summary relating to side effects [and] contraindications. . . shall be presented in a clear, conspicuous, and neutral manner." The details of those disclosures is expressly delegated to "regulations which shall be issued by the Secretary" of HHS. That relevant regulation providing the rules for DTC ads, housed at 21 C.F.R. § 202.1, is 5,765 words—about a thousand words longer than the original Constitution plus the Bill of Rights (whose First Amendment, of course, prohibits compelled speech).

Unsurprisingly given that length, that regulation exhaustively and granularly describes the size, scope, and content of the government's compulsory scripts, complete with vague flourishes instructing advertisers to use "consumer-friendly language and terminology" and to ensure that "the advertisement does not include audio and visual elements . . . likely to interfere with comprehension of the" disclaimer.⁵ That's a bit of a moving target with an eye-of-the-beholder problem—an advertiser's understanding of "consumer-friendly" likely is quite divorced from that of a political appointee bent on eliminating DTC advertising.⁶

¹ FDA, FDA Launches Crackdown on Deceptive Drug Advertising, Sept. 9, 2025, https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising.

² Rachel Cohrs Zhang, *RFK Jr.'s Drug-Ad Crackdown Threatens a \$10 Billion Market*, Bloomberg Law, July 17, 2025. ³ 21 U.S.C. § 352(n).

⁴ *Id*.

⁵ 21 C.F.R. § 202.1(e)(ii).

⁶ Zac Morgan, There's No "One Weird Trick" Around the Constitution: Analyzing the Attempts to End DTC Pharma Marketing, 40 WLF Legal Backgrounder 9 (Aug. 4, 2025), https://www.wlf.org/2025/08/04/publishing/there-is-no-

Bringing clarity to this vagueness would be a welcome regulatory reform. The problem, of course, is that Secretary Robert F. Kennedy, Jr.'s HHS is on a mission to disrupt and deter DTC advertising. So we expect that any new clarifying language from the federal government will go in the direction of piling new and additional burdens on pharmaceutical ads. The Secretary might specify that spoken-word disclaimers take up a specific percentage of an ad, perhaps from 30 to over 50 percent. Or he might direct the visuals of ads during the reading of the side-effect disclaimers —requiring black-and-white imagery (like a negative political ad) or banning visuals of happy, active users.

If the Secretary takes that approach, he will be inviting a serious constitutional challenge. The Supreme Court has expressly held that "paid advertisement[s] of one form or another," including the "speech of pharmaceutical marketing" itself, are under "the protection of the First Amendment." When it comes to protected speech, the starting presumption is that the government is prohibited from messing with a private speaker's message—especially for the sake of imposing intentionally unwieldly content requirements. And even when the State is acting in good faith, merely because the government would prefer a different script, or its assemblage of "factual information might be relevant to the listener, and . . . could encourage or discourage" a financial transaction—that still isn't sufficient to oust the general rule barring the government from "burdening a speaker with unwanted speech." ¹⁰

While commercial speech is not as rigorously protected as other forms of communication, ¹¹ any changes to the DTC disclaimer regime would have to survive, at a minimum, exacting scrutiny. ¹²

That standard is a "strict test," that requires the government to assert a sufficiently vital state interest, and "be 'narrowly drawn" to it—"[t]he regulatory technique may extend only as far as the interest it serves." HHS would likely point to a generalized interest in protecting the health and safety of consumers, but mere genuflection in the direction of a legitimate state goal isn't enough. The government must prove, with actual evidence, that its length or content requirements "directly advances" that mission. Under that standard, the Ninth Circuit jettisoned a San Francisco commercial disclaimer requirement that required advertisers to

one-weird-trick-around-the-constitution-an-analysis-of-attempts-to-end-dtc-pharma-marketing/ ("During his (brief) campaign for the White House, Secretary Kennedy vowed to use executive action to ban so-called direct-to-consumer (DTC) ads").

⁷ Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 761 (1976).

⁸ Sorrell v. IMS Health Inc., 564 U.S. 552, 576 (2011).

⁹ Riley v. Nat'l Fed'n of the Blind of N.C., Inc., 487 U.S. 781, 798 (1988).

¹⁰ Nat'l Inst. of Family & Life Advs. v. Becerra, 585 U.S. 755, 775 (2018) (quoting Riley, 487 U.S. at 800).

¹¹ *United States v. Williams*, 553 U.S. 286, 298 (2008) (noting "the less privileged First Amendment status of commercial speech").

¹² Cent. Hudson Gas & Elec. Corp v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980); Ams. for Prosperity Found. v. Bonta, 594 U.S. 595, 609 (2021) ("Narrow tailoring is crucial where First Amendment activity is chilled—even if indirectly"). Central Hudson is sometimes referred to as applying intermediate scrutiny, but the Chief Justice's controlling opinion in Bonta suggests that forms of review that are not strict scrutiny, but require narrow tailoring (as Central Hudson does, 447 U.S. at 564) trigger "exacting scrutiny." Bonta, 594 U.S. at 608 (Roberts, C.J., controlling).

¹³ Buckley v. Valeo, 424 U.S. 1, 66 (1976) (per curiam) (describing the exacting scrutiny analysis).

¹⁴ Cent. Hudson, 447 U.S. at 565 (quoting In re Primus, 436 U.S. 412, 438 (1978)).

¹⁵ *Id.* at 566.

surrender 20 percent of an ad's space for the government's messaging.¹⁶ And should a court determine that HHS's new regime is sufficiently divorced from regulating commercial speech and designed to merely suppress expression, it's possible that an even more heightened form of review may apply.¹⁷

Censors usually turn to bad caselaw to try to avoid rigorous review, and we expect that HHS will be no different. In *Zauderer v. Office of Disciplinary Counsel*, ¹⁸ the Supreme Court held that the First Amendment permitted on-ad disclaimers where the government was focused on deterring fraudulent and deceptive advertising. ¹⁹ True enough, *Zauderer* imposes a lighter burden on the government, but *Zauderer* also requires that the government's compelled messaging be "purely factual and uncontroversial." ²⁰ The types of length and content requirements that HHS may impose are unlikely to meet that standard—those rules are designed to make the product *less* appealing to consumers, not to advance a legitimate interest in protecting the health and safety of Americans. A compelled speech requirement becomes "controversial" the minute that the government's dictated message seeks to countermand a commercial proposition. Since HHS's likely innovations would serve that illegitimate purpose, exacting scrutiny would apply.

That review will not merely focus on the harm that HHS is imposing on advertisers, but also the harm to listeners. As Frederick Douglass put it long ago, "To suppress free speech is a double wrong. It violates the rights of the hearer as well as those of the speaker." The Supreme Court has specifically noted that the curtailing of information about prescription drugs "hits the hardest [on] the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs." Since drug advertising can help a consumer determine "where their scarce dollars are best spent," a "particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate."

If the government wishes to criticize drug ads, it is of course welcome to do so—but it may not impose the "double wrong" of censorship. It "is the command of the Constitution" that "the remedy to be applied is more speech, not enforced silence" or the government takeover of commercial messaging.²⁴

* * *

¹⁶ Am. Bev. Ass'n v. City & Cnty. of S.F., 916 F.3d 749, 757 (9th Cir. 2018) (rejecting study proffered by government as evidence for necessity of the disclaimer because "[t]hat study used warnings covering only 10% of the image . . . therefore, the 20% requirement is not justified" given "its likely burden on protected speech").

¹⁷ See NetChoice v. Weiser, 2025 WL 3101019 (D. Colo. Nov. 6, 2025) (rejecting government's effort to treat a general disclosure requirement about the purported ills of social media as a regulation of commercial advertising).

^{18 471} U.S. 626 (1985).

¹⁹ *Id.* at 651–52; *Ibanez v. Fla. Dep't of Bus. and Prof. Regul., Bd. of Accountancy*, 512 U.S. 136, 146 (1994) (compelled disclaimers may be "an appropriately tailored check against deception or confusion").

²⁰ Zauderer, 471 U.S. at 651; NIFLA, 585 U.S. at 768 ("Zauderer has no application" where the government goes beyond providing "information about the terms under which [goods or] services will be available") (internal quotation marks, citation, and ellipses omitted).

²¹ Frederick Douglass, A Plea for Free Speech in Boston (Dec. 3, 1860).

²² Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 763 (1976).

²³ Id. at 763.

²⁴ Whitney v. Cal., 274 U.S. 357, 377 (1927) (Brandeis, J., concurring).

Secretary Kennedy has made his disdain for pharmaceutical advertising plain. The system is blinking red that something significant is coming down the pike to further muzzle this already heavily regulated form of commercial speech. To the extent that the administration is listening to voices suggesting that it may do so through new compelled-speech requirements and receive deferential First Amendment review from the courts, that's wrong. The government "may not suppress" or deter "the dissemination of views"—even the view that the audience should talk to their doctor about a specific drug—"because" the federal government finds them "unpopular, annoying[,] or distasteful."²⁵

²⁵ Murdock v. Pa., 319 U.S. 105, 116 (1943).