No. 24-189

In The
# Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY, ET AL.,

*Petitioners,*

v.

FOOD & DRUG ADMINISTRATION, ET AL.,

*Respondents*.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

**BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING PETITIONERS**

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## QUESTIONS PRESENTED

1. Whether provocative and misleading government-mandated graphic warnings on product packaging and advertising are "purely factual and uncontroversial" for purposes of applying *Zauderer*.

2. Whether massive and gratuitous warnings are "unjustified or unduly burdensome" for purposes of satisfying *Zauderer*.

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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 an amicus curiae in important compelled-speech cases. *See, e.g.*, *United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1 (1986).

## INTRODUCTION

"The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). Yet if the decision below stands, the government will enjoy largely unchecked power to compel any business to parrot the government's viewpoint, no matter how misleading or controversial a message it conveys. None of this Court's First Amendment precedents blesses so sweeping a governmental power. Among other defects, the Fifth Circuit's decision badly misreads *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). That misreading flouts the constitutional protections this Court has long granted all speakers, including businesses.

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* No party's counsel authored any part of this brief. No person or entity, other than WLF and its counsel, paid for the brief's preparation or submission. WLF timely notified all counsel of record of its intent to file this brief.

The Fifth Circuit relied on *Zauderer* to justify FDA's forcing cigarette makers and retailers to disseminate the government's anti-smoking messages and sensational images. But *Zauderer* does not hold, and this Court has never suggested, that a commercial speaker's First Amendment rights are minimal any time the government wants to force it to echo the government's views.

On the contrary, a law compelling speech is no less pernicious than one banning it; the State as ventriloquist is no better than the State as censor. By forcing Plaintiffs "to speak a particular message" against their will, FDA's compelled warnings "alte[r] the content of [their] speech." *Nat'l Inst. of Fam. & Life Advocs. (NIFLA) v. Becerra*, 585 U.S. 755, 766 (2018) (quoting *Riley*, 487 U.S. at 795). Nothing in *Zauderer* remotely suggests that the government may commandeer a business into serving as an involuntary mouthpiece for controversial viewpoints it opposes—much less for discouraging consumers from buying its goods. Because that is a grave constitutional violation under any level of constitutional scrutiny, this Court should intervene and set things right.

## STATEMENT

The Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, grants FDA limited authority to regulate tobacco products and marketing. Among other things, the TCA amends § 4 of the Fair Packaging and Labeling Act to require nine new textual warnings, or "label statements," that must be displayed on a rotating basis with the same frequency. 15 U.S.C.

§§ 1333(a)(1), (b)(2), (c)(2). A label statement must occupy the top 50 percent of the front and back panels of all cigarette packaging and at least the top 20 percent of all cigarette advertising. *Id.* § 1333(b)(2). The TCA also directs the Secretary of Health and Human Services to promulgate rules requiring every label statement to include "color graphics depicting the negative health consequences of smoking." *Id.* § 1333(d).

In 2011, FDA issued a final rule specifying nine graphic warnings to accompany the label statements. *See* FDA, *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011). The graphic warnings featured sensational images ostensibly depicting the consequences of smoking, such as diseased lungs or a cadaver on an autopsy table. *Id.* Five tobacco companies challenged the rule on First Amendment grounds. Finding not a "shred of evidence" that the new warnings would further FDA's stated interest in reducing smoking, the D.C. Circuit in 2012 vacated that rule as an unconstitutional compulsion of the tobacco companies' speech. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1221–22 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

Years later, in March 2020, FDA issued the new Rule. *See* FDA, *Required Warnings for Cigarette Packaging and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020). The Rule omits seven of the TCA's textual warnings, adds nine FDA-created label statements, and imposes eleven corresponding graphic images. Pet. App. 66a–67a. Aimed at manufacturers and retailers alike, the Rule makes it

a crime to make, package, sell, advertise, or offer for sale cigarettes without the mandated warnings. 21 C.F.R. §§ 1140.10(c), (d). Failure to include the warnings on all cigarette packaging and advertising renders cigarettes "misbranded" under the Rule, which permits the government to seize them. 21 U.S.C. § 334(a)(2), (g); 85 Fed. Reg. at 15,709;

To justify the new Rule, FDA has abandoned its earlier interest in reducing smoking. Unable to prove that graphic warnings will have any real-world impact on smoking behavior, FDA now asserts a purely informational interest—fostering "greater public understanding" of the risks of smoking—as its sole justification for commandeering private speech. 85 Fed. Reg. at 15,650.

Plaintiffs—four cigarette manufacturers and five cigarette retailers—challenged the Rule's compelled-warnings on First Amendment grounds. After granting the parties' joint motion to postpone the Rule's effective date, the District Court ultimately granted summary judgment for Plaintiffs on their First Amendment claim.

First, the District Court concluded that the Rule's warnings do not qualify for relaxed First Amendment scrutiny under *Zauderer* because they are not purely factual and uncontroversial. FDA presented no evidence that "each image-and-text pairing conveys only one, unambiguous meaning that is factually correct." Pet. App. 90a. Given their "capacity for multiple reasonable interpretations," the Rule's warnings were not "objectively 'accurate'" as *Zauderer* requires. *Id.* at 92a.

Second, the District Court held that the Rule's warnings cannot survive intermediate scrutiny under *Central Hudson Gas & Electric v. Public Service Commission*, 447 U.S. 557 (1980), because they are not narrowly tailored. Pet. App. 95a. FDA failed to show that "compelling these large, graphic warnings is necessary in light of other options." *Id.* Other measures, such as increased government funding for anti-smoking education, would be more narrowly tailored to achieve the Rule's stated aim without abridging Plaintiffs' freedom of speech. *Id*.

The Fifth Circuit reversed. In the Fifth Circuit's view, *Zauderer* applies anytime the government compels purely factual and uncontroversial speech, no matter the government's interest. Pet. App. 3a, 24a. The panel cited this Court's decision in *NIFLA* to justify its holding that FDA's informational interest sufficed. *Id.* at 23a Because *NIFLA*, struck down a California-mandated disclosure for crisis-pregnancy centers but "did not refer to any requisite claimed state interest in preventing misleading speech," the Fifth Circuit saw no need for FDA to show that the new graphic warnings are necessary to correct misleading or deceptive commercial speech. *Id.* (citing *NIFLA*, 585 U.S. 768–69, 776–77). Instead, the court held that FDA's graphic warnings easily satisfy *Zauderer* "despite the emotional impact the graphics may have." Pet. App. 19a.

The Fifth Circuit denied rehearing en banc. Pet. App. 111a.

## SUMMARY OF ARGUMENT

**I.** *Zauderer* clarified that "free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing * * * the harmless from the harmful." 471 U.S. at 646. Yet the Fifth Circuit badly mangles *Zauderer*, ignoring just how much the Court's modest compelled-speech holding hinged on the case's unique facts. At bottom, commandeering private speakers to spread the government's message allows the government to promote its own agenda at the expense of First Amendment rights. The Fifth Circuit's watered-down take on *Zauderer* ignores this threat to free speech. This Court should grant review and clarify *Zauderer*'s narrow scope once and for all.

**A.** Thirteen times in *Zauderer,* this Court emphasized that the test it announced applies only to government efforts to correct misleading or deceptive commercial advertising. Two subsequent decisions from the Court reaffirm that principle. Yet the lower courts are hopelessly divided on whether this Court meant what it said. If anything, *Zauderer* further exposes the constitutional defect in FDA's position here. To advance a purely informational interest in "fostering greater public understanding" of smoking risks, 85 Fed. Reg. at 15,650, FDA invokes *Zauderer* to justify compelling manufacturer and retailer speech. But this Court has never sustained a speech mandate under *Zauderer* outside the narrow confines of requiring a business to prevent consumer deception by curing false or misleading advertisements. None exist here. By expanding *Zauderer*'s scope and sweep, the decision below drastically erodes the First Amendment's prohibition against compelled speech.

This Court's recent *NIFLA* decision created confusion about *Zauderer*'s reach when it restated the test without a requirement that the disclosure be necessary to correct deception. Some judges have interpreted that restatement of the *Zauderer* test as a change, while others have said that this Court does not overturn precedent implicitly. This question—about *when* Zauderer applies—is fairly encompassed by the first question presented. The Court should reaffirm that *Zauderer* applies only when a disclosure is necessary to correct deception.

**B.** This Court's recent commercial-speech cases show that *Zauderer* applies only when the compelled speech is uncontroversial. Far from being "purely factual and uncontroversial," as both *Zauderer* and *NIFLA* require, the FDA's graphic warnings themselves are misleading. At best, the warnings seek to dramatically exaggerate the health harms of smoking by suggesting that very rare consequences of smoking are in fact common. At worst, the warnings are an "unabashed attempt[] to * * * browbeat consumers into quitting." *R.J. Reynolds*, 696 F.3d at 1216–17. Neither goal offers a valid governmental justification for compelling speech. This is yet another reason the Fifth Circuit erred by applying *Zauderer*.

**II.** Although the Rule's warnings are impermissible compelled speech subject to strict scrutiny, the Rule also fails to satisfy the government's evidentiary burden under either *Zauderer* or *Central Hudson*. First, even if *Zauderer* applies, FDA may not mandate a disclosure if it is "unjustified." *Zauderer*, 471 U.S. at 651. Here the Rule is unjustified because FDA has not shown that it will materially improve the public's understanding

of the risks of smoking. Likewise, under *Central Hudson*, the Rule "must directly advance" FDA's stated interest in improving public understanding of the risks of smoking "in a material way." *Cent. Hudson*, 477 U.S. at 566; *Edenfield*, 507 U.S. at 774. Yet again, FDA's shaky record evidence cannot meet this burden.

**A.** FDA's studies are deeply flawed. As the Office of Management and Budget concluded, FDA selectively recruited its study participants using convenience sampling whose outcomes are not nationally representative. Even worse, FDA's cost-benefit analysis failed even to quantify the Rule's supposed benefits. No surprise, then, that FDA hid crucial data from the public, which had no opportunity to comment on its peer-review report or FDA's response to it. And without explanation, FDA failed to seriously consider several alternatives.

**B.** Even if taken at face value, however, FDA's studies undercut the Rule's effectiveness. The main takeaway from FDA's data is that the public overwhelmingly understands that smoking is harmful. As FDA's own PATH survey shows, 99.5% of individuals believe that cigarette smoking endangers health, with 91% believing that it is "very or extremely harmful." What's more, FDA ignored its own study's findings that participants simply did not believe FDA's sensational new warnings. And FDA ignored, downplayed, and misrepresented its own peer-review feedback, which identified core defects in FDA's studies.

## ARGUMENT

### I. REVIEW IS NEEDED TO CLARIFY *ZAUDERER*'S SCOPE AND SWEEP.

Laws that compel speech are subject to strict scrutiny or, at a minimum, intermediate scrutiny. *See Riley v. Nat'l Fed. of Blind*, 487 U.S. 781, 797–98 (1988). But the Fifth Circuit applied the relaxed *Zauderer* standard when analyzing the constitutionality of the Rule's new graphic warnings scheme. When it applies, *Zauderer* requires only that a law not be "unduly burdensome." 471 U.S. at 651. But "a close examination of courts' treatment of *Zauderer* reveals a doctrine at odds with itself." Note, *Repackaging* Zauderer, 130 Harv. L. Rev. 972, 986 (2017).

Lower courts are sharply divided about when (and how) *Zauderer* governs. *Repackaging*, 130 Har. L. Rev. at 973. Some courts don't even think this Court meant to create a separate test for compelled speech in *Zauderer*. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 559 n.8 (6th Cir. 2012). The D.C. Circuit has suggested that *Zauderer* and *Central Hudson* both apply the same level of intermediate scrutiny to commercial-speech regulations. *Am. Meat Inst.*, 760 F.3d at 26–27. Members of this Court have questioned *Zauderer*'s reasoning and have called for it to be reexamined. *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 254 (2010) (Thomas, J., concurring); *see also Am. Beverage Ass'n v. San Francisco*, 916 F.3d 749, 762 (9th Cir. 2019) (Ikuta, J., concurring) (discussing how this Court has taken a more originalist approach to compelled commercial speech

since *Zauderer* was decided). This state of confusion cries out for this Court's review.

### A. This Court should clarify that *Zauderer* applies to only deceptive or misleading advertising.

FDA insists, and the Fifth Circuit agrees, that *Zauderer* allows it to commandeer private speech to further its interest in "fostering greater public understanding," 85 Fed. Reg. at 15,650. But *Zauderer* strictly limits its holding to curing speech that is "false or deceptive." *Zauderer*, 471 U.S. at 638. The government may mandate speech only "to dissipate the possibility of consumer confusion or deception." *Id.* at 651. Indeed, this Court upheld the state's advertising disclaimer only after finding that the possibility of deception was "self-evident" and that "substantial numbers of potential clients would be so misled" without Ohio's disclosure rule. *Id.* at 652.

Despite its commercial-speech context, *Zauderer* recognizes that "an advertiser's rights are adequately protected" only so long as "disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651. Outside that narrow context of supplementing misleading ads with disclosures to prevent consumer deception, *Zauderer* simply does not apply. The Court has never disclaimed this rule. True, this Court recently applied *Zauderer* when reviewing pre-enforcement facial relief from Florida- and Texas-mandated disclosures aimed at regulating the speech of social media platforms. *Moody v. NetChoice, LLC*, 144 S. Ct. 2383 (2024). But no party there disputed the adequacy of the States' interests, so this Court

never considered the question. *Id.* at 2439 n.57 (Barrett, J., concurring) ("NetChoice did not contest—and accordingly forfeited—whether *Zauderer* applies here."); *see also NetChoice, LLC v. Paxton*, 49 F.4th 439, 485 (5th Cir. 2022) (noting that "the Platforms do not dispute" the adequacy of Texas's interest in "enabl[ing] users to make an informed choice").

In *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136, 146 (1994), for example, the Court relied on *Zauderer* to invalidate a Florida regulation mandating a disclaimer on any ad that (truthfully) held out a professional as a Certified Financial Planner. Because *Zauderer* applies only to "an appropriately tailored check against deception or confusion," the Court held that Florida's compelled-speech mandate could not survive First Amendment scrutiny without evidence of "potentially real, not purely hypothetical" consumer deception. *Id.* If the "protections afforded commercial speech are to retain their force," *Ibanez* explained, courts "cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden." *Id.* (quoting *Zauderer*, 471 U.S. at 648–49). Had the Court shared the Fifth Circuit's elastic view of *Zauderer*, *Ibanez* would have *upheld* Florida's compelled-speech mandate despite no evidence of consumer deception.

Likewise, in *Milavetz,* the Court considered a First Amendment challenge to a federal law requiring attorneys and other debt-relief professionals to include disclosures in their advertisements. 559 U.S. at 232–33. Congress required those disclosures to prevent consumers from being misled about the services being offered. *Id.* Deciding that *Zauderer* supplied the proper First Amendment test, the Court

reiterated that the "essential feature[]" of the disclosures upheld in *Zauderer* was that they were aimed at "inherently misleading commercial advertisements." *Id.* at 250 (quoting *Zauderer*, 471 U.S. at 651). Because that prong was satisfied—a showing FDA has not made here—the Court upheld the disclosure under *Zauderer*.

As the decision below confirms, this Court's recent precedent in *NIFLA* has become a source of confusion about whether *Zauderer*'s deception prong remains. When setting forth the *Zauderer* test in *NIFLA*, this Court omitted any mention of a "correction of deception" requirement. Many lower court judges correctly believe that the correction of deception requirement is still part of *Zauderer*. For example, Judge Nguyen objected to the Ninth Circuit's "expansion" of the *Zauderer* test "to commercial speech that is not false, deceptive, or misleading." *Am. Beverage Ass'n*, 916 F.3d at 767 (Nguyen, J., concurring). Judge Nguyen correctly believes that mere informational interests fall outside of *Zauderer*'s scope. Rather, *Zauderer* applies only when there are doubts about a "commercial message's accuracy"—"not its completeness." *Id.* at 767–68. Like the Fifth Circuit, however, Judge Ikuta evidently disagrees with Judge Nguyen. In her view, *NIFLA* "broke new ground" for the *Zauderer* test so that it no longer contains a correction-of-deception element. *Id.* at 758–67.

By expanding the universe of acceptable justifications for government-compelled speech, the decision below undermines this Court's historical rationale for giving commercial advertising somewhat reduced, but still considerable, First Amendment

protection. The "greater 'objectivity' of commercial speech," the Court has said, "justifies affording the State more freedom to distinguish false advertisements from true ones." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499–500 (1996) (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Counc., Inc.*, 425 U.S. 748, 771 n.24 (1976)). Put differently, truthful commercial speech receives greater constitutional protection than false or misleading commercial speech.

But that rationale collapses as a justification for *compelling* speech when, as here, the mandatory disclosure is *not* aimed at preventing consumer deception. When, as here, the government seeks to compel speech for some other reason, "the greater objectivity of commercial speech" simply cannot justify treating commercial and noncommercial speakers differently. As the Court reiterated in *NIFLA*, Philip Zauderer's incomplete statements "would have been 'fully protected' if they were made in a context other than advertising." *NIFLA*, 585 U.S. at 771 (quoting *Zauderer*, 471 U.S. at 637 n.7).

This doctrinal confusion was "outcome determinative" here. Pet. App. 19a. FDA disclaims any interest in preventing consumers from being deceived by Plaintiffs' speech. And it is undisputed that Plaintiffs' relevant commercial speech is neither false nor misleading. After all, Plaintiffs are prohibited by law from making false or misleading claims through cigarette packaging or advertising. That alone suffices to disqualify *Zauderer* as the appropriate standard of First Amendment review. Yet the Fifth Circuit mistakenly relied on *NIFLA* to relieve FDA from any showing of consumer deception.

As Justice Souter noted more than twenty-five years ago, "however long the pedigree of [compelled-speech] mandates may be, and however broad the government's authority to impose them, *Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages." *Glickman v. Wileman Bros. & Elliott*, 521 U.S. 457, 490 (1997) (Souter, J., dissenting); *see Milavetz*, 559 U.S. at 257 (Thomas, J., concurring). The decision below jettisons this crucial limit on *Zauderer*'s scope; this Court should grant review and vindicate it.

### B. This Court should clarify that *Zauderer* applies to only uncontroversial disclosures

*Zauderer* applies only when a required disclosure is "uncontroversial." *NIFLA*, 585 U.S. at 768 (quoting *Zauderer*, 471 U.S. at 651). Again, the lower courts desperately need guidance on this requirement. "It is unclear how we should assess and what we should examine to determine whether a mandatory disclosure is controversial." *Nat'l Assoc. of Mfrs. v. SEC*, 800 F.3d 518, 528 (D.C. Cir. 2015) (*"NAM"*) (quoting *Am. Meat Inst.*, 760 F.3d at 34 (Kavanaugh, J., concurring in the judgment)); *see also Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 628 (D. Vt. 2015) (claiming that courts do not "affix[] the 'controversial' label lightly"), with *Nat'l Ass'n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1258 (E.D. Cal. 2020) (acknowledging that "what * * * 'uncontroversial' means has not been completely explained by the Supreme Court").

True, in some cases "determining whether a disclosure is 'uncontroversial' may be difficult." *Am. Meat Inst.*, 760 F.3d at 34 (Kavanaugh, J., concurring in the judgment). This is not one of those cases. Under any plausible interpretation, FDA's latest graphic warnings are misleading and thus highly controversial.

Far from being "purely factual and uncontroversial," as both *Zauderer* and *NIFLA* require, the FDA's graphic warnings themselves are misleading. While no image "has a single, objective meaning that could make it 'purely factual,'" many reasonable interpretations are medically inaccurate and thus misleading. Pet. App. 88a–92a. At best, the warnings seek to dramatically exaggerate the health harms of smoking by suggesting that very rare consequences of smoking are in fact common. At worst, the warnings are an "unabashed attempt[] to * * * browbeat consumers into quitting." *R.J. Reynolds*, 696 F.3d at 1216–17. Neither goal offers a valid governmental justification for compelling speech.

"Where the government orders disclosures as a way to advance its side in a controversial matter," then "the disclosure mandate" should "bear[] greater constitutional scrutiny." Ellen P. Goodman, *Visual Gut Punch: Persuasion, Emotion, and the Constitutional Meaning of Graphic Disclosure*, 99 Cornell L. Rev. 513, 552 (2014). Here the Fifth Circuit implied that it would consider the warnings' factual accuracy under the "uncontroversial" prong. Pet. App. 27a n.48 ("We expressly refrain from suggesting that a factual statement is necessarily an accurate one."). Yet as part of its analysis, the Fifth Circuit never

addressed whether the warnings themselves are misleading.

The D.C. Circuit, however, holds that "uncontroversial" must refer to whether "a message * * * is controversial for some reason other than a dispute about simple factual accuracy." *NAM*, 800 F.3d at 527–30 & n.28. This makes sense, of course, because *Zauderer* requires that a disclosure be both "purely factual" *and* "uncontroversial." Besides conflicting with this Court's and the D.C. Circuit's precedent, the Fifth Circuit's decision also conflicts with the Ninth Circuit, which holds that even "literally true" statements may "nonetheless [be] misleading, and, in that sense, untrue" under *Zauderer*. *CTIA—The Wireless Ass'n v. Berkeley*, 928 F.3d 832, 847 (9th Cir. 2019).

Under the First Amendment, FDA cannot require companies to spread its idiosyncratic viewpoint, particularly "where the messages themselves are biased against or are expressly contrary to the corporation's views." *Pac. Gas & Elec.*, 475 U.S. at 15 n.12 (plurality opinion). On the contrary, when it comes to a controversial issue of public debate, "the general rule is that the speaker and the audience, *not the government*, assess the value of the information." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578 (2011) (cleaned up) (emphasis added).

Of course, even if FDA's new graphic warnings were purely factual—they aren't—that would not "divorce the speech from its moral or ideological implications." *Stuart v. Camnitz*, 774 F.3d 238, 246 (4th Cir. 2014). "If the disclaimer creates confusion,

rather than eliminating it, the only possible constitutional justification for [the] speech regulation is defeated." *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080, 1080 (2002) (Thomas and Ginsburg, JJ., dissenting from denial of certiorari).

Above all, the government never has a legitimate reason to force companies to deliver misleading information about their products to their own consumers. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Entm't Merchants Ass'n*, 564 U.S. 786 (2011); *see also R.J. Reynolds*, 696 F.3d at 1216 (a compelled disclosure fails First Amendment scrutiny if it "could be misinterpreted by consumers"). Misleading disclosures are inherently controversial.

It would be ironic if FDA could transform *Zauderer*, a First Amendment test created to require advertisers to correct or clarify false or misleading speech, into a justification for foisting false or misleading speech onto the public. But that is precisely what the Fifth Circuit allowed FDA to do. The Court should end this confusion among the lower courts by reviewing the Fifth Circuit's decision to apply *Zauderer* here.

## II. REVIEW IS NEEDED BECAUSE FDA'S CLAIMED INFORMATIONAL INTEREST CANNOT JUSTIFY THE RULE.

Review is also warranted because FDA's own evidence confirms that its mere "informational interest" in educating the public is inadequate to justify the rule. In other words, the Rule fails to satisfy either *Zauderer*'s or *Central Hudson*'s

required evidentiary showing. First, even if *Zauderer* supplies the right test, FDA may not mandate a disclosure if it is "unjustified." *Zauderer*, 471 U.S. at 651. Here the Rule is unjustified because it will not materially improve the public's understanding of the risks of smoking, which is FDA's only stated goal.

Likewise, under *Central Hudson*, the Rule "must directly advance" FDA's stated interest in improving public understanding of the risks of smoking "in a material way." *Edenfield*, 507 U.S. at 774. FDA's record evidence simply cannot clear that hurdle. It is not enough that the Rule "provides only ineffective or remote support for the government's purposes," or that it has "little chance" of advancing the FDA's goal. *Id.* at 770–71.

Because no credible empirical evidence links the Rule's mandated warnings to FDA's only stated goal, FDA's informational is interest particularly inadequate here. *See* Pet. 40. This Court's review is thus needed to clarify that the Rule cannot survive any level of First Amendment scrutiny.

### A. FDA's studies are deeply flawed.

Facts are stubborn things, but studies are pliable. Bent on reaching its predetermined conclusions no matter what, FDA placed a heavy thumb on the scales for its various studies. These methodological flaws make FDA's underlying studies unreliable.

FDA relied on two quantitative studies to justify the Rule. The first study tested whether the Rule's textual warnings produced a statistically significant change in participants' beliefs about

smoking risks. *See* RTI Int'l, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* (Apr. 2018), https://perma.cc/9FZM-AZPV. The second study tested whether the Rule's graphic warnings had that same effect. *See* RTI Int'l, *Experimental Study of Cigarette Warnings: Study 2 Report* (May 2019), https://perma.cc/A9HX-4ELW. Both studies were deeply flawed.

According to the Office of Management and Budget, FDA selectively recruited the participants for both studies "using convenience sampling methods" with no "known probability of selection." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://perma.cc/8S84-SEKW. As a result, FDA's quantitative studies are "not intended to generate nationally representative outcomes." *Id.* As the saying goes: garbage in, garbage out.

FDA also relied on three qualitative studies. But FDA did not design those studies to test the accuracy of the Rule's warnings or the messages they convey to consumers. Rather, FDA focused merely on whether the warnings conveyed new information, grabbed participants' attention, or were believed or understood by participants. *See* RTI Int'l, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions* at 6–7 (July 2015), https://perma.cc/45WX-P86H; Siegel+Gale, *FDA Graphic Health Warning Image Concept Testing* at 11–13 (June 2016), https://perma.cc/NHW8-JR8H; RTI Int'l, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* at 3 (Apr. 2018), https://perma.cc/6RM9-LDGR. But none of those

variables fairly measures the Rule's effectiveness at *improving* the public's understanding of the *true risks* of smoking.

Nor is that all. "[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 507 (D.C. Cir. 2019) (cleaned up). Here, FDA's cost-benefit analysis failed even to quantify the Rule's benefits. *See* FDA, *Preliminary Regulatory Impact Analysis* at 2 (Aug. 2019), https://perma.cc/JWU5-5AH7 ("[T]here is a high level of uncertainty around quantitative economic benefits at this time, so we describe them qualitatively."); FDA, *Final Regulatory Impact Analysis* at 17 (Mar. 2020), https://perma.cc/ZN2S-BUC4 ("[T]here is a high level of uncertainty around quantified economic benefits at this time[,] and we therefore apply a break-even analysis.").

Even worse, FDA hid crucial data from the public during the rulemaking. "[S]tudies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). Despite repeated requests, FDA refused to release the final data sets from its two quantitative studies. *See, e.g.*, Letter from A. Klingler, Docket No. FDA-2019-N-3065-0001 (Sept. 9, 2019); Letter from Altria Client Services, Docket No. FDA-2019-N-3065-0001 (Sept. 5, 2019).

FDA also failed at first to release the underlying data, or even the study reports, for its

three qualitative studies. 84 Fed. Reg. at 42,767, 42,771. When—nearly a month after the comment period closed—FDA finally placed the qualitative study reports on the docket, it gave the public only fifteen days to comment. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966 (Nov. 12, 2019).

This Court need not guess why FDA hid its data from stakeholders during the rulemaking. In a revealing "Memo to File" included in the administrative record, FDA openly worried that disclosure would "allow third party attempts to analyze the data in different and potentially selective, biased or misleading ways other than what FDA pre-specified in the statistical analysis plan." E.D. Tex. Dkt. 59–3 at 11 (administrative record excerpts). But the core assumption behind rulemaking is that FDA's "pre-specified" methodological assumptions will be scrutinized, challenged, and even criticized by stakeholders. FDA has no right to obstruct that process.

FDA also failed to seriously consider alternative approaches. It ignored several less-restrictive alternatives suggested by stakeholders—public-education campaigns, differently placed and differently sized warnings, and revised textual warnings. *See* C.A. ROA 1266–67, 1586–87, 1593–1615, 1630–31, 1698; Comment Letter of RAI Services Co. at 31–32, Docket No. FDA-2019-N-3065 (Oct. 11, 2019). Even when it considered more cost-effective alternatives, FDA supplied no rational explanation for rejecting them. For example, when FDA considered mandating only nine warnings instead of

eleven, it concluded that nine warnings would be less costly. FDA, *Preliminary Regulatory Impact Analysis*, *supra*, at 51–54. Even so, FDA stuck with eleven warnings and never showed that the greater costs imposed by two more warnings are offset by greater benefits. The Fifth Circuit ignored these evidentiary flaws, but this Court should grant review and scrutinize them.

### B. Even if reliable, FDA's own evidence undercuts its position.

Even if FDA's evidence is accepted as reliable, it still undermines any notion that the Rule effectively enhances the public's understanding of smoking risks. Simply put, a compelled disclosure does not remedy an informational harm by telling people things they "already know." *NIFLA*, 585 U.S. at 777. And that is precisely what FDA's evidence shows the Rule does here.

FDA's own studies reveal that most of the Rule's warnings describe already well-known smoking risks. *See* C.A. ROA 1581, 1597–98, 1602–06; RTI Int'l, *Qualitative Study on Cigarettes and Smoking*, *supra*, at 20, 33, 35; Comment Letter of RAI Services Co., *supra*, Ex. C, Stmt. of J. Klick ¶¶ 5.43, 5.45, 5.48, 5.50, 5.58, 5.59, 5.60; Dannielle E. Kelley et al., *Effective Message Elements for Disclosures About Chemicals in Cigarette Smoke*, 20 Nicotine & Tobacco Rsch. 1047, 1051 (2018). Indeed, Americans overwhelmingly understand that smoking is harmful. 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." C.A. ROA 1597–98. Comment Letter of RAI Services Co., *supra*, Stmt. of J. Klick

¶ 5.20. FDA cannot "educate" the public by merely repeating information the public already knows. *NIFLA*, 585 U.S. at 777.

Again, FDA's first quantitative study tested whether the textual warnings led to a statistically significant change in participants' beliefs about smoking risks. But when compared to the TCA's textual warnings, seven of the nine FDA-created warnings—for "head-and-neck cancer," "bladder cancer," "erectile dysfunction," "amputation," "diabetes," "macular degeneration," and "cataracts"—did not increase the participants' belief that smoking has the negative health outcome tied to that warning. *See* C.A. ROA 1471–72; 1485–87; RTI Int'l, *Study 1 Report*, *supra*, at 40–42. On the contrary, participants found that the FDA-created statements were "less believable." *Id.* at 40. Rather than address these defects, FDA nixed questions on "believability" from its second quantitative study. As FDA's own peer-review report pointedly asked, "What happened to believability?" Versar, *Final Summary Report: External Letter Peer Review of FDA's Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act* at 34 (Nov. 19, 2019), https://perma.cc/JVM9-Q4B7. FDA has never answered that question. The Fifth Circuit showed no interest in answering it either.

Likewise, FDA's second quantitative study tested whether the Rule's graphic warnings led to any statistically significant change in views about smoking risks. Yet it showed that five of the Rule's eleven graphic warnings had no significant effect on participants' views, and that five more had only a small effect that quickly dissipated. C.A. ROA 1482–

92, 1485–87; RTI Int'l, *Study 2 Report*, *supra*, at 42–45.

What's more, FDA ignored its own study's findings that participants simply did not believe the FDA-created textual warnings. Indeed, the first qualitative study's "most prevalent" finding was that participants had a "widespread negative reaction" to warnings that smoking "causes" a disease, rather than "can cause," "may cause," or "increases the risk of" a disease. RTI Int'l, *Qualitative Study on Cigarettes and Smoking*, *supra*, at 7, 52; *see also id.* at 15, 17, 19, 26, 27, 31, 33, 34, 35, 36, 38, 45, 46. Despite these valid concerns, nearly all the Rule's FDA-created warnings say that smoking "causes" the specific negative health outcome. FDA simply ignored its own study participants' feedback.

FDA's study participants also "expressed a desire for more information about the relationship between the amount and duration of smoking . . . to the health effects of smoking." *Id.* at 7; *see also id.* at 38, 52. Although this was among the study's "key findings," FDA never included this clarifying information on the warnings. Participants also were dubious of warnings about certain smoking risks—like erectile dysfunction or diabetes—without more detail about how smoking "causes" them. *See id.* at 23–24, 45, 53. Yet FDA, despite its supposed goal of fostering "greater public understanding" of the risks of smoking, 85 Fed. Reg. at 15,650, ignored this finding in the final Rule.

FDA has also ignored, downplayed, and misrepresented its own peer-review feedback. FDA portrayed its peer-review report as overwhelmingly favorable. *See* 85 Fed. Reg. at 15,661. Yet peer

reviewers identified core weaknesses with FDA's studies because they were based on an "undetermined and never clearly defined" conceptual model. *Final Summary Report*, *supra*, at 14. FDA's sole reliance on "self-reported learning" and "new information," for example, lacked "convincing validity" as measures of the Rule's effectiveness. *Id.* at 14; *see also* 27–28, 33.

As peer reviewers explained, neither criterion—"self-reported learning" nor "new information"—can tell us whether the Rule's warnings would improve public understanding of smoking risks; they are non-standard measures of questionable validity. *Id.* at 14, 18, 28. No surprise, then, that FDA deprived the public of the chance to comment on the peer-review report or FDA's response to it. *See* RTI Int'l, *Study 1 Report*, *supra*, at 4–5; RTI Int'l, *Study 2 Report*, *supra*, at 1–2. This is typical for FDA, which displayed a curious tendency to downplay and even hide the underlying data for its own studies throughout the rulemaking.

FDA bears the burden of proving that its drastic compelled-speech remedy solves a real-world problem. Yet none of FDA's evidence supports FDA's flimsy justification for the Rule. This is just one more reason, among many, to grant the petition.

## CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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