No. 24-189

In the Supreme Court of the United States

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

v.

FOOD AND DRUG ADMINISTRATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

For decades, cigarette packages and advertisements have been required to bear government-mandated warnings about the health risks of smoking. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, to require updated warnings, accompanied by illustrations, that must occupy at least 50% of the front and back panels of cigarette packages and at least 20% of cigarette advertisements. Congress directed the Secretary of Health and Human Services, acting through the Food and Drug Administration (FDA), to develop the illustrations that would accompany the new warnings and authorized the Secretary to modify the text of the warnings. After extensive litigation over a prior rule, FDA promulgated a second rule in 2020 setting forth the required warnings and accompanying illustrations. The question presented is as follows:

Whether the court of appeals correctly determined that the new warnings on cigarette packages and advertisements required by FDA do not violate the First Amendment.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-47a) is reported at 96 F.4th 863. The opinion of the district court (Pet. App. 51a-109a) is not published in the Federal Supplement but is available at 2022 WL 17489170.

JURISDICTION

The judgment of the court of appeals was entered on March 21, 2024. A petition for rehearing was denied on May 21, 2024 (Pet. App. 110a-111a). The petition for a writ of certiorari was filed on August 19, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This case concerns the warnings that cigarette manufacturers are required to include on cigarette packaging and advertising to inform consumers of the health

risks of smoking. "Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year among cigarette smokers and those exposed to secondhand smoke." 85 Fed. Reg. 15,638, 15,652 (Mar. 18, 2020). "Although cigarette smoking prevalence has generally declined over the past several decades, approximately 34.2 million U.S. adults smoke cigarettes," along with more than one million middle- and high-school students. *Ibid.*

Given those dangers, Congress has long required that "all cigarettes manufactured, imported, or packaged for sale or distribution within the United States" display warnings to consumers. Pet. App. 3a; see *id.* at 3a-4a (detailing the health warnings first required in the 1960s). In 1984, Congress updated the required warnings to make "Americans more aware" of the relevant health risks so that individuals could make "informed decisions." Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 2, 98 Stat. 2200. The 1984 law required that cigarette packaging and advertising include one of four warnings from the Surgeon General, such as "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy." 15 U.S.C. 1333(a)(1) and (2) (Supp. II 1984). Manufacturers place the warnings required by the 1984 law "on the side panel of each cigarette package, occupying approximately 5% of [the] surface area." Pet. App. 4a n.9.

In 2009, Congress determined that prior efforts had "failed adequately to curb tobacco use by adolescents." Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), Pub. L. No. 111-31, Div. A, § 2(6), 123 Stat. 1777 (21 U.S.C. 387 note). Congress found that,

despite age restrictions on the sale of tobacco products, the "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons," and those efforts have "resulted in increased use of such products by youth." § 2(15), 123 Stat. 1777-1778. Congress further found that the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." § 2(31), 123 Stat. 1779. And Congress estimated that "[r]educing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease," and "result[ing] in approximately $75,000,000,000 in savings attributable to reduced health care costs." § 2(14), 123 Stat. 1777.

Congress was especially concerned that the 1984 Surgeon General's warnings had proven to be inadequate, including because of the billions of dollars spent by cigarette companies to market their products as "healthful to minors." Tobacco Control Act § 2(17), 123 Stat. 1778; see H.R. Rep. No. 58, 111th Cong., 1st Sess., Pt. 1, at 4 (2009) (House Report). Experience with the 1984 warnings had shown that the warnings failed to "effectively convey the risks of smoking," including to minors, and that the small warnings were "easily overlooked." *Discount Tobacco City & Lottery, Inc.* v. *United States*, 674 F.3d 509, 563 (6th Cir. 2012) (opinion of Stranch, J.), cert. denied, 569 U.S. 946 (2013). Even if consumers did notice them, some of the 1984 warnings presupposed a "'college reading level'" of the English language to be properly understood—a level of reading comprehension

that "schoolchild[ren]" obviously lacked. *Ibid.* (citation omitted).

Congress addressed those shortcomings in two ways in the Tobacco Control Act. First, Congress revised the text of the warnings for the first time since 1984. The Act requires that the packaging and advertising for all cigarettes manufactured, packaged, or imported for sale in the United States include one of "nine new warnings that would rotate regularly." Pet. App. 5a; see 15 U.S.C. 1333(a)(1) and (b)(1). Congress specified that the warnings "shall comprise the top 50 percent of the front and rear panels" of each package or, for advertising, "at least 20 percent of the area of the advertisement." 15 U.S.C. 1333(a)(2) and (b)(2).

Second, Congress directed the Secretary of Health and Human Services to "issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the new written warnings. 15 U.S.C. 1333(d)[1].[1] Congress also authorized the Secretary to "adjust the type size, text and format" of the written warnings "as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." *Ibid.*; cf. 15 U.S.C. 1333(d)[2] (additional authority to modify the warnings).

Congress directed the Secretary to engage in the requisite rulemaking within 24 months of the enactment of the Tobacco Control Act. 15 U.S.C. 1333(d)[1]. Congress also provided that none of the new warnings would take effect until "15 months after the issuance" of the

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[1] As amended, Section 1333 contains two provisions denominated as Subsection (d). See Tobacco Control Act §§ 201(a), 202(b), 123 Stat. 1842-1846.

Secretary's regulations. Tobacco Control Act § 201(b), 123 Stat. 1845.

2. The Secretary, acting through the Food and Drug Administration (FDA), published a final rule in 2011 to specify new warnings under the Tobacco Control Act. 76 Fed. Reg. 36,628, 36,629 (June 22, 2011).

While that rulemaking process was ongoing, a group of cigarette companies—including petitioner R.J. Reynolds Tobacco Company (RJR)—challenged the Tobacco Control Act on various grounds in the Western District of Kentucky. *Discount Tobacco*, 674 F.3d at 521. As relevant here, the plaintiffs contended that being required to display the Act's new warnings would constitute "compelled speech" in violation of the First Amendment. *Id.* at 554 (opinion of Stranch, J.). The Sixth Circuit rejected that challenge. Applying this Court's decision in *Zauderer* v. *Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), the Sixth Circuit held that the Act's new written warnings are permissible "disclosure requirements" for commercial speakers. *Discount Tobacco*, 674 F.3d at 555. The Sixth Circuit also held that at least some illustrations could be upheld on the same basis, and therefore that the statutory provision requiring such illustrations was not facially unconstitutional. See *id.* at 559-560, 562.

After FDA published the 2011 rule, a divided panel of the D.C. Circuit concluded in separate litigation—brought again by RJR, with other cigarette companies, see Pet. App. 10a—that the specific images that FDA had required in the 2011 rule could not be sustained under *Zauderer* and otherwise violated the First Amendment. See *R.J. Reynolds Tobacco Co.* v. *FDA*, 696 F.3d 1205, 1213-1221 (D.C. Cir. 2012), overruled in part by *American Meat Inst.* v. *United States Dep't of Agric.*,

760 F.3d 18 (D.C. Cir. 2014) (en banc). As relevant here, the majority reasoned that *Zauderer* applies only to the compelled disclosure of "purely factual and uncontroversial" information, *id.* at 1216 (citation omitted), and it concluded that the images in the 2011 rulemaking did not qualify. In the majority's view, some of those images could have been misinterpreted to suggest that smoking poses greater risks than currently known, and others were designed to "evoke an emotional response" rather than to convey "warning information." *Ibid.* Judge Rogers dissented; she would have upheld the 2011 rule. *Id.* at 1223-1238.

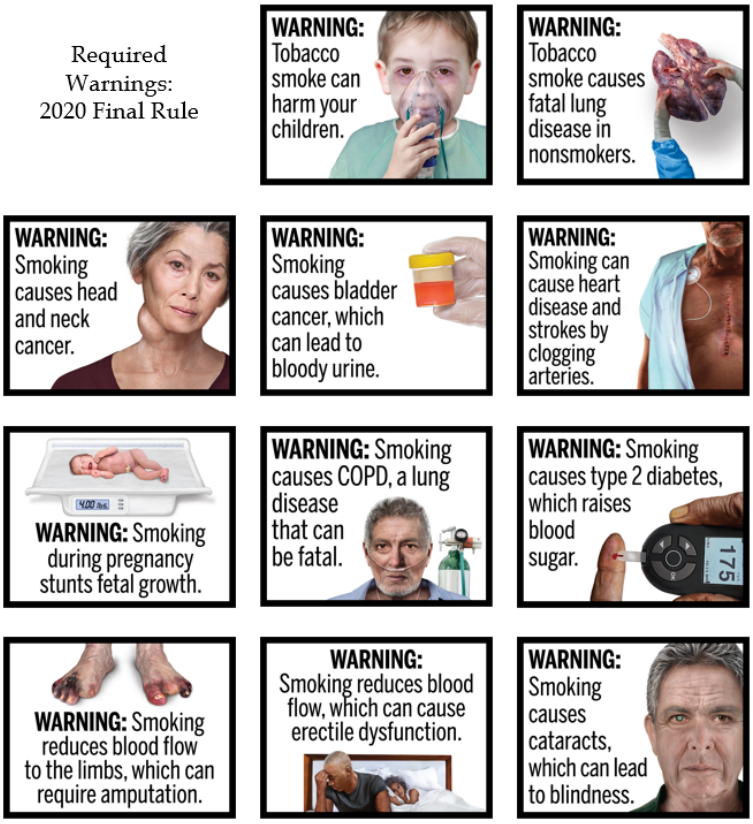
The D.C. Circuit vacated the 2011 rule's new warning requirements (which the district court had enjoined) and remanded to the agency. *R.J. Reynolds*, 696 F.3d at 1221-1222. As a result, the warnings in the 2011 rule never took effect, and the 1984 Surgeon General's warnings continue to be used. See Pet. App. 4a n.9.

3. After the D.C. Circuit's decision, FDA went back to the drawing board for eight years. The agency reviewed the existing scientific literature "on current consumer knowledge and misperceptions about the health risks of smoking," 84 Fed. Reg. 42,754, 42,766 (Aug. 16, 2019); convened a series of "qualitative focus groups with adolescent smokers, adolescents at risk for starting smoking, and adult smokers," *id.* at 42,767; and "conducted a large quantitative consumer research study to assess" whether revised warning statements would "promote greater public understanding of the risks associated with cigarette smoking," *ibid.* After several rounds of study, FDA selected five of the written warnings in the Act, along with ten additional warnings, to pair with graphics for further testing. *Id.* at 42,769.

With respect to the graphics, FDA determined that a "photorealistic illustration" would best allow for depicting the "specific features of the health conditions as described by the textual warning statements," devoid of any "non-essential elements." 84 Fed. Reg. at 42,770; cf. 15 U.S.C. 1333(d)[1] (requiring that the graphics "depict[] the negative health consequences of smoking"). The agency therefore "undertook a rigorous multistep process to develop, test, and refine" photorealistic images that are "factually accurate" and that "depict common visual presentations of the health conditions" described in the warnings, or that show how symptoms or diseases in the warnings are "typically experienced," in a "realistic and objective format." 84 Fed. Reg. at 42,770. The agency retained a certified medical illustrator to make the photorealistic images and then refined them over the course of 20 focus groups and a further large quantitative consumer research study. See *id.* at 42,770-42,772.

That process led FDA ultimately to select 11 text-and-image pairings in a final rule published in 2020. 85 Fed. Reg. at 15,640. The agency maintained the exact wording of two of the warnings set forth in the Tobacco Control Act and modified or replaced the text of the other warnings (as permitted by the Act). See Pet. App. 13a & n.22. The final text-and-image pairings are set forth below:

Required Warnings: 2020 Final Rule



In the preamble to the final rule, FDA explained that "[t]here is no controversy about whether cigarette smoking causes the negative health consequences that form the content of the warnings." 85 Fed. Reg. at 15,646. The text of each warning describes an undisputed health risk of smoking, and the accompanying images show common presentations of the risks described in the text. See *ibid.*

4. Petitioners—RJR and a group of other cigarette manufacturers and retailers—brought this suit in the United States District Court for the Eastern District of Texas to challenge FDA's 2020 rule. Pet. App. 70a. As

relevant here, petitioners contend that the rule's required warnings violate the First Amendment and the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.* The district court entered summary judgment for petitioners on First Amendment grounds and vacated the rule. Pet. App. 51a-109a. The government appealed, and the Fifth Circuit unanimously reversed and remanded, rejecting petitioners' First Amendment theory and directing the district court to consider petitioners' APA claims in the first instance. *Id.* at 1a-47a.

The court of appeals determined that the First Amendment question turns on whether the new warnings fall within the ambit of "*Zauderer*'s deferential scrutiny." Pet. App. 19a. After reviewing this Court's precedent and its own case law, see *id.* at 19a-24a, the court of appeals stated that *Zauderer* permits the government to compel commercial speech—such as product warnings or advertising disclosures—as long as the compelled speech is "purely factual and * * * uncontroversial," "justified by a legitimate state interest," and "not unduly burdensome," *id.* at 24a. The court found each of those requirements satisfied here. *Ibid.*

With respect to the factual and uncontroversial nature of the warnings, the court of appeals observed that a 2014 report by the Surgeon General, discussed in the preamble to the rule, had "found that cigarette smoking causes the negative health consequences identified in the textual warnings." Pet. App. 28a. Because petitioners did not contest the accuracy of the report, the court deemed the "factual content of the textual warnings * * * undisputed." *Ibid.* (citation omitted); see *id.* at 33a (observing that petitioners "never suggest[ed] any good-faith debate" about the truthfulness of the textual warnings). The court therefore viewed the "crux of the

dispute" as centering on whether adding the images to the textual warnings altered the "constitutional analysis," and the court concluded that it did not. *Id.* at 28a. In particular, the court rejected petitioners' contention that the images render the rule unlawful because they allegedly convey a "provocative" message or might "drive[] a reaction" in the viewer. *Id.* at 29a-30a. The court explained that a given person's "emotional response" to a factual statement does not render the statement any less factual. *Id.* at 30a; see *id.* at 32a.

The court of appeals also explained that the images required by the 2020 rule avoided the problems that the D.C. Circuit had perceived with respect to the different images required by the 2011 rule. Pet. App. 30a. The D.C. Circuit had described those images as "primarily intended to evoke an emotional response." *Ibid.* (quoting *R.J. Reynolds*, 696 F.3d at 1216). Here, the Fifth Circuit found that any emotional response to the new images would be "at most * * * incidental" to a viewer's "retention of information about the health risks" depicted in the images. *Ibid.* The court emphasized that the photorealistic images in the 2020 rule provide "a straightforward, science-based, objectively truthful depiction of the accompanying text." *Id.* at 29a. Indeed, the court stated that the images "are no different from those a medical student might see in a textbook," and several are "exactly the type" that the Sixth Circuit had suggested would pass muster in its earlier decision rejecting a facial challenge to the Tobacco Control Act. *Ibid.* (discussing *Discount Tobacco*, *supra*).

Applying *Zauderer*, the court of appeals further determined that the warnings are reasonably related to the government's interest in "raising consumer awareness" of the health risks of smoking. Pet. App. 39a. The

court noted that FDA had before it "significant evidence that consumers do not notice, much less internalize, the text-only warnings in the *status quo*." *Ibid.* The court also found that the new warnings "are not unduly burdensome." *Id.* at 45a. The court acknowledged that the new warnings will "impose a burden" on petitioners, who may suffer "financial harm." *Id.* at 42a, 44a. But any such burden, the court explained, would not be "*undue*," in part because petitioners have no legitimate interest in "withholding useful and factual information from their customers." *Ibid.*

Petitioners sought rehearing en banc, which the court of appeals denied without any noted dissent. Pet. App. 110a-111a. The case therefore returned to the district court on remand. That court has stayed all further proceedings pending this Court's disposition of the present petition. D. Ct. Order (June 26, 2024).

ARGUMENT

The court of appeals correctly determined that FDA may require cigarette packaging and advertising to display the warnings set forth in the agency's 2020 rule, without violating the First Amendment, in light of this Court's decision in *Zauderer* v. *Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). Petitioners do not ask this Court to revisit *Zauderer*. They instead challenge only the application of that precedent to the specific warnings at issue here. See, *e.g.*, Pet. i, 13-14. This Court does not ordinarily grant review "when the asserted error consists of * * * the misapplication of a properly stated rule of law," Sup. Ct. R. 10, and petitioners identify no sound basis to depart from that practice here. The decision below was a correct application of *Zauderer* and does not conflict with any decision of this Court or another court of

appeals. In any event, further review would be unwarranted at this time because the case comes to the Court in an interlocutory posture. The petition for a writ of certiorari should be denied.

1. The Court's review is unwarranted at this time because this case is in an interlocutory posture. Petitioners challenged the warnings set forth in FDA's 2020 rule on both First Amendment and APA grounds, and petitioners' APA claims have never been adjudicated. When the case was initially before the district court, that court ruled for petitioners solely on First Amendment grounds. Pet. App. 97a-98a. On appeal, petitioners invoked their APA claims as a potential alternative basis for affirmance, but the court of appeals declined to address those claims in the first instance, instead remanding for further proceedings. *Id.* at 45a-46a.

Under this Court's ordinary practice, the interlocutory posture of a case "alone furnishe[s] sufficient ground for * * * denial." *Hamilton-Brown Shoe Co.* v. *Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916); see *Brotherhood of Locomotive Firemen & Enginemen* v. *Bangor & Aroostook R.R.*, 389 U.S. 327, 328 (1967) (per curiam) (explaining that a case remanded to the district court "is not yet ripe for review by this Court"); *Virginia Military Inst.* v. *United States*, 508 U.S. 946, 946 (1993) (Scalia, J., respecting the denial of the petition for writ of certiorari) (similar).

Denying review because of the interlocutory posture of the case is especially appropriate here because some of petitioners' stated criticisms of the 2020 warnings sound in arbitrary-and-capricious review under the APA. For example, petitioners suggest (Pet. 26-27) that some of the health consequences described in the textual warning statements are not typically experienced as

depicted in the images, despite record evidence to the contrary. If the district court finds that petitioners' APA claims lack merit, and if that determination is upheld in any subsequent appeal, petitioners will be able to raise their current claim, together with any other claims that may arise in those subsequent proceedings, in a single petition for a writ of certiorari. See *Major League Baseball Players Ass'n* v. *Garvey*, 532 U.S. 504, 508 n.1 (2001) (per curiam). And conversely, if this Court were to grant review now and affirm, petitioners would be free to continue to attack the same rule on APA grounds in the district court, with yet another round of appellate proceedings. The better course, consistent with this Court's traditional practice, is to await final judgment in the lower courts before determining whether this Court's review is warranted.

2. In any event, petitioners' contention (Pet. 21-28, 33-41) that the court of appeals misapplied *Zauderer* lacks merit. In *Zauderer*, this Court established that the government may require product warnings or other informational disclosures in commercial speech—*e.g.*, advertising—without violating any First Amendment right against compelled speech when the required disclosures convey "purely factual and uncontroversial information" about the goods or services being offered and are not "unjustified or unduly burdensome." 471 U.S. at 651; see *National Inst. of Family & Life Advocates* v. *Becerra*, 585 U.S. 755, 768 (2018) (*NIFLA*). That standard recognizes that "disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech," and that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," an

advertiser's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Zauderer*, 471 U.S. at 651 (citing *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)).

The court of appeals correctly concluded that the text-and-image warnings in the 2020 rule consist of factual and uncontroversial information about the serious health risks of smoking and are thus properly evaluated under *Zauderer*. The court also correctly concluded that the warnings satisfy the standards set forth in *Zauderer* because the warnings are reasonably related to the government's interest in promoting public understanding of those risks and are not unduly burdensome. Petitioners' arguments to the contrary lack merit.

a. *Factual.* The warnings required by the 2020 rule comprise both text and images. There is no dispute that smoking causes each of the health conditions described in the text of the warnings. Indeed, petitioners themselves have emphasized that they are "not disputing that smoking can cause the consequences that are identified in the textual warning statements." C.A. Oral Argument at 17:12-17:19 (Dec. 5, 2023); see Pet. App. 33a ("[N]either party disputes the Warnings' claims."). And even apart from petitioners' failure to contend otherwise, the evidence before the agency established beyond cavil that each of the textual statements is "supported by a broad consensus of scientific research." 85 Fed. Reg. at 15,645; see *id.* at 15,671-15,684 (detailed findings regarding the basis for each warning). The court of appeals accordingly had no difficulty concluding that the warnings convey "information supported by facts and * * * conclusions driven by those facts." Pet. App. 27a. The text of each warning is therefore "factual"

as that term is commonly understood. The warnings state facts, not opinions.

The images illustrating each of those factual statements are themselves also "factual" for purposes of *Zauderer*, as the court of appeals correctly recognized. Pet. App. 28a-32a. This Court explained in *Zauderer* that "[t]he use of illustrations or pictures in advertisements serves important communicative functions," and that images, like text, can provide "accurate representation[s]" that may "serve to impart information directly." 471 U.S. at 647-648. The Court there was discussing the regulated party's use of an image in advertising, see *id.* at 630-631, but the same observations apply to an illustration used in a product warning.

The images that FDA selected are factually accurate representations of the negative health consequences described in the text of each warning. That is no accident. As the agency explained in the preamble to its final rule, "FDA used a certified medical illustrator to design images that depicted common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced, and that present the health conditions in a realistic and objective format devoid of non-essential elements." Pet. App. 29a (quoting 85 Fed. Reg. at 15,646). The record shows that "each of the images provides 'a straightforward, science-based, objectively truthful depiction of the accompanying text,'" akin to the images "in a textbook." *Ibid.*; see 85 Fed. Reg. at 15,671-15,684 (discussing image-by-image the scientific basis for the chosen illustration and its relationship to the information conveyed by the accompanying text).

Petitioners nonetheless contend (Pet. 23) that the warnings are "misleading" and therefore fall outside

the ambit of *Zauderer*. Petitioners do not dispute that, as a matter of fact, smoking causes each of the negative health consequences described in the warnings and, further, that those conditions can manifest as illustrated. Their claim, instead, is that consumers may be misled by the images into believing that the negative health consequences of smoking are more common than they in fact are—either because the negative consequences occur less frequently than petitioners take the images to imply, or because a person might be able to receive medical treatment before a health problem reaches the state depicted in the images. See Pet. 23-28.

Any suggestion that the warnings overstate the risks of smoking is at odds with the record before the agency, which established that smoking significantly increases the risk of each condition. See 85 Fed. Reg. at 15,671-15,684. FDA explained, for example, that "smoking is the most powerful risk factor predisposing individuals to" peripheral arterial disease, which is responsible for "'over 90% of all limb amputations in the Western world.'" *Id.* at 15,681 (citation omitted). In addition, "smokers have approximately 45 percent higher risk of diabetes than nonsmokers," and an estimated "1.8 million Americans have diabetes due to smoking." 84 Fed. Reg. at 42,759. And "[m]ale smokers have been found to be 40 to 50 percent more likely to have erectile dysfunction due to diminished blood flow." *Ibid.*

Going warning-by-warning, FDA also explained why each image depicts "a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced." 85 Fed. Reg. at 15,672; see *id.* at 15,671-15,684. To take just one example, FDA specifically explained that "[i]t is not unusual for cervical lymph node metastasis," depicted in the

head-and-neck-cancer warning, "to be the first symptom of head and neck carcinoma that causes the patient to seek treatment." *Id.* at 15,674. To the extent that petitioners dispute the findings that FDA relied on in reaching those judgments, petitioners' challenge to the rule would be better considered under the rubric of the APA rather than constitutional law.

Petitioners labor to suggest (Pet. 23-24) that FDA's own studies found that the images would be misleading. But in some of the consumer research studies that petitioners invoke, viewers considered the images before the images were paired with warning statements; for example, when looking at a version of the image for the heart-disease warning (Pet. 27) in the absence of the accompanying statement, some study participants expressed uncertainty as to what was being depicted. C.A. ROA 1307; see *id.* at 1300. In the actual warnings required by the final rule, "each image is paired with a fact-based, textual warning," and viewers will see both simultaneously. Pet. App. 31a. "That context matters." *Ibid.*

Similarly, petitioners' speculation (Pet. 26-27) that the image accompanying the erectile-dysfunction warning could—in isolation—also be suggestive of depression, sleeplessness, or marital problems is beside the point. In context, petitioners offer no reason to think a viewer of the image paired with the text will be at all confused about the warning and its import.

b. *Uncontroversial.* The court of appeals also correctly concluded that the warnings are "uncontroversial" under *Zauderer*. Pet. App. 32a-34a. The court understood prior cases to establish that a compelled disclosure would fail that requirement if the "truth of the statement is not settled or is overwhelmingly disproven," or if the

"inherent nature of the subject raises a live, contentious political dispute." *Id.* at 32a-33a; cf. *NIFLA*, 585 U.S. at 769 (finding *Zauderer* inapplicable to state law compelling licensed pregnancy crisis centers to post notices about the availability of state-supported abortion services, "anything but an 'uncontroversial' topic"); *American Meat Inst.* v. *United States Dep't of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014) (en banc) (finding labeling requirement "uncontroversial" where the challenger "d[id] not disagree with the truth of the facts required to be disclosed").

These warnings are not controversial in either sense. As the court of appeals observed, even petitioners do not "suggest any good-faith debate" about the truth of the warning statements, and the statements are amply supported by the best available science. Pet. App. 33a. The warnings are also not controversial in the sense of requiring the speaker to convey a message regarding a matter of significant "national political debate," *ibid.*, such as abortion.

Nor can petitioners manufacture a controversy about the new warnings by repeatedly asserting that they are "provocative" (Pet. 2, 4, 14-15, 21-22, 28, 30) or "ideological" (Pet. 2, 14-15, 21, 23). The content of the warnings is neither. For example, petitioners make no effort to explain how being required to warn consumers that "[s]moking can cause heart disease and strokes by clogging arteries" (p. 8, *supra*) requires them to say anything "ideological." To the extent that petitioners contend that the warnings are ideologically "value-laden" because they convey an implicit "anti-smoking message" (Pet. 1), that contention would be at odds with petitioners' own recognition that the existing 1984 Surgeon General's warnings are "purely factual and uncontro-

versial." Pet. App. 28a (brackets omitted). One of the 1984 warnings explicitly counsels that quitting smoking reduces serious health risks and yet, by petitioners' own lights, that warning is an uncontroversial statement of fact. See *id.* at 4a ("Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.").

By "provocative," petitioners appear to mean that the warnings may provoke an emotional or visceral response in some viewers. See Pet. 22. The court of appeals correctly recognized, however, that whether a viewer has an "emotional response to a statement is irrelevant to its truth" and thus to whether there is any controversy about its truth. Pet. App. 30a; see *id.* at 34a. And to allow the hypothetical reaction of some viewers to dictate whether or not the disclosures should be analyzed under *Zauderer* would amount to a kind of heckler's veto, wrongly shifting the focus of the inquiry from the content of the speech to listeners' reactions.

Petitioners are also wrong to suggest (Pet. 22) that FDA designed the images to be "shocking." In its rulemaking, FDA explained the process it undertook to develop and refine the images, and no part of that process involved deliberately making them "more grotesque." *Ibid.* (emphasis omitted). While the serious health consequences of smoking may be upsetting to see, the images depict those consequences in a straightforward way. To be sure, petitioners and other companies that sell cigarettes might naturally "dislike * * * the warnings," which inform consumers that those products cause serious harms when used as intended. Pet. App. 34a. But to treat petitioners' own antipathy towards the warnings as sufficient to render them no longer "factual and uncontroversial" for *Zauderer* purposes would be unsound. See *ibid.*

c. *Tailoring*. Under *Zauderer*, requiring the disclosure of factual and uncontroversial information is a permissible regulation of commercial speech if the disclosure requirements are "reasonably related to the [government's] interest" and not "unduly burdensome." 471 U.S. at 651. In the commercial-speech context, this Court has emphasized that the "fit" between the government's interest and its chosen means of furthering that interest must be "reasonable," "not necessarily perfect." *Board of Trs. of the State Univ. of N.Y.* v. *Fox*, 492 U.S. 469, 480 (1989). Thus, the government need not use the "'least restrictive means'" of furthering its interest, and a disclosure requirement is not invalid "merely because other possible means by which the [government] might achieve its purposes can be hypothesized." *Zauderer*, 471 U.S. at 651 n.14.

i. The court of appeals correctly applied those principles here, determining that the government has a legitimate interest in promoting "'greater public understanding' of the risks of smoking," Pet. App. 35a (quoting 85 Fed. Reg. at 15,650); that the new warnings are reasonably related to and justified by that interest, *id.* at 38a-41a; and that the warnings do not impose an undue burden on petitioners, *id.* at 41a-45a. Those determinations turned largely on the specific products and warnings at issue in this case and would not warrant this Court's review for that reason alone. Petitioners also fail to show any error in the lower court's fact-bound application of *Zauderer*.

Cigarettes present an unparalleled threat to public health, and the warnings in the 2020 rule are amply justified in light of that threat. Cigarette smoking is the leading cause of preventable death in the United States, responsible for more than 480,000 deaths per year. 84

Fed. Reg. at 42,755. This figure is unmatched by any other consumer product and surpasses the number of deaths attributable to motor vehicle accidents, firearm incidents, alcohol use, and all illegal drug use combined. *Ibid.* Cigarettes are also uniquely pernicious because they cause death and disease even when used as intended and cannot be used safely in any amount.

Accordingly, since 1966, Congress has required warnings on cigarette packaging so that "the public may be adequately informed" of the dangers of smoking. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 2(1), 79 Stat. 282. But experience has shown that prior warnings did not adequately address the scope and scale of the public health threat posed by cigarette smoking, particularly adolescent smoking. See pp. 2-4, *supra*. Congress enacted the Tobacco Control Act in 2009 to address those shortcomings, including by vesting FDA with express authority to alter or adjust cigarette warnings in order "promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. 1333(d)[2]. The evidence before the agency in the 2020 rulemaking confirmed that providing information to consumers is vitally important. As FDA explained, the public continues to "hold[] misperceptions about the health risks caused by smoking." 85 Fed. Reg. at 15,638. FDA also explained that larger, updated warnings are needed because "the existing Surgeon General's warnings currently used in the United States go unnoticed and are effectively 'invisible.'" *Ibid.*

ii. Petitioners principally contend that the warnings required by the 2020 rule are unduly burdensome under *Zauderer* because they must occupy at least the upper 50% of the front and back of cigarette packaging (and

20% of cigarette advertisements)—a requirement that petitioners liken to "shouting" at consumers (Pet. 34) and that, they contend, unduly limits the opportunities for distinctive branding on the remainder of the packaging (Pet. 34-36).

The court of appeals considered those same arguments and persuasively explained why they do not show any violation of the First Amendment. See Pet. App. 41a-45a. This Court's decision in *Zauderer* requires considering whether a disclosure requirement is "*unduly* burdensome." 471 U.S. at 651 (emphasis added). "In other words, the regulation cannot impose a burden excessive or disproportionate to the benefits gained." Pet. App. 42a (citing this Court's decision in *NIFLA*, *supra*, as an instructive example).[2]

Whatever modest burden may be imposed on petitioners' ability to use their product packaging or advertising to differentiate their products from those of their competitors must be evaluated against the benefits of better informing consumers about the health risks of smoking. As already explained, FDA found a "pervasive

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[2] While serving on the D.C. Circuit, Justice Kavanaugh expressed the view that *Zauderer* is best understood as a specific application of the more general test that this Court has employed to evaluate regulations of commercial speech. See *American Meat Inst.*, 760 F.3d at 33 (Kavanaugh, J., concurring in the judgment) (discussing *Zauderer*, *supra*, and *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557, 566 (1980)). On that approach, the 2020 rule would also satisfy any requirement that a regulation of commercial speech be "tailored in a reasonable manner" for the same reasons as discussed in the text. *Ibid.* The government has consistently maintained and continues to take the view that the warnings required by the 2020 rule would be permissible regulations of commercial speech under *Central Hudson* even if, as petitioners contend, *Zauderer* were inapplicable. See Gov't C.A. Br. 34-41.

lack of knowledge about and understanding of the many negative health consequences of smoking." 85 Fed. Reg. at 15,654. For example, FDA cited evidence that 33% of adult smokers are unaware that smoking is a proven cause of cancer, and fewer than half of adults and youth identified cardiovascular disease as being among the harms caused by smoking. 84 Fed. Reg. at 42,761. And "abundant evidence" shows that "juveniles" in particular "are not sufficiently aware of the actual risks of tobacco use," *Discount Tobacco City & Lottery, Inc.* v. *United States*, 674 F.3d 509, 528 (6th Cir. 2012), cert. denied, 569 U.S. 946 (2013)—a significant fact given that the majority of regular adult smokers become addicted by age 18.

FDA also found "significant evidence" that "[t]he updated warnings serve to remedy the harm that buyers might (1) not know about tobacco's harms or (2) ignore the existing Surgeon General's warnings." Pet. App. 39a-40a. FDA found that each of the warnings selected provides new information to a significant number of viewers. 85 Fed. Reg. at 15,671-15,684. And for many conditions, including bladder cancer, head and neck cancer, type 2 diabetes, cataracts, and erectile dysfunction, the warnings provide new information to more than three quarters of viewers. *Ibid.* FDA explained that increased warning size and the inclusion of images aids comprehension of the health risks of smoking, including for adolescents. 84 Fed. Reg. at 42,762-42,763.

Cigarette smoking is responsible for over 480,000 deaths in the United States each year (p. 2, *supra*), and the government therefore very much has a "real-world interest" (Pet. 39) in informing consumers about the risks associated with this uniquely deadly product. The same interest has been the basis for the various cigarette

warnings that have been required since 1966—the constitutionality of which petitioners do not contest—as well as countless other product safety warnings. Indeed, this Court recently declined to "question the legality of health and safety warnings long considered permissible," *NIFLA*, 585 U.S. at 775, most of which are supported by a similar interest. Cf. *American Meat Inst.*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment) (reiterating that there is "no dispute about Congress's authority to require health warnings on cigarette packages"). Petitioners' hypothesized warnings on "fast food, candy, and wine" (Pet. 5) do not involve products that pose any remotely similar danger.

Petitioners cannot undermine that government interest by claiming (Pet. 39-40) that the public already knows that smoking is hazardous. As explained above (at p. 23), FDA in fact found that many consumers are not aware of important negative health consequences of smoking. And the government has an interest in informing consumers of those specific risks even if consumers are aware in a general sense that "cigarette smoking is harmful to health" (Pet. 40). Providing such information may enable more informed choices by consumers based on their own conditions and concerns. For one consumer, the risk of type 2 diabetes may be more salient based on family history or social exposure than the risk of lung cancer. All of those harms are real and undisputed, and the record shows that the textual statements and images required by the final rule will promote public understanding of those risks.

Petitioners suggest in places (Pet. 4-5, 35-36) that the warnings are unduly burdensome because their product advertising is already limited in other ways by an agreement that cigarette companies entered into as part of

settling claims arising from decades of deceptive practices. If anything, however, the history of cigarette companies "knowingly and actively conspir[ing] to deceive the public about the health risks and addictiveness of smoking" only underscores that warnings are critically important for these products. *Discount Tobacco*, 674 F.3d at 562 (opinion of Stranch, J.) (citing *United States* v. *Philip Morris USA Inc.*, 566 F.3d 1095, 1105-1108, 1119-1120, 1122-1124 (D.C. Cir. 2009) (per curiam), cert. denied, 561 U.S. 1025 (2010)).

iii. Petitioners likewise err in asserting (Pet. 31) that the government failed to consider less-burdensome alternatives, such as smaller or text-only warnings. Notably, the 50%-coverage requirement is prescribed by the Tobacco Control Act itself, see 15 U.S.C. 1333(a)(2), and was upheld as facially constitutional in *Discount Tobacco*, see 674 F.3d at 567 (opinion of Stranch, J.). Given that petitioners do not dispute the facial constitutionality of the Act in this Court—and some would be estopped from doing so in light of *Discount Tobacco*—it is difficult to see how they could nonetheless maintain that the same 50%-coverage requirement becomes improper when embodied in an agency rule carrying out the Act. And neither the Act nor the rule requires cigarette packages to be displayed on retail shelves in the manner depicted in the petition (at 35), with the bottom portion of the front panel obscured.

Moreover, it is simply not true that FDA failed to consider alternatives. The record shows that FDA—and Congress before it—took into account studies comparing the relative effectiveness of various options, including smaller or text-only warnings, before concluding that larger warning statements with graphics are warranted. See, *e.g.*, 85 Fed. Reg. at 15,638, 15,655-15,658;

84 Fed. Reg. at 42,762-42,765, 42,779; House Report 4. That conclusion was further supported by experience with the current text-only warnings required by the 1984 law. See pp. 2-4, *supra*. The record likewise refutes petitioners' suggestion that FDA failed to consider public-information campaigns. See 85 Fed. Reg. at 15,657-15,658. Any disagreement petitioners may have with the thoroughness of the agency's reasoning concerning those or any other alternatives would be better addressed under the APA.

3. Petitioners do not identify any sound basis for further review. The decision below does not conflict with any decision of this Court or another court of appeals, nor does it otherwise warrant review.

a. No other court of appeals has addressed the 2020 rule, let alone reached a result inconsistent with the decision below. In *Discount Tobacco*, the Sixth Circuit rejected a similar constitutional challenge to the Tobacco Control Act itself, upholding the Act's warning requirements under *Zauderer*. In Judge Stranch's controlling opinion, the Sixth Circuit determined that the Act's requirement for graphical warnings was subject to review under *Zauderer* because illustrations "can convey factual information, just as textual warnings can." *Discount Tobacco*, 674 F.3d at 562 (emphasis omitted). The court saw "no reason why a picture could not * * * accurately represent a negative health consequence of smoking, such as a cancerous lung." *Id.* at 560. Indeed, the court observed that students "look at pictures or drawings in textbooks of both healthy and damaged cells, tissues, organs, organ systems, and humans because those pictures convey factual information about medical conditions and biological systems." *Id.* at 559.

The Fifth Circuit in this case correctly perceived that *Discount Tobacco* supports rejecting petitioners' similar First Amendment challenge to the 2020 rule. See, *e.g.*, Pet. App. 28a & n.50, 29a (citing and relying on the Sixth Circuit's reasoning and observing that "[w]e see no reason to split from our sister circuit"). Petitioners assert (Pet. 38) that the Sixth Circuit rested its decision on an incorrect understanding of *Zauderer* and failed to consider whether the warning requirements were unduly burdensome. But the Sixth Circuit in fact did address that issue, finding that "[t]he government has provided ample evidence supporting the size requirement for the new labels, and [p]laintiffs have not shown that the remaining portions of their packaging are insufficient for them to place their brand names, logos or other information." *Discount Tobacco*, 674 F.3d at 530-531 (opinion of Stranch, J.) (citation omitted); see Pet. App. 41a-42a (adhering to the Sixth Circuit's approach).

b. On the other hand, a divided panel of the D.C. Circuit vacated an earlier FDA rule implementing the warning requirements in the Tobacco Control Act. See *R.J. Reynolds Tobacco Co.* v. *FDA*, 696 F.3d 1205, 1221-1222 (2012), overruled in part by *American Meat Inst.* v. *United States Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). That decision is the centerpiece of petitioners' asserted circuit conflict. See Pet. 15-21. But the D.C. Circuit was considering a materially different set of text-and-image warnings, and nothing in its decision indicates that the court would necessarily also have viewed the images FDA adopted in the 2020 rule—after taking into account the D.C. Circuit's concerns with the prior ones—as similarly problematic. Petitioners' own litigation conduct suggests that they too did not regard

the D.C. Circuit's decision as necessarily dictating an outcome in their favor here, given that they chose instead to bring this suit in the Eastern District of Texas.

The D.C. Circuit panel majority viewed the warnings prescribed by FDA's 2011 rule as falling outside the ambit of *Zauderer* for two reasons, neither one of which would apply here. The majority principally reasoned that *Zauderer* applies only to disclosures "designed to correct misleading commercial speech," and it viewed the 2011 warnings as going beyond doing so. *R.J. Reynolds*, 696 F.3d at 1213. The en banc D.C. Circuit overruled that aspect of *R.J. Reynolds*, and even petitioners no longer contend that *Zauderer* is so limited. See *American Meat Inst.*, 760 F.3d at 22-23 (overruling *R.J. Reynolds* to the extent that it "limit[ed] *Zauderer* to cases in which the government points to an interest in correcting deception"). Every circuit to confront the question has likewise rejected the view that *Zauderer* applies only to the "consumer-deception context." Pet. App. 35a & nn.59-62 (citing cases).[3]

The D.C. Circuit panel majority also reasoned, alternatively, that the images in FDA's 2011 rule went beyond compelling the disclosure of "'purely factual and uncontroversial' information," either because the images could be "misinterpreted by consumers" or because they were, in the majority's view, "intended to evoke an emotional

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[3] Even if it had not been overruled, that aspect of the D.C. Circuit's *R.J. Reynolds* decision would not help petitioners here. In the present rulemaking, FDA explained that the revised warnings are necessary in part to correct the consumer misperceptions arising from "half a century of fraud" by "the largest players in the industry," who repeatedly and intentionally misled consumers about the risks of smoking. 85 Fed. Reg. at 15,645; cf. *Discount Tobacco*, 674 F.3d at 562 (opinion of Stranch, J.) (discussing this "decades-long deception").

response" rather than convey information. *R.J. Reynolds*, 696 F.3d at 1216 (citation omitted). But the majority was focused on specific aspects of those images that do not appear in the revised warnings that petitioners challenge here. For example, the majority observed that images used in the 2011 warnings of "a woman crying, a small child, and [a] man wearing a T-shirt emblazoned with the words 'I QUIT' d[id] not offer any information about the health effects of smoking." *Ibid.* And the warnings in the 2011 rule, but not the warnings at issue here, included what the majority deemed a "provocatively-named" hotline, 1-800-QUIT-NOW. *Ibid.*

As the Fifth Circuit explained in the decision below, the revised warnings in the 2020 rule are "unlike the images before the D.C. Circuit" in important respects. Pet. App. 30a. The revised photorealistic images are "meant to be interpreted literally," in that they illustrate in a straightforward and accurate way the negative health consequence in the paired textual warnings. *Ibid.* (citation omitted). And the images FDA required in the 2020 rule "are not 'primarily intended to evoke an emotional response' but instead to draw attention to the warning and depict a possible medical consequence of smoking." *Ibid.* (quoting *R.J. Reynolds*, 696 F.3d at 1216). The Fifth Circuit therefore correctly determined that the new warnings should be sustained "even * * * adopt[ing] the D.C. Circuit's reasoning." *Ibid.* Petitioners offer no reason to think the D.C. Circuit itself would disagree with that assessment were it to consider a challenge to the 2020 rule.

c. Petitioners separately contend (Pet. 29-33) that the Fifth Circuit's application of *Zauderer* to the facts of this case conflicts with decisions of four other courts of appeals. But petitioners fail to show that any other

court of appeals would reach a different result than the Fifth Circuit did here if presented with the same record.

In *American Beverage Ass'n* v. *City & County of San Francisco*, 916 F.3d 749 (2019) (en banc), the Ninth Circuit held that a local ordinance requiring "health warnings on advertisements for certain sugar-sweetened beverages" constituted impermissible compelled speech under *Zauderer* because the warnings were so large as to be "'unduly burdensome.'" *Id.* at 753 (citation omitted). But petitioners are wrong to suggest (Pet. 29-30) that *American Beverage* establishes that the Ninth Circuit would have resolved this case differently. The holding in that case was highly fact-specific: "[T]he record" before the court "show[ed] that a smaller warning—half the size—would accomplish [the city's] stated goals." *American Beverage*, 916 F.3d at 757. The record here is materially different. As discussed above, the government has for decades required smaller, textual warnings on cigarette packages, and both Congress and FDA found that those prior warnings go largely unnoticed and leave many consumers unaware of the harms caused by smoking.

In *Entertainment Software Ass'n* v. *Blagojevich*, 469 F.3d 641 (2006), the Seventh Circuit considered a state law requiring the label "18" to appear in a four-square-inch area on the packaging of any video game that met the state's definition of a "sexually explicit" game. *Id.* at 652. Petitioners acknowledge (Pet. 30) that the Seventh Circuit was applying strict scrutiny in that case, not *Zauderer*, and its dictum about labels on menus (*ibid.*) has no bearing on the warnings at issue here. To the contrary, the Seventh Circuit expressly distinguished "a surgeon general's warning of the carcinogenic properties of cigarettes" from the warnings the

court was addressing. *Entertainment Software*, 469 F.3d at 652. The Seventh Circuit also emphasized the fact-specific nature of its inquiry, noting that the record lacked any evidence as to "why a smaller sticker would not suffice." *Ibid.*

Finally, petitioners invoke three decisions, including again *R.J. Reynolds*, that they take to stand for the proposition that a "purely informational interest is not sufficient to justify compelled disclosures for *Zauderer* purposes." Pet. 31; see Pet. 31-33 (citing *R.J. Reynolds*, *supra*; *International Dairy Foods Ass'n* v. *Amestoy*, 92 F.3d 67 (2d Cir. 1996); and *CTIA - The Wireless Ass'n* v. *City of Berkeley*, 928 F.3d 832 (9th Cir.), cert. denied, 140 S. Ct. 658 (2019)).[4] But even taking petitioners' understanding of those cases at face value, they do not show any conflict with the decision below. The Fifth Circuit did not rely in this case on any arguably "circular" interest in compelling disclosure for its own sake. Pet. 32 (citation omitted). The Fifth Circuit instead recognized that the government has a "legitimate" and "substantial" interest in better informing consumers of the negative health consequences of smoking. Pet. App. 40a & n.71; see pp. 20-21, *supra*.

4. Petitioners briefly request (Pet. 43-44) that, as an alternative to plenary review, the Court grant the petition, vacate the judgment below, and remand for

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[4] With respect to *CTIA*, petitioners also rely elsewhere (Pet. 20-21) on the Ninth Circuit's observation that a statement may be "literally true but nonetheless misleading and, in that sense, untrue," 928 F.3d at 847. The Fifth Circuit did not suggest otherwise here, but rather found that these textual warnings are not misleading. Pet. App. 28a. The Ninth Circuit likewise found the cellphone radiation warnings in *CTIA* not misleading, applied *Zauderer*, and rejected a First Amendment challenge. 928 F.3d at 847-849.

reconsideration in light of the Court's intervening decision in *Moody* v. *NetChoice, LLC*, 144 S. Ct. 2383 (2024). That request should be rejected.

In *NetChoice*, the Fifth Circuit had concluded that the content moderation activities of some social media platforms do not constitute the platforms' own speech and therefore that state regulation of those activities does not implicate the First Amendment. See 144 S. Ct. at 2396. The Fifth Circuit had also upheld a state law requiring social media platforms to provide an individualized explanation when removing a user's content, in part on the theory that providing such an explanation was not "unduly burdensome under *Zauderer*." *Ibid.* This Court reversed and remanded, principally holding that the Fifth Circuit (and the Eleventh Circuit in a similar case) had failed to properly take account of the standards governing facial constitutional challenges. See *id.* at 2408-2409.

Petitioners do not explain how this Court's decision in *NetChoice* would shed any new light on the decision below here. This appeal does not involve a facial challenge to the constitutionality of a statute, nor does it raise any question about whether the regulated party is engaged in speech. To be sure, in the decision below the Fifth Circuit cited and discussed its now-vacated prior opinion in *NetChoice*, but it did so only for points of law that this Court did not then later address or clarify in *NetChoice*. See, *e.g.*, Pet. App. 23a-24a (citing the since-vacated *NetChoice* opinion when distilling the requirements for satisfying *Zauderer*); *id.* at 32a-34a (citing the since-vacated *NetChoice* opinion when discussing what makes a statement "uncontroversial" under *Zauderer*). And because this Court's intervening decision in *NetChoice* does not speak to the Fifth Circuit's

analysis in this case, *NetChoice* provides no sound basis for giving petitioners a second bite at the apple.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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