Legal Backgrounder

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Regulation of Consumer Drug Ads: Legislative Dos and Don'ts

by Zac Morgan

As any American who's even briefly watched television knows, pharmaceutical broadcast ads aren't like commercials for any other product. Rather than just delivering the company's most effective pitch, direct-to-consumer (DTC) drug ads are accompanied by a lengthy disclaimer spelling out potential side effects and contraindications—all but advising against "asking your doctor" about whether the product "is right for you."

This side-effects-and-contraindications disclosure (called the "major statement") is compelled by the Food, Drug, and Cosmetic Act (FDCA).[1] The current administration wants to expand the major statement—probably to do something like "specify that spoken-word disclaimers take up a specific percentage of an ad, perhaps from 30 to over 50 percent" or to "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."[2]

But HHS Secretary Robert F. Kennedy, Jr.—the administration's cheerleader on this issue—can't force an expansive disclaimer under existing law, which allows him to adjust the disclaimer only "to ensure the major statement is easy to understand."[3] To gain power to "make novel and disruptive changes to the major-statement disclaimer regime," the administration must go to Congress.[4]

What does the FDCA already say drug ads must say?

Under current law, if a pharmaceutical ad doesn't carry the proper disclaimer, the underlying drug can be declared "misbranded." Misbranding is no joke—the drug becomes illegal to sell,[5] the company and its executives are subject to civil and criminal penalties,[6] and the drug's inventory may

[1] 21 U.S.C. § 352(n).

[2] Zac Morgan, *Proscriptions for Prescription Drug Ads Can't Surmount First Amendment Hurdles*, 40 WLF Legal Backgrounder 16 (Dec. 8, 2025).

[3] Zac Morgan, *Clear, Conspicuous, and Not Gonna Happen: Statutory Roadblocks Against FDA Overreach on DTC Pharma Ad Regulation*, 41 WLF Legal Backgrounder 2 (Feb. 11, 2026).

[4] *Id.*

[5] 21 U.S.C. § 331.

[6] *Id.* § 333.

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be seized by the federal government.[7]

Congress added the major-statement requirement to the FDCA in 1962. At that time, the U.S. Supreme Court had yet to "strike down an act of Congress on First Amendment grounds,"[8] and it was unresolved whether the Constitution even applied to commercial speech. Not until 1976 would the Supreme Court affirm (in a case about pharmaceutical advertising, no less) the constitutional value of commercial advocacy.[9] So it's not terribly surprising that the 1962 Congress wasn't overly concerned with the constitutional niceties of regulation, or much worried how even a "brief summary relating to side effects, contraindications, and effectiveness" might derail a 30-second ad.[10]

As FDA notes, "[t]he 'brief summary' includes a lot of information, so it is usually presented on its own page of a print ad."[11] The allegedly "brief" summary must list "all necessary information related to"[12] "side effects, warnings, precautions, and contraindications."[13] In practice, this recital of virtually every possible discomfort that might occur if the wrong person consumes or misuses a drug can't be "brief."

Fortunately in the 1990s, FDA clarified that broadcast ads need only provide an on-communication disclaimer of the "*major* side effects and contraindications"[14] so long as the ad gave "adequate provision" for a consumer to learn more elsewhere.[15] (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.)

What Congress shouldn't do

While the Executive Branch can't change the law, the Legislative Branch can pass one—so long as it complies with the First Amendment.

Let's start with a bad example. Senator Bernie Sanders (I-Vt.) has introduced legislation that would consider a drug misbranded if commercially advertised.[16] That's mildly clever—the proposal technically doesn't prohibit speech, it just renders the product illegal if a company tries to promote it. But there's no "one weird trick" around the Constitution.[17] It's well-settled that "the Constitution's enumerated rights" can't be ousted by "coercing people into giving them up" at the pointy end of a statute.[18]

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[7] *Id.* § 334.

[8] Akhil Reed Amar, *The Bill of Rights: Creation and Reconstruction* 290 (1998). The case was *Lamont v. Postmaster General*, 381 U.S. 301 (1965), which struck down a federal law that required the postal service to hold mail deliveries of "communist political propaganda" until an intended recipient affirmatively asked for delivery. *Id.* at 302–304.

[9] *Va. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

[10] 76 Stat. 780, 791–92, Pub. L. 87-781 (Oct. 10, 1962).

[11] FDA, *Drug Advertising: A Glossary of Terms*, https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms.

[12] 21 C.F.R. § 202.1(e)(1)(i)(B).

[13] *Id.* C.F.R. § 202.1(e)(1).

[14] *Id.* § 202.1(e)(1)(i)(A) (emphasis supplied).

[15] *Id.* § 202.1(e)(1)(i)(B).

[16] S. 2068, *End Prescription Drug Ads Now Act*, 119th Congress (2025).

[17] 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).

[18] *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (internal quotation marks and citation omitted).

What about writing Secretary Kennedy's potential dream list into the statute? Could Congress eliminate the adequate provision rule, require black-and-white imagery during the reading of the major-statement, or mandate that any voiceover and on-screen text eat up 30 to 50 percent of an ad? No.

While the Supreme Court has upheld disclaimer regimes in the campaign finance context, it's done so when the disclaimers were extremely brief.[19] And in the commercial speech context, even the usually permissive Ninth Circuit balked at a health-and-safety disclaimer that consumed 20 percent of a business's speech.[20] Nor may the government hijack a private message solely to countermand a commercial transaction.[21]

What Congress could do

There are, of course, beneficial and constitutional measures Congress could take rather than larding up commercials with unwieldly disclaimers. While it would be preferable to abolish the compelled speech rules entirely, this isn't a zero-sum game. Congress can still preserve the substance of the FDCA's disclosure regime while expanding freedom of speech.

For example, Congress could amend the FDCA to recognize the adequate provision. That would save that speech-maximizing measure—which exists only in regulation—from being undone by a future rulemaking.[22] Alternatively, if such a rulemaking succeeded, Congress should use its power under the Congressional Review Act (CRA) to kill the regulation and give it "no force or effect."[23] That would also have the side effect (pun intentional) of banning the Executive Branch from promulgating "a new rule that is substantially the same" as the voided one.[24]

Or even better, Congress could modernize the disclaimer rules to account for changes in technology. Both the "brief summary" and "major statement" mandates come from a pre-smartphone world. That world carried real limits. If you wanted to include the brief summary in a print ad, you had to provide the whole thing right there. Likewise, broadcast ads are time-limited audio-visual media—if you want to immediately deliver information to the viewer, you must provide it on-screen or via voiceover.

No longer. Ninety-one percent of American adults own a smartphone.[25] That includes 78 percent of seniors and 90 percent of Americans aged 50–64—the target audience for most prescription drugs.[26] Rather than force ads to carry clunky disclaimers, Congress could just require ads to carry a QR code in the corner—maybe for five or ten seconds in a broadcast commercial.

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[19] *E.g.*, *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 367 (2010) (upholding four-second verbal disclaimer).

[20] *Am. Bev. Ass'n v. City and Cnty. of S.F.*, 916 F.3d 749, 757 (9th Cir. 2018).

[21] *See WLF v. Henney*, 56 F. Supp. 2d 81, 85–86 (D.D.C. 1999) (First Amendment forbids restrictions designed to "balance" a company's opinion and understanding of its own product), *judgment vacated in part due to lack of Article III controversy*, 202 F.3d 331 (D.C. Cir. 2000).

[22] As FDA has announced an intention to do just such a rulemaking, such a change would likely need to be placed into a must-pass bill like the National Defense Authorization Act. 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.

[23] 5 U.S.C. § 802(a). Of course, CRA invocations are subject to a presidential veto. *Cf. Immigration and Naturalization Serv. v. Chada*, 462 U.S. 919 (1983).

[24] 5 U.S.C. § 801(b)(2).

[25] Pew Rsch. Ctr., *Mobile Fact Sheet* (Nov. 20, 2025); https://perma.cc/VP6E-CRSP.

[26] *Id.*

Scan the QR code with a smartphone's camera and be immediately transported to a large font brief-summary or major-statement. No burdensome disclaimers needed. Full information in the palm of an interested viewer's hand.

A QR code rule would distribute the information quickly (and in a static format, which a viewer can go back through for as long as she wishes)—while preserving nearly the entirety of the commercial communication for the private speaker.[27] That serves both the federal government's asserted interest in "transparency, an extra-constitutional value" while maximizing "speech, a constitutional right."[28]

If Congress is to act, it should make *that* law—not Senator Sanders's or Secretary Kennedy's.

[27] *Cent. Hudson Gas and Elec. Corp v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980) (restrictions on commercial speech must be "narrowly drawn") (internal quotation marks and citation omitted).

[28] *Van Hollen v. Fed. Election Comm'n*, 811 F.3d 486, 501 (D.C. Cir. 2016).