

No. 25-40137

IN THE UNITED STATES COURT OF
APPEALS FOR THE FIFTH CIRCUIT

R.J. REYNOLDS TOBACCO Co.; Santa Fe Natural Tobacco Co., Inc.; ITG
Brands LLC; Liggett Group, LLC; Neocom, Inc.; Rangila Enterprises,
Inc.; Rangila LLC; Sahil Ismail, Inc.; Is Like You, Inc.;
Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION; U.S. Department of Health and
Human Services; Martin A. Makary, Commissioner of Food and Drugs;
Robert F. Kennedy, Jr., Secretary, U.S. Department of Health and
Human Services;
Defendants-Appellants.

On Appeal from the United States District Court for the Eastern
District of Texas, Case No. 20-176 (Barker, J.)

**BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS
CURIAE SUPPORTING APPELLEES AND AFFIRMANCE**

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August 25, 2025

CERTIFICATE OF INTERESTED PERSONS

Case No. 25-40137

R.J. Reynolds Tobacco Co., et al.

v.

Food and Drug Administration, et al.

I certify that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in this case's outcome. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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August 25, 2025

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae to oppose the federal government's attempts to unlawfully compel speech. *See, e.g., R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012) (*D.C. Reynolds*), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). It also appeared as amicus curiae in this case when it was last before the Court. *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863 (5th Cir. 2024) (*Reynolds*).

WLF's Legal Studies Division, its publishing arm, regularly publishes papers about the unlawful nature of government efforts to suppress speech it does not like. *See, e.g.,* Howard L. Dorfman, *CMS's DTC Drug Ad Price-Disclosure Mandate: An Ill-Conceived and Illegal Proposal*, WLF Legal Opinion Letter (Jan. 25, 2019), <https://perma.cc/3ZFB-UWND>.

* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress passed a law, the Tobacco Control Act, which directed FDA to impose nine specific warning labels on tobacco products. 15 U.S.C. § 1333(a)(1). Yet the FDA's Final Rule requires eleven warnings. 21 C.F.R. § 1141.10(a)(1)(i-xi). Only two of those warnings use Congress's explicit language. 21 C.F.R. § 1141.10(a)(1)(i-ii). As a result, there's no way for a court to fix FDA's frolic and detour from the law's requirement that it produce the "specified" disclaimers. 15 U.S.C. § 1333(c)(1). Eleven is not nine. Two is not nine. The Court should affirm the injunction on that basis alone.

Doing so will also avoid constitutional pitfalls. True, this Court has determined that the Rule's requirements survive the "deferential standard of review" for truthful and non-controversial government direction under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). *Reynolds*, 96 F.4th at 882. But Appellees have preserved their constitutional arguments against the Rule for later review, Appellees' Br. at 12, n.5, and this Court's understanding of what makes a compelled speech requirement "uncontroversial" (and therefore eligible for deferential review) was predicated on the viability of a since-vacated

case. *Reynolds*, 96 F.4th at 881-82 (applying *NetChoice v. Paxton*, 49 F.4th 439 (5th Cir. 2022), *vacated and remanded sub. nom Moody v. NetChoice*, 603 U.S. 707 (2024)). Since *Paxton* was vacated, there's no longer any meaningful support for this Court's prior holding that a compelled statement is controversial only "where the inherent nature of the subject raises a live, contentious political dispute." *Reynolds*, 96 F.4th at 881 (applying *Paxton*). Any future tribunal reviewing those claims must, without *Paxton* as ballast, reconsider the standard from scratch.

So what is the proper standard for when compelled speech is "Zauderer-controversial?" When the government seeks to hijack a proposed commercial transaction to try to countermand it rather than correct for deception. That means FDA's compelled speech regime must be reviewed under exacting scrutiny, which it is unlikely to survive. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980). Of course, if this Court concludes that the district court was right to enjoin the Rule, it is unlikely a future court will have to go down this path. As a result, the district court's injunction is also honoring constitutional avoidance.

In any event, if the Court considers the question before it a close call, it should apply the Supreme Court’s instruction that “[w]here the First Amendment is implicated, the tie goes to the speaker, not the censor” or compeller. *Fed. Election Comm’n v. Wis. Right to Life, Inc.*, 551 U.S. 449, 474 (2007) (Roberts, C.J., controlling). FDA does not deserve the benefit of the doubt.

ARGUMENT

I. NINE IS NOT ELEVEN. TWO IS NOT NINE.

Where Congress speaks with specificity and clarity, it forecloses administrative creativity. Courts “*must* reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate.” *Fed. Election Comm’n v. Dem. Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981) (emphasis supplied, spelling modernized); *SEC v. Sloan*, 436 U.S. 103, 117 (1978) (striking down “consistent and longstanding” agency interpretation that conflicted with “the clear contrary indications of the statute itself”).

The Tobacco Control Act’s disclaimer requirements are hardly subtle. It supplied language for FDA to use and did not leave any blanks

for the agency to “fill up the details.” *Wayman v. Southard*, 10 Wheat. 1, 43 (1825). Congress wrote nine required labels that cigarette packs and cigarette advertising must “bear.” 15 U.S.C. § 1333(a)(1). Not eight, not ten, not eleven. Nine. *Id.* But FDA chose to improv, not follow direction. 21 C.F.R. § 1141.10(a)(1)(iii-xi). And FDA’s authorship is comprehensive. Only two of the warnings Congress drafted survived agency redlining. 21 C.F.R. § 1141.10(a)(1)(i-ii).

Congress’s disclaimers don’t mention diabetes, 15 U.S.C. § 1333(a)(1), but FDA’s disclaimers do. 21 C.F.R. § 1141.10(a)(1)(iii). Congress’s disclaimers don’t mention cataracts, 15 U.S.C. § 1333(a)(1), but FDA’s do. 21 C.F.R. § 1141.10(a)(1)(v). Congress’s disclaimers don’t mention erectile dysfunction, 15 U.S.C. § 1333(a)(1), but FDA’s do. 21 C.F.R. § 1141.10(a)(1)(vii). Only two of FDA’s disclaimers bothered to use Congress’s language, 21 C.F.R. § 1141.10(a)(1)(i-ii), despite the Act’s requirement that packaged cigarettes display “one of the labels *specified*” by the Congress. 15 U.S.C. § 1333(b)(1) (emphasis supplied). And after its wholesale rewrite, FDA drew up associated (and provocative) graphics for these uncalled-for warnings. 21 C.F.R. § 1141.10(a)(2).

In doing so, FDA—the Executive Branch—unlawfully substituted its desires for those of the Legislature. Congress, not FDA, has the power to write laws. Even during the heyday of *Chevron* deference, FDA’s work would not have survived judicial review. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (“If the intent of Congress is clear, that is the end of the matter . . . the agency, must give effect to the unambiguously expressed intent of Congress”). It has always been the case that neither courts nor agencies may “second-guess policy decisions expressed in the plain text of the congressional enactments.” ROA 10808; *see Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 462 (2002) (“We will not alter the text to satisfy the policy preferences of the Commissioner”).

Worse yet, FDA’s freestyling renders the Rule incapable of salvage. Had it merely added two extraneous scripts, perhaps this Court could neatly sever those unlawful additions and save the rest. But FDA didn’t do that. It merged, divided, deleted, and added text—then created new graphics to pair with its flourishes. Stripping away FDA’s work would, at best, leave us with two warning labels, not Congress’s necessary nine. Nor is it within this Court’s power to fix that blunder, as FDA has

conceded. *See* Appellees’ Br. at 57. The Fifth Circuit has no more power to create graphics for Congress’s missing seven disclaimers than FDA had to ignore their existence.

II. THE INJUNCTION IS AVOIDING CONSTITUTIONAL PERILS.

Affirmance would also promote constitutional avoidance. Appellees have preserved their constitutional claims for later review, and this Court’s prior First Amendment doctrinal holding in this case has been undermined by recent Supreme Court caselaw. Appellees’ Br. at 12, n.5 (“Plaintiffs hereby preserve their constitutional arguments for potential subsequent review”).

A. The Supreme Court’s vacatur of the *Paxton* decision undoes this Court’s prior doctrine as to when compelled speech is *Zauderer*-controversial.

Recent events have buckled the foundation of the Court’s original First Amendment ruling in this case. In *Reynolds*, the Court concluded that “*Zauderer* applies where the compelled speech is (1) purely factual and (2) uncontroversial.” 96 F.4th at 877. So far, so good. But *Reynolds* broke new ground when it held that compelled speech is “uncontroversial” when the imposition is generally truthful and “the inherent nature of the subject” does not “raise[] a live, contentious

political dispute.” *Id.* at 881. That portion of the opinion directly relies on just two cases—*National Institute of Family and Life Advocates v. Becerra*, 585 U.S. 755 (2018) (*NIFLA*) and *NetChoice v. Paxton*. *NIFLA*, of course, was not a *Zauderer* case—it applied “ordinary First Amendment principles” and found that California’s ventriloquism flunked exacting scrutiny. 585 U.S. at 773, 779.

That means the *Reynolds* test for controversiality relies solely on *Paxton*. 96 F.4th at 881. Let’s take the relevant analysis in full:

In *NIFLA*, the Court found that the abortion-services notifications were controversial, 585 U.S. at 769, 138 S. Ct. 2361, but, in *NetChoice*, we found that disclosures of social media censorship decisions were not controversial, 49 F.4th at 485. From these disparate results, we distill the following: A factual statement is “controversial” under *Zauderer* where the truth of the statement is not settled or is overwhelmingly disproven or where the inherent nature of the subject raises a live, contentious political dispute. In other words, that the speaker does not like the message does not make it controversial; there must be something more. *See Chamber of Commerce*, 85 F.4th at 770 (weighing the level of political controversy) . . . if mere connection to a live, contentious, political issue sufficed, *NetChoice* would have prevailed.

Id. That’s really it. Sure, some caselaw, including a pre-*Zauderer* opinion, is *see* cited without commentary in a footnote. *Reynolds*, 86 F.4th at 881, n.57 (see citing *Consol. Edison Co. of N.Y. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 530, 535 (1980); *Pac. Gas & Elec. Co. v. Pub. Utils.*

Comm'n, 475 U.S. 1, 8-9 (1986); *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1277-78 (9th Cir. 2023)). As for the Court's unadorned *see* citation to *Chamber of Commerce v. SEC*, 85 F.4th 760 (5th Cir. 2023), that's a case this Court correctly characterized as “[a]pplying *Zauderer* and *NetChoice*.” 96 F.4th at 877 (citing *Chamber of Commerce*, 85 F.4th at 768-72); *Chamber of Commerce*, 85 F.4th at 769 (argument on controversiality “foreclosed by *NetChoice*”). As for “review[ing] the cases” at issue, *Reynolds*, 96 F.4th at 881, the Court's “uncontroversial” standard—and subsequent order to reverse the district court—hinged solely on *Paxton*. *Id.* at 881-82 (applying *Paxton*-reliant standard).

But *Paxton* has been vacated, *Moody*, 603 U.S. at 726, and is no longer good law. *O'Connor v. Donaldson*, 422 U.S. 563, 577, n.12 (1975) (Supreme Court “decision vacating the judgment of the Court of Appeals deprives that court's opinion of precedential effect”). The *Reynolds* Court could not have foreseen this, of course. *Reynolds* was handed down on March 21, 2024, and the petition for rehearing en banc was denied on May 21, 2024. *Reynolds*, Case No. 23-40076 (5th Cir.), ECF No. 162. Even so, *Moody* vacated *Paxton* on July 1, 2024. As a result, any later tribunal

reviewing the constitutional questions in this case must take a fresh look at the standard of review.

B. When compelled speech seeks to countermand a proposed commercial transaction, the government’s script becomes controversial.

Sans *Paxton*, what is the correct test? Consider why *Zauderer* exists in the first place: so that the government may use compulsory disclaimers as “an appropriately tailored check against deception or confusion.” *Ibanez v. Fla. Dep’t of Bus. and Prof. Regul., Bd. of Accountancy*, 512 U.S. 136, 146 (1994). The requirement that the government’s scripts be “uncontroversial” cannot be divorced from that anti-deception foundation. The *Zauderer* Court repeatedly emphasized that the test it announced applied only when correcting misleading or deceptive commercial advertising. *E.g.*, 471 U.S. at 651 (“We have emphasized that because disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech, warnings or disclaimers might be appropriately required in order to dissipate the possibility of consumer confusion or deception”) (punctuation and capitalization altered, citations omitted).

The Tobacco Control Act’s disclaimers, however, aren’t aimed at deception or fraud. It simply grafts Congress’s anti-smoking message (“WARNING: Smoking can kill you”), 15 U.S.C. § 1333(a)(1), on pro-smoking platforms, such as a pack for sale or cigarette advertising. It would be one thing if the Act’s labels applied only to ads claiming cigarettes were *not* addictive, or did *not* cause cancer, or did *not* harm children, *id.*, but neither the Act nor the more pugnacious Rule evince such modesty. The government simply hijacks valuable space on packages and advertisements for its anti-smoking crusade.

Under *Zauderer*, compelled speech is controversial the minute that the government’s dictated message seeks to countermand a commercial proposition. *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); see Ellen P. Goodman, *Visual Gut Punch: Persuasion, Emotion, and the Constitutional Meaning of Graphic Disclosure*, 99 Cornell L. Rev. 513, 552 (2014) (“Where the government orders disclosures as a way to advance its side in a controversial matter, the disclosure mandate bears greater constitutional

scrutiny”). And that’s what’s going on here, unless Congress and FDA intended frightful warnings of dire health problems and death to *promote* cigarette use. As the D.C. Circuit noted, “[a] review of the statute and the administrative record makes clear that the graphic warnings are intended to encourage current smokers to quit and dissuade other consumers from ever buying cigarettes.” *D.C. Reynolds*, 696 F.3d at 1218. Because that effort to interrupt and halt a commercial transaction is “*Zauderer*-controversial,” the Act’s mandates fall out of *Zauderer*’s narrow net and must survive heightened scrutiny.

C. The Act’s compelled disclaimers are unlikely to survive exacting scrutiny.

That does not mean, of course, that the government is precluded from slapping disclaimers on cigarette ads. It just must do the work of demonstrating that its demand is narrowly tailored to directly advance a substantial interest. *Cent. Hudson*, 447 U.S. at 564; *Ams. for Prosperity Found. v. Bonta*, 594 U.S. 595, 608 (2021) (“Regardless of the type of association, compelled disclosure requirements are reviewed under exacting scrutiny”). And under exacting scrutiny, these warning labels are likely unconstitutional. *Cf. D.C. Reynolds*, 696 F.3d at 1222.

The Executive Branch has characterized the Act’s mission as “promoting greater public understanding of the negative health consequences of smoking.” FDA, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15638, 15640 (Mar. 18, 2020). Applying the inapposite *Zauderer* standard, this Court found that was a “legitimate” state interest. *Reynolds*, 96 F.4th at 883. But while all “substantial” interests are necessarily “legitimate,” not all “legitimate” interests rise to the level of “substantiality.”

As an abstract matter, the federal government certainly has a heightened interest in the life and safety of its citizens. But as then-Judge Gorsuch once observed, “[t]he more abstract the level of inquiry, often the better the governmental interest will look.” *Yellowbear v. Lampert*, 741 F.3d 48, 57 (10th Cir. 2014). But what about the concrete interest invoked here—improving public understanding that smoking is bad? That’s a different story. The American people are already well-aware of the dangers of smoking. As FDA’s own PATH survey shows, 99.5% of individuals believe that cigarette smoking harms health, with 91% believing that it is “very or extremely harmful.” Comment Letter of RAI Services Co., Ex. C (Stmt. of J. Klick ¶ 5.20), Docket No.

FDA-2019-N-3065 (Oct. 11, 2019). Can it really be a substantial governmental interest for Congress to try to push near-unanimity on the risks of smoking to actual unanimity?

Nor is it obvious that an unadorned interest in *education* is really at issue. FDA claims that “increased smoking cessation and decreased initiation” are not the government’s aims. 85 Fed. Reg. at 15650. But it seems unlikely that Congress wants a better-educated population for a better-educated population’s sake. The text of the statute is clear: Congress wanted Americans not to smoke because smoking kills. *D.C. Reynolds*, 696 F.3d at 1218. And for the sake of argument, let’s spot the government a substantial governmental interest in stamping out smoking. Are the nine statutory warnings the least-speech-restrictive means by which the Legislative Branch could further that interest? No, not even close.

The Constitution provides many tools for Congress to carry out such a mission without taking over private speech for public purposes. Congress could always ban outright the sale or use of tobacco, for instance, as it has for other harmful products. *See* 21 U.S.C. § 812 (establishing “schedules of controlled substances”). That would affect no

one's speech rights, since there is no First Amendment right to advertise an illegal transaction. *Pittsburgh Press Co. v. Pittsburgh Comm'n on Hum. Relations*, 413 U.S. 376, 388 (1973). Or Congress could levy significant taxes on tobacco production or consumption, to price producers and users out of the market. U.S. Const. art. I, § 8. Congress could even prohibit health insurance companies from insuring tobacco users or decline to cover the costs of tobacco-related illnesses through federally funded healthcare programs like Medicare. None of these approaches infringe the First Amendment's "right to refrain from speaking," *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), and all of them would directly advance Congress's actual interest in deterring cigarette use.

No doubt, these alternatives might be politically difficult to accomplish. But hard work for the political branches is no excuse for softening liberty. Besides, the failure of the political branches to wrestle with difficult solutions is just another cost of mandatory disclosure. Because disclaimers are assumed to work and are cheap for the government to impose, they "undermine other regulation and ease pressure on lawmakers to enact better but more controversial regulation.

Thus bad law drives out better.” Omri Ben-Shaher and Carl Schnieder 170, *More Than You Wanted to Know: The Failure of Mandated Disclosure* (Kindle Ed. 2014).

But even if disclaimers were the least restrictive means, Congress’s nine specific disclaimers won’t work anyway—and certainly won’t work as well as more narrowly tailored options. *Ams. for Prosperity Found.*, 594 U.S. at 609 (“Narrow tailoring is crucial where First Amendment activity is chilled—even if indirectly”). FDA has not shown that any given images-and-text avalanche, even if they honored the statute, would substantially change behavior in the end. *See Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 568 (1980) (“*Meaningful* disclosure does not mean *more* disclosure”) (emphasis in original). FDA’s own study of the effects of many potential graphic warnings, for example, showed that they yielded virtually no long-term statistically significant change in participants’ views about health risks. RTI Int’l, *Experimental Study of Cigarette Warnings: Study 2 Report* (May 2019); *see also* Appellee’s Br. at 42-47. “If a disclosure fails in the laboratory, it cannot withstand the tumult of real life.” Ben-Shahar & Schneider 47. And that’s without considering the long-term desensitizing effect that the labels, even

graphic ones, will have over time. People regularly get used to things that were once jarring.

This regime is unlikely to survive judicial application of the proper standard of review. The government has not necessarily demonstrated a substantial governmental interest is at stake—the American people already well know the dangers of smoking. But even if Congress’s original intent (a straight anti-smoking interest) suffices, the government cannot show that hijacking speech is a less-restrictive means of directly advancing that mission. And even if disclaimers *were* the most constitutionally sensitive approach, FDA cannot show that *these* specific disclaimers are the best tailored ones.

III. ANY “TIE” SHOULD BE RESOLVED IN FAVOR OF THE SPEAKER, NOT THE COMPELLER.

But let’s say that all of that is wrong. If the Court considers affirming the injunction to be close to a 50/50 proposition, it should still do so. The First Amendment is at least implicated by both Act and Rule. In fact, even if *only* the APA question is all that’s before the Court, that’s still true—a Rule that has survived First Amendment scrutiny still *implicates* the First Amendment. If it didn’t, there would be no need to conduct the First Amendment review in the first place.

The Supreme Court has instructed that “[w]here the First Amendment is implicated, the tie goes to the speaker, not the censor.” *Wis. Right to Life, Inc.*, 551 U.S. at 474 (Roberts, C.J., controlling). Censors and compellers do not get the benefit of the doubt. Even when a court is no longer directly considering constitutionality, something of the First Amendment still remains to resolve close questions. *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 73 (1963) (Douglas, J., concurring) (“The wrong is compounded when the issue, though closely balanced in the minds of sophisticated men, is resolved against freedom of expression and on the side of censorship”).

CONCLUSION

FDA's unfaithful execution of the statute was properly enjoined, and that injunction serves greater constitutional equities. The district court should be affirmed.

Respectfully submitted,

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August 25, 2025

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,456 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

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August 25, 2025

CERTIFICATE OF SERVICE

I hereby certify that, on August 25, 2025, I served all counsel of record via the Court's CM/ECF system.

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