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

REPLY TO BRIEF IN OPPOSITION

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INTRODUCTION

Although FDA spills much ink in an unpersuasive defense of the correctness of the Fifth Circuit's holding that *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), permits these massive warnings, it makes almost no effort to dispute the four straightforward circuit splits identified in the petition. First, whereas the D.C. Circuit held *Zauderer* inapplicable to materially identical graphic warnings because they were provocative and ideological, the Fifth Circuit declared those features "irrelevant" to *Zauderer*'s applicability—a point FDA simply ignores. Pet.App.29a-30a. Second, whereas the D.C. and Ninth Circuits held that *Zauderer* does not apply to misleading disclosures, the Fifth Circuit failed to address the misleading nature of the warnings *at all* and held that even false or inaccurate warnings can be "purely factual" under *Zauderer*—a point FDA also ignores. Third, FDA cannot reconcile the Fifth Circuit's decision to uphold these massive warnings with the Seventh and Ninth Circuits' holdings invalidating far smaller and less-obtrusive warnings as too burdensome. Finally, three circuits hold that a purely informational interest cannot justify compelled disclosures under *Zauderer*. And here, FDA *admits* that the Fifth Circuit relied solely on a purely informational interest in "better informing consumers" (as opposed to, for example, reducing smoking)—yet FDA inexplicably denies a conflict. BIO 31. These legal conflicts require the Court's resolution.

FDA likewise does not meaningfully contest the exceptional importance of the questions presented. It does not dispute that the graphic warnings in this

case are unprecedented in American history. And as Petitioners and amici emphasized, the decision below would allow the government to compel shocking warnings on all manner of products in order to bully consumers into not using them.

These factors alone justify granting the petition. The flaws in FDA's merits arguments only underscore the need for this Court's review.

ARGUMENT

I. THE FIFTH CIRCUIT'S HOLDING THAT *ZAUDERER* APPLIES WARRANTS REVIEW.

A. FDA Fails To Undermine The Clear Splits On Whether *Zauderer* Applies To Provocative And Misleading Disclosures.

The Fifth Circuit's holding that *Zauderer* applies here creates two square conflicts with the D.C. Circuit, which refused to apply *Zauderer* to materially identical warnings because they were provocative and misleading. Pet. 14-21. The decision below also conflicts with the Ninth Circuit on the misleading point. FDA barely responds to these splits.

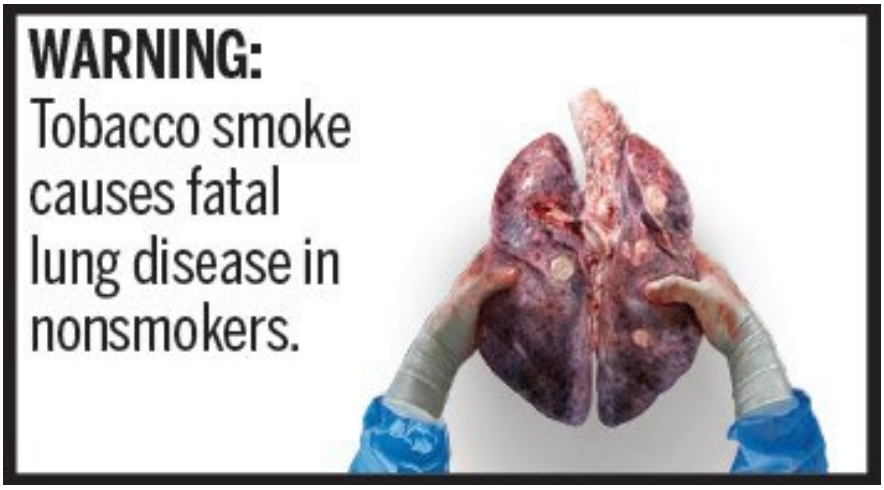
1. To start, FDA ignores that the D.C. and Fifth Circuits gave fundamentally different answers to the question whether provocative or ideological compelled disclosures are subject to *Zauderer*: The D.C. Circuit concluded, even though "none of the[] images [were] patently false," they nevertheless were not subject to *Zauderer* because they were "unabashed attempts to evoke emotion…and browbeat consumers into quitting." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216-17 (D.C. Cir. 2012), *overruled in part on other grounds by Am. Meat Inst. v. USDA*, 760 F.3d 18,

31 (D.C. Cir. 2014) (en banc). By contrast, the Fifth Circuit deemed it "irrelevant" whether the images "convey[] an ideological or provocative message," "reject[ing]" that as an "imaginative, novel limitation" on *Zauderer*. Pet.App.29a-30a. FDA wholly ignores that portion of the decision below.

Instead, FDA claims that the D.C. Circuit focused on specific aspects of the prior warnings. BIO 29. But though it enumerated "example[s]," the D.C. Circuit invalidated *all* of the prior warnings. 696 F.3d at 1216. And while the prior warnings included a hotline, that was decidedly *not* why the D.C. Circuit invalidated them: The dissent would have struck only the hotline, but the majority disagreed and invalidated the warnings in their entirety. *Id.* Indeed, the majority addressed the hotline only fleetingly, *id.*, focusing instead on the *images*, which as Petitioners' side-by-side comparisons show, are materially identical to the current images:

Invalidated by D.C. Circuit

Approved by Fifth Circuit

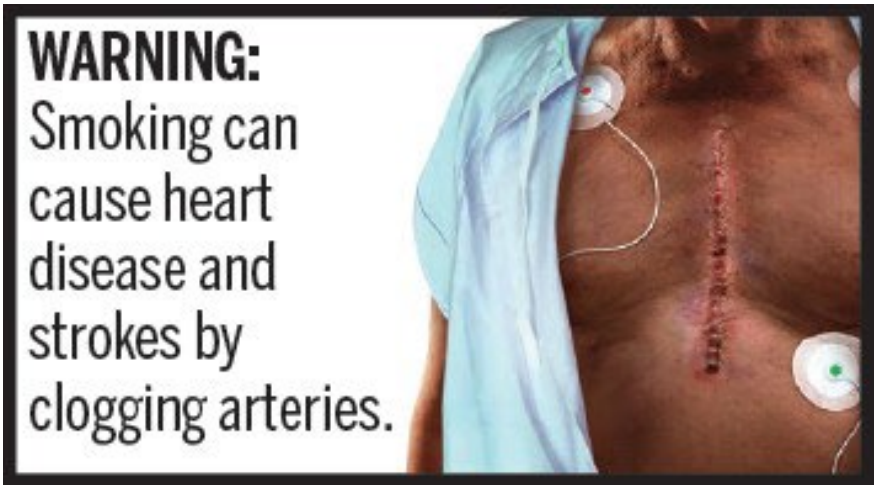


Invalidated by D.C. Circuit

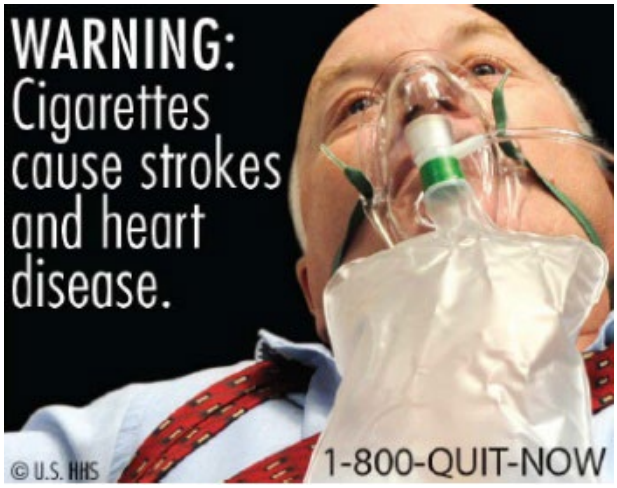
Approved by Fifth Circuit

Invalidated by D.C. Circuit

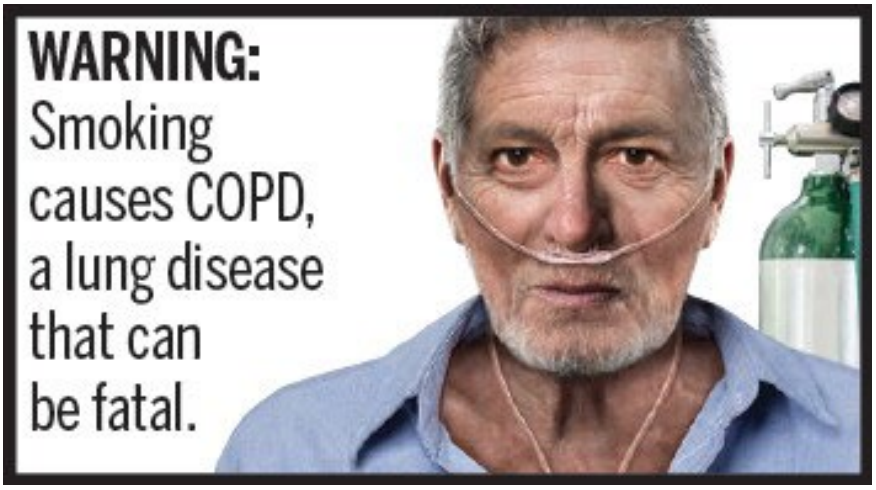
Approved by Fifth Circuit



Invalidated by D.C. Circuit



Approved by Fifth Circuit



Next, FDA attempts to elide a conflict by repeating the Fifth Circuit's alternative ipse dixit that the warnings "are not 'primarily intended to evoke an emotional response.'" BIO 29. But the Fifth Circuit

identified no way in which the old warnings were intended to evoke emotion that is not also present in the current warnings, and the record confirms that consumers perceived the current warnings as intended to shock and scare. Pet. 21-23.

2. As to the split on whether *Zauderer* applies to misleading warnings, the closest FDA comes to a response is a single sentence in a footnote suggesting that the Fifth Circuit determined the "textual warnings are not misleading." BIO 31 n.4. But the cited portion of the opinion demonstrates the opposite and confirms the split: The Fifth Circuit held that the textual warnings are "factual" even if they "exaggerate[]" smoking risks and thus are misleading. Pet.App.28a. The opinion also "expressly" states that compelled speech need not be "true" or "accurate" to be "purely factual" under *Zauderer*. Pet.App.27a & n.48.

That plainly conflicts with the Ninth Circuit's holding that "[i]nformation that is purely factual is necessarily 'factually accurate'" for *Zauderer* purposes. *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1276 (9th Cir. 2023); *see also CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 847 (9th Cir. 2019). And it likewise conflicts with the D.C. Circuit, which, after all, invalidated materially identically warnings precisely because they "could be misinterpreted by consumers." *RJR*, 696 F.3d at 1216; *supra* 4-7.

3. FDA's paltry discussion of splits focuses on *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012). Petitioners never claimed that case created a split. Plus, the decision is inapposite: It involved a facial challenge to the

statute, not an as-applied challenge to the specific warnings mandated by the rule. Pet. 38-39. But even if it were relevant, it would only deepen the split.

B. The Fifth Circuit's Holding That *Zauderer* Applies To Provocative And Misleading Warnings Is Wrong.

1. The decision below is grievously wrong because it applies *Zauderer* to warnings that convey a subjective, ideological message that people should not smoke. Pet. 21-23. FDA's response ignores the *graphics* entirely (following the lead of the Fifth Circuit, which took a similar approach, Pet.App.28a). Indeed, FDA fails to identify any other case that applies *Zauderer* to a mandatory warning that includes a government-selected image.[1]

Instead, FDA asks how the textual statements require Petitioners to "say anything 'ideological,'" BIO 18, disregarding that the rule requires Petitioners to say much more than the text. It requires Petitioners to devote the top 50% of both sides of packaging and top 20% of advertising to grotesque and frightening images that are materially identical to those the D.C. Circuit invalidated. *Supra* 4-7. Simply looking at these warnings makes clear they are intended to—and will—shock and frighten. Unsurprisingly, that is what 85% of actual survey respondents (not hypothetical hecklers, BIO 19) thought. C.A.ROA.7638-39, 7715.

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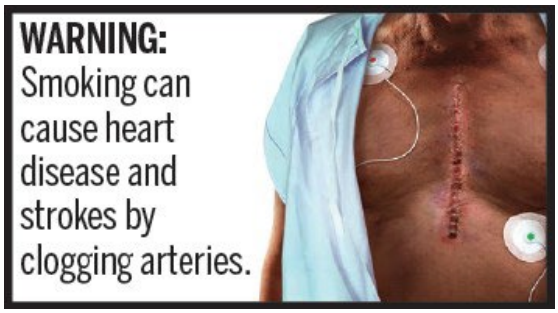
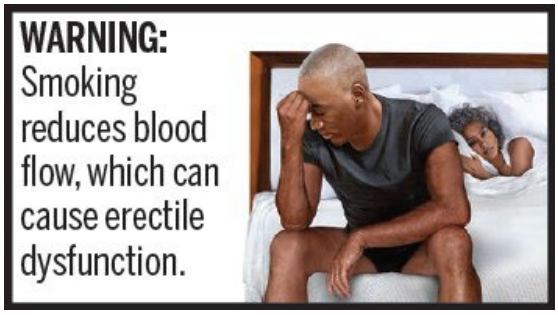
[1] *Zauderer* did not endorse the use of illustrations in government-mandated disclosures. BIO 15. Instead, its discussion of images addressed a government *prohibition* of illustrations in advertisements (and simply observed that images are not *always* misleading). 471 U.S. at 647-49.


WARNING:
Smoking causes head and neck cancer.

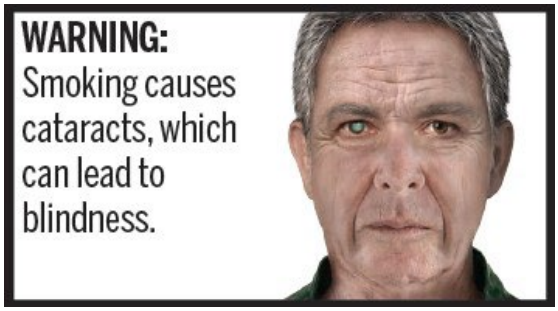

WARNING:
Smoking can cause heart disease and strokes by clogging arteries.

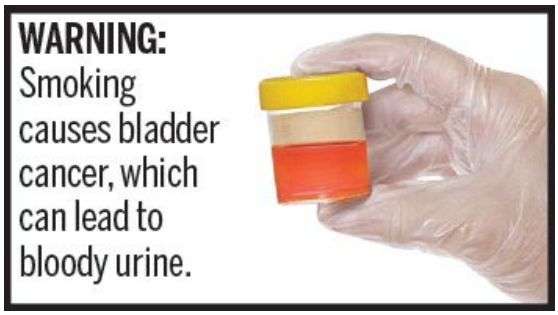

WARNING:
Smoking reduces blood flow, which can cause erectile dysfunction.

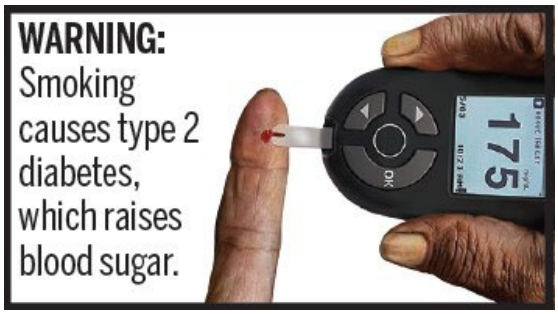

WARNING: Smoking reduces blood flow to the limbs, which can require amputation.

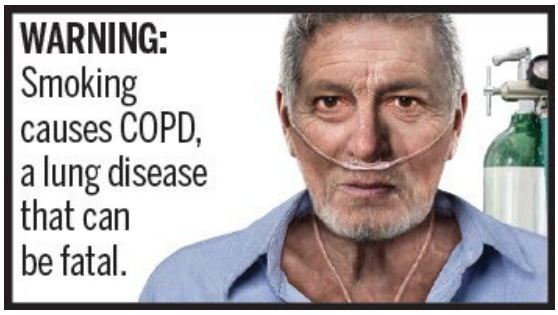

WARNING:
Tobacco smoke can harm your children.


4.00 lbs.
WARNING: Smoking during pregnancy stunts fetal growth.


WARNING:
Smoking causes cataracts, which can lead to blindness.


WARNING:
Smoking causes bladder cancer, which can lead to bloody urine.



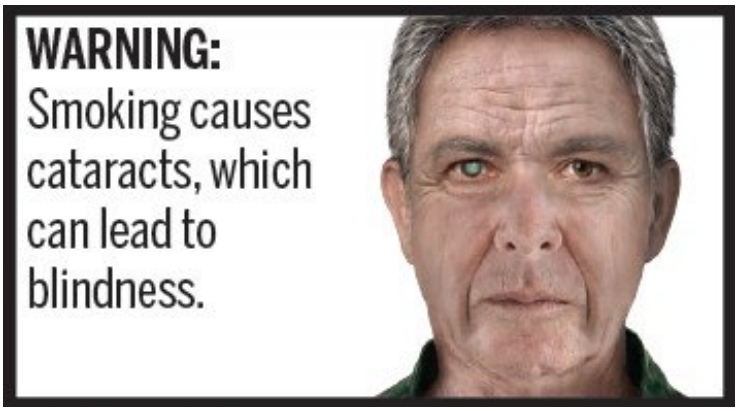


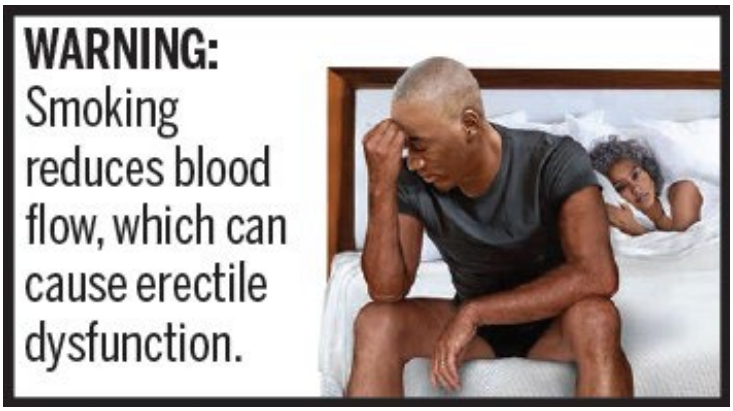
Indeed, if the text could justify these graphics, then nothing would prohibit the government from requiring fast-food cashiers to shout purely accurate calorie counts when serving customers. Pet. 22-23. FDA offers no response to this basic point.

2. The decision below is also wrong because it applies *Zauderer* to compelled disclosures that are misleading. FDA does not dispute that *Zauderer* is inapplicable to misleading disclosures. And it

concedes that, to be non-misleading, the warnings must convey the health effects of smoking as they are "common[ly]" or "typically experienced." BIO 7, 15-16. Yet FDA does not refute Petitioners' showing that many of the warnings depict *uncommon* and *atypical* presentations of such effects. Pet. 24-27. Take the "Neck Tumor" warning. FDA says a tumor is often the first symptom of head-and-neck cancer (BIO 16-17), but makes no attempt to show that it is typically the size of a baseball, as depicted in the warning. And uncontroverted record testimony indicates the opposite. Pet. 24-25.

The same goes for the cataracts and erectile-dysfunction images:





FDA does not even attempt to carry *its* (undisputed) burden of proving that cataracts typically cause blindness, nor does it dispute the record evidence that blindness occurs in only 0.48% of U.S. cataracts patients. C.A.ROA.7860. As to the erectile-dysfunction image, FDA baldly asserts that viewers will not be confused about the warning. BIO 17. But Petitioners identified record evidence to the contrary, Pet. 27, and FDA has no response.

FDA's remaining arguments lack merit.

First, whether smoking increases the odds of each condition is immaterial. BIO 16. As FDA concedes,

the issue is whether the warnings misrepresent how those conditions *commonly* manifest. They do. Pet. 23-28.

Second, FDA asserts that Petitioners' arguments "would be better considered under the rubric of the APA rather than constitutional law." BIO 17, 26. FDA offers zero citations and zero explanation for its view. Plus, consider the implications of FDA's this-is-just-an-APA-issue theory: If Congress or a State—neither of which is subject to the APA—were to compel speech, a speaker would have no legal recourse.

Third, FDA suggests that any confusion caused by the images is fixed by the accompanying text. BIO 17. But despite its (conceded) burden, FDA cites no evidence for its assertion. And record evidence shows that survey respondents were confused even when the text and images were combined. *See* C.A.ROA.2236 ("still confusing"). FDA's position that the text renders the warnings non-misleading is also inconsistent with its assertion that some individuals cannot read at a comprehension level necessary to understand the text (in which case the text cannot remedy the misleading graphics). BIO 3-4, 23.

II. THE FIFTH CIRCUIT'S HOLDING THAT *ZAUDERER* IS SATISFIED WARRANTS REVIEW.

A. FDA Fails To Undermine The Clear Splits On Whether Massive And Gratuitous Warnings Satisfy *Zauderer*.

The Fifth Circuit's holding that the warnings satisfy *Zauderer* creates two splits: (1) with the Ninth and Seventh Circuits' holdings that even smaller and less-obtrusive warnings were too burdensome and

(2) with the D.C., Second, and Ninth Circuits' holdings that a purely informational interest cannot justify compelled disclosures. Pet. 29-33. FDA offers no convincing response to the first and all but concedes the second.

1. FDA does not dispute that the Ninth and Seventh Circuits have held that smaller and less-obtrusive *text-only* warnings (20% of certain advertisements and less than 10% of packaging, respectively) were too burdensome. *Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749, 757 (9th Cir. 2019) (en banc); *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 & n.13 (7th Cir. 2006).

FDA's only response to the Ninth Circuit case is to claim that the record there "show[ed] that a smaller warning—half the size—would accomplish [the city's] stated goals." BIO 30. But FDA ignores the even *clearer* evidence here of less-restrictive alternatives that would be at least as effective. Pet. 30. And FDA's assertion that the *existing warnings* are ineffective does not remotely carry its burden to show that smaller or less-obtrusive versions of the *2020 warnings* would be insufficient here. That is what the en banc Ninth Circuit required, so the Fifth Circuit's contrary holding creates an undeniable split.

Nor can FDA dispute that the Seventh Circuit likewise required the government to "explain why a smaller sticker would not suffice"—and used commercial speech (menus) to illustrate its point. 469 F.3d at 652 & n.13. FDA concededly failed to do so here, and the Fifth Circuit gave it a free pass.

2. FDA does not dispute that three circuits have held that a purely informational interest is

insufficient. BIO 31 (citing *RJR*, 696 F.3d at 1221; *CTIA*, 928 F.3d at 844; *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996)). And FDA concedes its interest is purely informational. The rule is based not on evidence that it will reduce smoking (no such evidence exists), but solely on FDA's interest in "better informing consumers." BIO 22. Instead, it disputes any split because the Fifth Circuit pronounced FDA's concededly informational interest "legitimate" and "substantial." BIO 31. But that only *confirms* the split.

B. The Fifth Circuit's Holding That Massive And Gratuitous Warnings Satisfy *Zauderer* Is Wrong.

FDA does not dispute that the warnings are unprecedented. It simply suggests its tailoring need not be "perfect." BIO 20. But *FDA* "has the burden" to prove that its compelled disclosures are not "unduly burdensome" and "extend no broader than reasonably necessary." *Nat'l Inst. of Family & Life Advocates v. Becerra*, 585 U.S. 755, 776 (2018) ("*NIFLA*"). FDA failed this test by ignoring obvious, less-restrictive, reasonable alternatives.

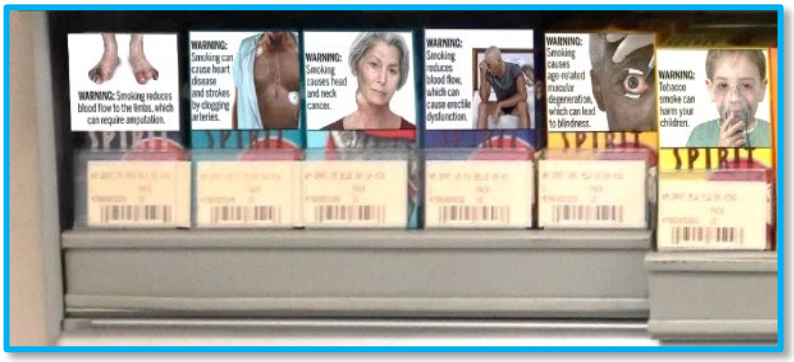
1. FDA does not explain how the warnings differ from shouting "DON'T SMOKE!!!" *See* Pet. 33-34. Nor does it dispute Petitioners' *legal* point that, due to their "few avenues of communication" with consumers, the warnings "place a greater…burden on [their] speech." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564-65 (2001); Pet. 36.

Instead, FDA attempts to evade the burdens imposed by the warnings (Pet. 34-36) by deeming them "modest." BIO 22. Which begs the question: If

these unprecedented warnings are not unduly burdensome, what *would* be?

Current Retail Display

Modified Retail Display



FDA then attempts to defend the Fifth Circuit's holding by "evaluat[ing]" the burden "against the benefits of better informing consumers about the health risks of smoking." BIO 22. FDA's repeated invocation of smoking's risks is a red herring because *FDA does not claim that the warnings will reduce smoking*. And, crucially, FDA fails to explain how providing additional information about purportedly lesser-known risks can be material when the record

shows that the public "already know[s]" smoking is dangerous. *NIFLA*, 585 U.S. at 776-77. Indeed, FDA relies on decades-old data (BIO 23) but ignores its *own recent data* showing that a higher percentage of adults believe smoking causes lung disease (94%) and heart disease (88%) than know the Earth revolves around the sun (74%). *See* Pet. 40; C.A.ROA.1581, 1604-06. FDA's data likewise show that the warnings failed to change beliefs about smoking. Pet. 40.

2. FDA does not contest that analyzing the undue-burden prong requires considering reasonably available alternatives. *NIFLA*, 585 U.S. at 777-78; Pet. 36-37. Instead, FDA seeks refuge in *Discount Tobacco*. BIO 25. But for the reasons discussed (*supra* 8-9; Pet. 38-39), that case does not give FDA license to run roughshod over the myriad less-burdensome alternatives.

FDA also suggests that it *did* take "into account studies comparing the relative effectiveness of various options." BIO 25. But as FDA admits, it never *tested* (or seriously considered) those options; it simply relied on generic conclusions that larger warnings and images are better. 85 Fed. Reg. 15,638, 15,650-51 (Mar. 18, 2020). Indeed, FDA *disclaimed* any need to consider alternatives not contemplated by the TCA—including smaller and differently placed warnings. *Id.*

Lastly, FDA "identifie[s] no evidence" that a public-advertising campaign would be insufficient, which should doom its position, as in *NIFLA*. 585 U.S. at 775. FDA concededly has never conducted a public-education campaign about any of these risks.

III. FDA Concedes That This Case Presents Exceptionally Important Issues.

FDA does not disavow that the decision below would allow the government to compel shocking warnings on all types of products to bully consumers into not using them—everything from fast food and candy to gas stoves and guns. *See* Pet. 41-43; Altria Br. 3-4, 18-19; Advertiser Br. 3-4, 18-20. In fact, the government is *already* citing the decision below to support an SEC regulation compelling disclosure of climate risks. SEC Br. 101-04, *Iowa v. SEC*, No. 24-1522 (8th Cir. Aug 5, 2024), 2024 WL 3706890.

FDA's only response is a citation-free assertion that products like fast food, candy, and wine "do not…pose any remotely similar danger." BIO 24. So what? FDA does not assert—let alone persuasively explain—why the level of danger would make a difference to the First Amendment analysis, particularly since FDA's only asserted interest is a purely informational one. Besides, FDA is wrong: Studies show (for example) that unhealthy eating causes significantly more deaths globally than cigarettes. *See, e.g.*, Allison Aubrey, *Bad Diets Are Responsible For More Deaths Than Smoking, Global Study Finds*, NPR (Apr. 3, 2019), https://tinyurl.com/ybsvswrw.

IV. FDA's Vehicle Objection Is Meritless.

FDA claims the Court should deny review because Petitioners' APA claims remain pending below. BIO 12-13. But "interlocutory" status is "no impediment to certiorari" where, as here, the petition presents clear circuit splits and an "important and clear-cut issue of law." Stephen M. Shapiro et al., *Supreme Court Practice* §§ 4.4(h), 4.18 (11th ed. 2019). Indeed, FDA

has itself secured interlocutory review in a case this Term. *FDA v. R.J. Reynolds Vapor Co.*, No. 23-1187, 2024 WL 4394118 (U.S. Oct. 4, 2024). And this Court routinely grants interlocutory review to resolve important First Amendment questions. *See, e.g.*, *Free Speech Coal. v. Paxton*, 144 S. Ct. 2714 (2024); *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2396 (2024); *NIFLA*, 585 U.S. at 765.

Moreover, FDA has committed to delay the compliance clock only while this case is pending before this Court. *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-cv-00176 (E.D. Tex. June 21, 2024), ECF No. 115 at 3. Thus, if this Court denies review and Petitioners do not obtain further judicial relief, they will be forced to implement unconstitutional warnings (at significant cost) while the case winds its way back to the Court. That is untenable: "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion).

V. FDA FAILS TO REFUTE THE APPROPRIATENESS OF A GVR.

At a minimum, the Court should grant, vacate, and remand in light of *NetChoice*. Pet. 43-44. As FDA acknowledges (BIO 32), the Fifth Circuit relied heavily on its then-binding but now-vacated *NetChoice* decision. FDA speculates that the vacatur would have no impact on the Fifth Circuit's holding, but the Fifth Circuit should make that determination itself.

CONCLUSION

This Court should grant the petition.

NOVEMBER 5, 2024

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