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Clear, Conspicuous, and Not Gonna Happen: Statutory Roadblocks Against FDA Overreach on DTC Pharma Ad Regulation

by Zac Morgan

Summary: *An FDA regulation requiring dramatically expanded disclosure of side effects and contraindications in direct-to-consumer drug ads would not, after* Loper Bright*, survive a legal challenge alleging that the agency is exceeding its statutory authority.*

Robert F. Kennedy, Jr., the current HHS Secretary, is a longtime skeptic of the pharmaceutical industry and, in the past, has vowed to ban direct-to-consumer (DTC) advertising of pharmaceutical drugs.[1] Right now, his department is in the midst of a self-described "crackdown" on DTC broadcast ads, to the point where FDA Commissioner Marty Makary has taken to social media to openly brag about how much speech the current administration has chilled. Worse yet, Makary assures us that the government is "just getting started."[2]

Although Kennedy wants to eradicate drug ads, neither he nor Congress may do so. The Constitution forbids prohibiting commercial advertising.[3] So we would not be surprised if HHS were to take a subtler approach by shaping the content of ads—subbing in as a co-author of scripts and co-director of content. "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."[4] Not only would those new rules make ads more expensive (a longer disclaimer for side effects and contraindications means buying more time to carry the company's own pitch), they also could render those pitches counterproductive (negative political ads aren't designed to get you to vote for the target).

[1] 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).

[2] Comm'r Makary Post (Feb. 2, 2026 – 7:45 PM); https://perma.cc/MNN7-Q4NP.

[3] *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Va. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

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

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There are First Amendment issues that are fatal to that approach.[5] But a reviewing court wouldn't need to reach a constitutional claim. Such a regulation would be an unfaithful implementation of the Food, Drug, and Cosmetic Act (FDCA) itself, which cabins the ability of the Secretary to impose onerous disclaimers on drug ads.

Unlike the rules for, say, audio disclaimers for electioneering communications under the federal campaign finance laws,[6] the full script for the side effects and contraindications disclosure (called the "major statement") isn't written in the statute. Instead, the Act requires ads to bear contact information for an FDA tip line and that "the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner."[7] The statute then largely hands off the drafting pen to the HHS Secretary, stating that ads must include "such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations" produced by his office.[8]

Any new regulation would likely lean heavily on the FDCA's insistence that DTC ads list the "major statement" in a "clear, conspicuous, and neutral manner."[9] The current regulations fleshing out that provision already require the audio component of the disclaimer to be "readily understandable," while visual components must be "read easily."[10] The ad may "not include audio or visual elements, alone or in combination, that are likely to interfere with the comprehension of the major statement."[11] There's some daylight between the statute and the regulation,[12] but those specific dictates at least plausibly follow from Congress's instruction that the major statement be easy to understand.[13]

Defenders of the Secretary's crackdown might note that "clear, conspicuous, and neutral" are relatively broad terms. Fair enough. But ambiguity or breadth isn't license for anything goes. Unless a law is so inexplicable as to be unconstitutionally void-for-vagueness,[14] even the most "impenetrable" statutes "have a single, best meaning . . . 'fixed at the time of enactment.'"[15] And since the demise of *Chevron* deference at the hands of *Loper Bright*, the Secretary gets no leeway if his regulations rely on a second-best or merely "permissible construction of the statute."[16] He may only issue regulations hat work with the FDCA's "single, best meaning."[17]

So what's the best meaning of "clear, conspicuous, and neutral?"

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[5] *Id.*

[6] 52 U.S.C. § 30120(d)(2).

[7] 21 U.S.C. § 352(n).

[8] *Id.*

[9] *Id.*

[10] 21 C.F.R. § 202.1(e)(ii).

[11] *Id.* § 202.1(e)(ii)(E).

[12] As well as some potential vagueness issues—what does it mean for something to be "*likely* to interfere" with a viewer's "comprehension?"

[13] *Wayman v. Southard*, 10 Wheat. 1, 43 (1825) ("The line has not been exactly drawn which separates those important subjects, which must be entirely regulated by the legislature itself, from those of less interest, in which a general provision may be made, and power given to those who are to act under such general provisions to fill up the details.").

[14] Requiring a court to either facially strike the law or to "construe the statute, if that can be done consistent with the legislature's purpose, to avoid the shoals of vagueness." *Buckley v. Valeo*, 424 U.S. 1, 77–78 (1976) (per curiam).

[15] *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) (quoting *Wis. Cent. Ltd. v. United States*, 585 U.S. 274, 284 (2018)).

[16] *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984), *overruled by Loper Bright*, 600 U.S. at 412.

[17] *Loper Bright*, 603 U.S. at 400.

To start, those three words aren't bottomless "term[s] or phrase[s] that 'leave[] agencies with flexibility, such as 'appropriate' or 'reasonable.'"[18] In a vacuum, perhaps one could contend that a disclaimer taking up half of an ad would qualify as "conspicuous" or that black-and-white imagery is literally "neutral." But "a vacuum is no home for a textualist."[19] Individual words in a provision carry only the weight that context gives them.[20]

The terms "clear, conspicuous, and neutral"[21] are "conjoined in such a way as to indicate that they have some quality in common."[22] All those words are aimed at ensuring the major statement is easy to understand. And so individually and together, those three words must be read toward that end. Clarity and conspicuousness go to fair comprehension, not "any big size the Secretary wants." The word "neutral" means that a company can't impose a non-scientific gloss on the drug's side effects or contraindications—it must deliver "just the facts, ma'am."[23]

In fact, if the Secretary were to take up too much of an ad for a mandatory reading of the major statement or compelled the use of negative imagery during the major statement's presentation, the required disclaimer could no longer be considered "neutral." Forcing the major statement to eat up a disproportionate amount of the ad or convey that information in a "scary" fashion veers out of neutrality into taking sides against the drug itself. Trying to countermand a commercial proposition is an act of belligerence, not neutrality.

* * *

The cost for a company to invent a new drug, shepherd it through FDA's safety-and-efficacy process, and bring it to market is well north of a billion dollars.[24] "On average, an estimated $2.5 billion in revenue is required to support the invention of one new drug product."[25] And so "[w]ithout advertising it would not be possible to market a drug on a large enough scale to make safety and efficacy testing economically feasible."[26] The Secretary's drug ad "crackdown" threatens how companies maintain profitability and the capacity to continue developing new treatments for Americans' illnesses.

Congress, like the rest of us, knows this. And so it's not surprising that the Legislative Branch hasn't amended the FDCA to impose more onerous compelled speech rules for drug ads or to grant the Secretary explicit power beyond his delimited authority to ensure the major statement is easy to understand.[27] Until that happens, the Secretary can't make novel and disruptive changes to the major-statement disclaimer regime.[28]

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[18] *Id.* at 395 (quoting *Mich. v. EPA*, 576 U.S. 743, 752 (2015)).

[19] *Biden v. Neb.*, 600 U.S. 477, 517 (2023) (Barrett, J., concurring).

[20] *See Dubin v. United States*, 599 U.S. 110, 126 (2023) ("Because 'transfer' and 'possess' channel ordinary identity theft, *noscitur a sociis* indicates that 'uses' should be read in a similar manner to its companions.").

[21] 21 U.S.C. § 352(n).

[22] Antonin Scalia & Bryan Garner 162, *Reading Law: The Interpretation of Legal Texts* (Kindle Ed.).

[23] *Dragnet* (Nat'l Broadcasting Corp. 1951–59, 1967–70); *Dragnet* (Universal Pictures 1987).

[24] O. Wouters, et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, JAMA (Mar. 3, 2020, corrected Sept. 20, 2022) (estimating $1.3 billion mean "research and development investment required to bring a new drug to market" and noting that other researchers have suggested a mean estimate as high as $2.8 billion).

[25] Pet. for Writ of Cert. 31, *Bristol Myers Squibb Co. v. Kennedy*, Case No. 25-751 (U.S. 2025) (citing P. Dubois, et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. of Econ. 844, 861 (2015)).

[26] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) (summarizing the federal government's position).

[27] 21 U.S.C. § 352(n).

[28] *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 575 (2011) ("Many are those who must endure speech they do not like, but that is a necessary cost of freedom").