United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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March 21, 2024
Lyle W. Cayce
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No. 23-40076

R J Reynolds Tobacco Company; Santa Fe Natural Tobacco Company, Incorporated; ITG Brands LLC; Liggett Group LLC; Neocom, Incorporated; Rangila Enterprises, Incorporated; Rangila LLC; Sahil Ismail, Incorporated; Is Like You, Incorporated,

Plaintiffs—Appellees,

versus

Food & Drug Administration; United States Department of Health and Human Services; Robert M. Califf, *Commissioner of Food and Drugs*; Xavier Becerra, *Secretary, U.S. Department of Health and Human Services*,

Defendants—Appellants.

Appeal from the United States District Court
for the Eastern District of Texas
USDC No. 6:20-CV-176

Before Smith, Elrod, and Graves, *Circuit Judges*.

Jerry E. Smith, *Circuit Judge*:

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA" or "Act"), which revised the required warnings each cigarette manufacturer must place on its packages and advertise-

ments.[1] Modernizing the ubiquitous text of the Surgeon General's current warnings, the Act requires cigarette packages to include "color graphics depicting the negative health consequences of smoking to accompany the [updated] label statements." 15 U.S.C. § 1333(d). Those graphics and statements (together "Warnings") "shall comprise the top 50 percent of the front and rear panels of the package" of cigarettes and "at least 20 percent of the area of [any] advertisement . . . ." *Id.* § 1333(a)(2), (b)(2).

Tobacco companies quickly brought a facial challenge to the TCA's constitutionality, but the Sixth Circuit upheld it in 2012.[2] The FDA's first attempt at a rule interpreting and applying the Act fared less well, as the FDA failed to rebut an as-applied First Amendment challenge before the D.C. Circuit in 2014.[3] Now, ten years later, the FDA has tried again, so we are the third circuit to weigh in.

R.J. Reynolds Tobacco Company ("RJR") and other cigarette manufacturers and retailers claim that the FDA's newest attempt at implementing the Act's warning-label requirement violates the First Amendment, the Administrative Procedure Act ("APA"), and the requirements of the TCA itself. On cross-motions for summary judgment, the district court agreed with the plaintiffs' First Amendment challenge and granted summary judgment without reaching the remaining claims. But we disagree—the warnings are both factual and uncontroversial, so *Zauderer*[4] scrutiny applies, and the

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[1] Pub. L. No. 111-31, div. A, title II, §§ 201(a), 202(b), 206, 123 Stat. 1776, 1842–50 (2009) (codified as amended in scattered sections of Titles 15 and 21 U.S.C.).

[2] *See Discount Tobacco City & Lottery, Inc. v. United States,* 674 F.3d 509, 552 (6th Cir. 2012) (controlling opinion by Stranch, J.).

[3] *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled by Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

[4] *Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio*, 471 U.S. 626 (1985).

rule passes constitutional muster. Therefore, we reverse and remand the remaining claims for initial consideration by the district court.

I.

A. The TCA and Its Antecedents

In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act.[5] For the first time, all cigarettes manufactured, imported, or packaged for sale or distribution within the United States had to display "CAUTION: Cigarette Smoking May Be Hazardous to Your Health."[6]

Four years later, Congress revised that warning to state, "WARNING: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous To Your Health."[7] Then, in 1984, Congress again updated the warnings with the Comprehensive Smoking Education Act.[8] Under that act, the warnings now read,

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
>
> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

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[5] Pub. L. No. 89-92, 79 Stat. 282 (1965).

[6] *Id.* § 4.

[7] *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87.

[8] Pub. L. No. 98-474, 98 Stat. 2200 (1984).

Id. § 4.[9]

Between 1984 and 2009, though, Congress found that "efforts to restrict advertising and marketing of tobacco products," including the warnings, had "failed adequately to curb tobacco use by adolescents, [so] comprehensive restrictions on the sale, promotion, and distribution of such products [were] needed." TCA § 2(6). Thus, it enacted the TCA.

In the TCA, Congress made extensive and significant legislative findings, including that (1) minors still often see and are exposed to tobacco product advertising[10]; (2) 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"[11]; and (3) "[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[s]" and would "result in approximately $75,000,000,000 in savings attributable to reduced health care costs."[12]

In light of those findings, Congress believed it necessary to update the 1984 Surgeon General's Warnings with new ones. It chose nine new warnings that would rotate regularly, stating,

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

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[9] Until the FDA implements the TCA's requirements, manufacturers must continue to use those warnings from 1984. Manufacturers typically place the warnings on the side panel of each cigarette package, occupying approximately 5% of each's surface area.

[10] TCA § 2(15), (17), (18).

[11] *Id.* § 2(31).

[12] *Id.* § 2(14).

> WARNING: Cigarettes cause fatal lung disease.
>
> WARNING: Cigarettes cause cancer.
>
> WARNING: Cigarettes cause strokes and heart disease.
>
> WARNING: Smoking during pregnancy can harm your baby.
>
> WARNING: Smoking can kill you.
>
> WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
>
> WARNING: Quitting smoking now greatly reduces serious risks to your health.

15 U.S.C. § 1333(a)(1). The new warnings, Congress determined, must "comprise the top 50 percent of the front and rear panels of" each cigarette package and "at least 20 percent of the area of [any] advertisement . . . ." *Id.* § 1333(a)(2), (b)(2).

But updating the text and the font size of the warnings was not enough—Congress also wanted images with the textual warnings. So, it instructed the Secretary of Health and Human Services to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements." *Id.* § 1333(d). And Congress gave the Secretary the authority to "adjust the type size, text and format of the label statements" for clarity, conspicuousness, and legibility. *Id.* Recognizing the difficulty manufacturers may have in updating their packaging, though, Congress delayed enforcement of the regulations for fifteen months after their issuance. *Id.* § 1333 note.

Finally, acknowledging the likelihood of judicial review, Congress included a severability clause: If a court finds any part of the Act unlawful and invalid, that court should keep "the remainder" enforceable "to the fullest extent possible." TCA § 5.

B. The TCA's Implementation and Litigation History

1. Pre-Rule Litigation

Before the FDA could issue a rule under the TCA's graphics requirement, several manufacturers and sellers of tobacco products—including RJR[13]—sued the United States, alleging, *inter alia*, that the Act violated their First Amendment rights. *See Discount Tobacco*, 674 F.3d at 520–21; *see also id.* at 553. The district court granted summary judgment to the government on the First Amendment claim, and the Sixth Circuit, reviewing the plaintiffs' claims as a facial challenge to the Act, affirmed. *Id.* at 551–52.

The Sixth Circuit first determined the applicable standard of review, framing it as a choice between *Zauderer* and strict scrutiny. *See id.* at 554. It began with *Zauderer*. The court noted that "[t]he factual content of the textual warnings [wa]s undisputed." *Id.* at 558. So, for *Zauderer* not to apply, "[p]laintiffs would have to establish that a graphic warning cannot convey the negative health consequences of smoking accurately, a position tantamount to concluding that pictures can never be factually accurate, only written statements can be." *Id.* at 559. The court rejected that position, offering instead several examples of the "many graphic warnings that would constitute factual disclosures under *Zauderer*." *Id.* Those included

> a picture or drawing of a nonsmoker's and smoker's lungs displayed side by side; a picture of a doctor looking at an x-ray of either a smoker's cancerous lungs or some other part of the body presenting a smoking-related condition; a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition; a picture or drawing of a

[13] The plaintiffs were Discount Tobacco City & Lottery, Inc.; Lorillard Tobacco Company; National Tobacco Company, L.P.; RJR; Commonwealth Brands, Inc.; and American Snuff Company, LLC, FKA Conwood Company, LLC. *See Discount Tobacco*, 674 F.3d at 521 n2.

> person suffering from a smoking-related medical condition; and any number of pictures consisting of text and simple graphic images.

Id. Therefore, *Zauderer* supplied the applicable standard of review for the pre-enforcement facial challenge.

Applying *Zauderer*'s very deferential test, the Sixth Circuit held that "graphic and textual warnings that convey factual information about the health risks of tobacco use are reasonably related to the purpose of preventing consumer deception." *Id.* at 562. That deception, the court explained, arose inherently from the past decades of false advertising and misleading research by the companies that were proclaiming that tobacco had no health risks and was not addictive.[14] Further, the court found that the warnings were not unduly burdensome, despite the 50%-coverage requirement. *Id.* at 567.[15] Finally, the court rejected "the underlying premise [of the dissent] that a disclosure that provokes a visceral response must fall outside *Zauderer*'s ambit. Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions." *Id.* at 569. Instead, "whether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy." *Id.* (citing *Zauderer*, 471 U.S. at 650–51).

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[14] *See Discount Tobacco*, 674 F.3d at 562–63 (citing *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1105–08, 1119–20, 1122–24 (D.C. Cir. 2009) (per curiam)).

[15] That court pointed out the incongruity between plaintiffs' claiming that "the warnings will not reduce the use of their tobacco products" and their assertion that the warnings were so unduly burdensome as to drown out their advertising and marketing. *Id.* at 567.

2. The First Rule's Litigation

While the *Discount Tobacco* litigation was pending, FDA issued a Final Rule implementing the Act's graphics requirements.[16] The warnings used the exact language of the Act and included graphics of side-by-side healthy and damaged lungs, a dead body, and a crying woman.[17] Each warning also showed the phone number 1-800-QUIT-NOW.

Five companies—now led by RJR[18]—challenged the 2011 Rule, asserting the warnings violated the First Amendment. The district court granted the companies' motion for summary judgment, and the D.C. Circuit affirmed. *See R.J. Reynolds*, 696 F.3d at 1208. That court held that the warnings were not "a remedial measure designed to counteract specific deceptive claims made by the [c]ompanies" as required by *Zauderer*. *Id.* at 1215. Further, it ruled the chosen graphics were not "'purely factual and uncontroversial' information" because the images "could be misinterpreted by consumers" and "are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning." *Id.* at 1216 (quoting *Zauderer*, 471 U.S. at 651). So, by its reasoning, *Zauderer* scrutiny did not apply. *Id.* at 1217.[19]

Applying instead *Central Hudson*'s more stringent scrutiny, the court

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[16] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("2011 Rule").

[17] *Id.* at 36649–57, 36674.

[18] Plaintiffs there were RJR; Lorillard Tobacco Co.; Commonwealth Brands, Inc.; Liggett Group LLC; and Santa Fe Natural Tobacco Co., Inc. *See* Complaint at 4–5, *R.J. Reynolds*, 823 F. Supp. 2d 36 (D.D.C. 2011) (No. 1:11-CV-01482), 2011 WL 3611561.

[19] Instead of attempting to distinguish the Sixth Circuit's reasoning in *Discount Tobacco*—to which the dissent cited repeatedly—the majority in *R.J. Reynolds* never mentioned it, relying instead on the lack of deception and on the emotional implications of the graphics as grounds to apply *Central Hudson*.

struck down the rule as violative of the First Amendment. *Id.* at 1221–22 (citing *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)). "Assuming FDA's interest in reducing smoking rates is substantial," the D.C. Circuit explained that the 2011 Rule nonetheless failed *Central Hudson* scrutiny because it lacked even "a shred of evidence . . . showing that the graphic warnings will 'directly advance' [FDA's] interest in reducing the number of Americans who smoke." *Id.* at 1218–19.

3. The Current Rule's Litigation

Eight years later, in 2020, the FDA finally issued this Rule.[20] The FDA asserted that the Rule—and its eleven new warnings, reproduced below—were justified by "the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking."[21] FDA also claimed that the Rule "dissipat[es] the possibility of consumer confusion or deception," thereby advancing the government's interest in preventing "consumer misperceptions regarding the risks presented by cigarettes." 85 Fed. Reg. at 15645 (quoting *Zauderer*, 471 U.S. at 651).

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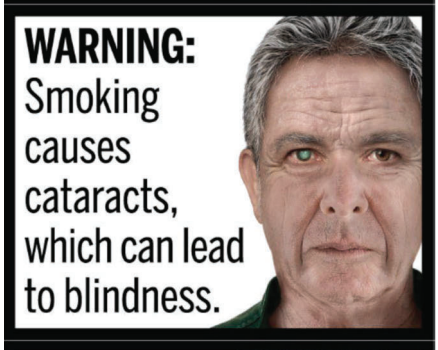
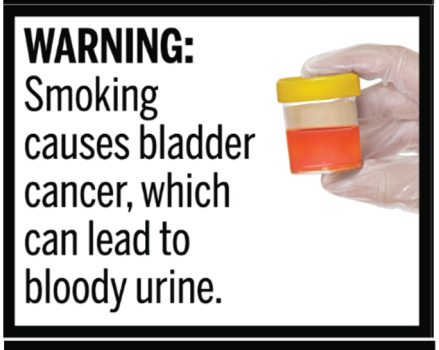
[20] *See Required Warnings for Cigarette Packaging and Advertisements*, 85 Fed. Reg. 15638 (Mar. 18, 2020) (codified at 21 C.F.R. §§ 1141.1–12). The FDA issued this rule only after litigious prompting. *See Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985, 2019 WL 1047149, at *3 (D. Mass. 2019).

[21] 85 Fed. Reg. at 15638; *see id.* at 15643–50; *see also* Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42754, 42778 (Aug. 16, 2019) (Proposed Rule).

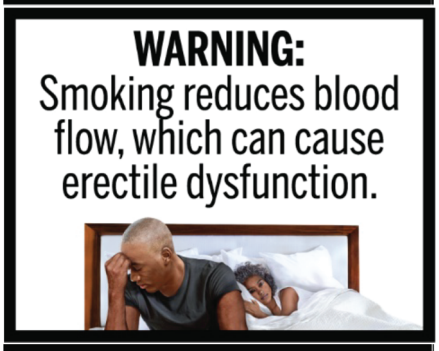
WARNING:
Smoking causes head and neck cancer.

WARNING:
Tobacco smoke causes fatal lung disease in nonsmokers.

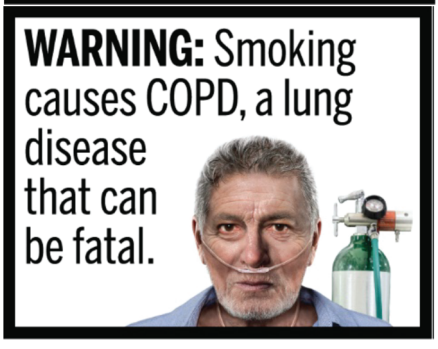

WARNING:
Smoking causes cataracts, which can lead to blindness.

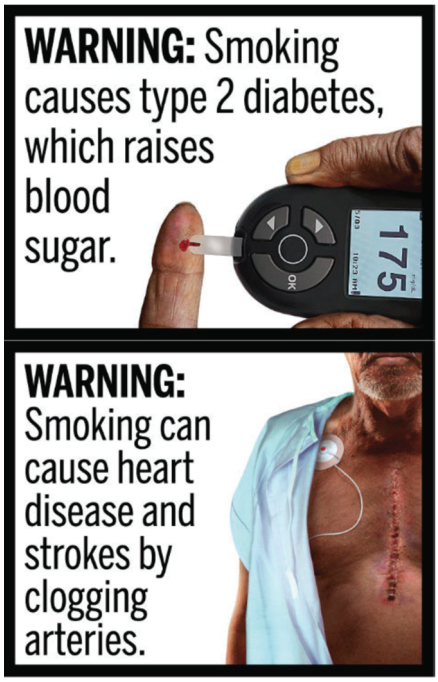

WARNING:
Smoking causes bladder cancer, which can lead to bloody urine.

WARNING:
Tobacco smoke can harm your children.


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

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


WARNING: Smoking causes COPD, a lung disease that can be fatal.



The Warnings do not precisely match the warnings required by the TCA—FDA kept one, split one of the TCA's warnings into two, updated three others, and replaced the remaining four with five new warnings.[22] The FDA claims that the authority to make those changes derives from § 201 of the TCA, which allows the agency to "adjust the . . . text . . . of the cigarette

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[22] FDA kept "Tobacco smoke can harm your children." It then split "Cigarettes cause cancer" into "Smoking causes head and neck cancer" and "Smoking causes bladder cancer, which can lead to bloody urine." 85 Fed. Reg. at 15673–75; *see also* 84 Fed. Reg. at 42768, 42774. It updated "Smoking during pregnancy can harm your baby" to read "Smoking during pregnancy stunts fetal growth." 85 Fed. Reg. at 15676; *see also* 84 Fed. Reg. at 42774. It clarified "Cigarettes cause strokes and heart disease" now to explain "Smoking can cause heart disease and strokes by clogging arteries." 85 Fed. Reg. at 15677; *see also* 84 Fed. Reg. at 42774–75. It expanded "Cigarettes cause fatal lung disease" into "Smoking causes COPD, a lung disease that can be fatal." 85 Fed. Reg. at 15678; *see also* 84 Fed. Reg. at 42775. Finally, it added "Smoking reduces blood flow, which can cause erectile dysfunction," 85 Fed. Reg. at 15680; "Smoking reduces blood flow to the limbs, which can require amputation," *id.* at 15681; "Smoking causes type 2 diabetes, which raises blood sugar," *id.* at 15682; and "Smoking causes cataracts, which can lead to blindness," *id.* at 15683; *see also* 84 Fed. Reg. at 42776–77.

health warnings . . . ." 85 Fed. Reg. at 15641–42 (quoting 15 U.S.C. § 1333(d)). As the FDA explained, the Surgeon General's 2014 report newly attributed eleven diseases to smoking, and the Warnings better reflected those findings.[23]

The Rule also included its own severability provision. There, the FDA explained,

> [T]he individual aspects of this rule are workable on their own and should go forward in the event that some are invalidated. . . . FDA has determined that severability both is consistent with Congressional intent and would best advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. . . . [I]n a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect . . . [because] each other portion of the rule would 'function sensibly' on its own . . . .

Id. at 15695.[24]

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[23] *See* 85 Fed. Reg. at 15652 (citing U.S. Dept. of Health and Human Services, The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General *iii* (2014)).

[24] Anticipating the district court's actions here, FDA also wrote,

> if a court were to invalidate some of the cigarette health warnings (i.e., text-and-image-pairings), but some of the pairings remained valid, FDA intends that the remaining required warnings would go into effect. As another example, if a court were to invalidate some but not all of the images within the cigarette health warnings, FDA intends that those images would be severed and the corresponding textual warning statements would go into effect without the invalidated images, along with the remaining cigarette health warnings that pair a textual warning statement with an image. As a third example, if a court were to invalidate all of the images within the cigarette health warnings, FDA intends for the invalidated images to be severed and all the warnings to go into effect with only their textual warn-

Less than a month after FDA promulgated the Rule, plaintiffs sued. They decried the Warnings as "unprecedented" and "precisely the type of compelled speech that the First Amendment prohibits." They alleged that each of the Warnings "misrepresent[s] or exaggerate[s] the potential effects of smoking." Further, they complained that "[c]ontrary to FDA's characterization, the peer reviewers raised serious, substantive concerns about FDA's studies" used to support the selected Warnings. Thus, plaintiffs contended, (1) the Rule violates the First Amendment, (2) the Act violates the First Amendment, and (3) the Rule violates the APA and the Act. Additionally, they urged the court to delay the implementation of the warning requirement until fifteen months after FDA issued a legally valid new rule.

Reviewing cross-motions for summary judgment, the district court began and ended with the First Amendment challenge to the Rule. It found that *Zauderer* did not apply because the Warnings were "not inherently 'accurate,' and 'purely factual and uncontroversial.'"[25] Rather, the imagery is fundamentally so "prone to ambiguous interpretation" that "it is unclear how a court would go about determining whether it[] . . . is 'accurate' and 'factual' in nature." 2022 WL 17489170, at *13–14. In other words, the court reasoned that no photorealistic image could ever be purely factual and uncontroversial because different viewers will ascribe to it different meanings. The inherent ambiguity in any graphic warning—*e.g.*, that viewers may interpret the heart disease warning to suggest that open-heart surgery "is the most common treatment for heart disease" or the best—means that the Warnings cannot be "'purely factual and uncontroversial' and objectively

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ing statements.

Id. at 15695.

[25] *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-CV-00176, 2022 WL 17489170, at *13 (E.D. Tex. Dec. 7, 2022).

accurate as required to allow relaxed *Zauderer* review." *Id.* at *14–15. Further, the court found that the graphic portions of the Warnings fell beyond *Zauderer*'s reach because they are inherently "provocative." *Id.*

The district court then turned to *Central Hudson*. *Id.* at *15. The court acknowledged that it is unsettled whether *Central Hudson* intermediate scrutiny, or instead strict scrutiny, applies to compelled speech. *Id.* But the government failed to satisfy *Central Hudson*'s narrow-tailoring requirement, so it *a fortiori* failed strict scrutiny. *Id.* at *17. The Rule was more extensive than necessary because the government had not increased funding for anti-smoking advertisements, increased its own anti-smoking communications, or "test[ed] the efficacy of 'smaller or differently placed warnings.'" *Id.* (quoting 85 Fed. Reg. at 13650).

The district court concluded by declining to sever the Warnings, even though it had considered only three of the eleven in detail. *Id.* That, the court ruled, was because "[t]he Act . . . does not allow the court to 'sever' the FDA's warnings by simply deleting their graphical component[s]." *Id.* at *18.

Relying on the preceding analysis, the district court declared that enforcing any part of the Rule against the plaintiffs would violate the First Amendment; it then vacated the entire Rule. FDA appeals.

II.

FDA raises four issues on appeal: whether (1) the Warnings violate the First Amendment, (2) the Rule survives APA review, (3) the district court should have considered each Warning individually and severed the unconstitutional from the constitutional, and (4) vacatur was a proper remedy. Before turning to those issues, though, we first must assure ourselves we even need to.

A. Preclusion

This is the second TCA-related case styled *R.J. Reynolds v. FDA*, and we are the third circuit to consider a challenge to that Act. In all three cases, RJR has been a party,[26] and in all three, the plaintiffs have challenged the validity of the same provisions of the Act under the First Amendment.[27] Yet the FDA has not asserted any form of preclusion.

Because they are affirmative defenses, the defendant must typically "plead and prove" res judicata or collateral estoppel for us to consider them.[28] When proper, though, we may raise preclusion *sua sponte*.[29] Yet we rarely do so, for it is a "drastic step" to "invok[e] res judicata for the first time on appeal and revers[e] the district court below as a consequence." *United Home Rentals, Inc. v. Tex. Real Est. Comm'n*, 716 F.2d 324, 330 (5th Cir. 1983).

We deem it unnecessary to take that drastic step here. Although this case meets the requirements for a district court to consider preclusion *sua sponte*—"all of the relevant facts are contained in the record and are uncontroverted"[30]—we could not resolve the entire case on preclusion alone. Even if we dismissed RJR's First Amendment challenge to the TCA as precluded, we would still need to resolve its challenge to the Rule. So, we

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[26] Like RJR, Santa Fe and Liggett were parties in *R.J. Reynolds*. *See supra* note 18.

[27] *Contra Whole Women's Health v. Hellerstedt*, 579 U.S. 582, 604–06 (2016), *abrogated on other grounds by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022).

[28] *Sacks v. Tex. S. Univ.*, 83 F.4th 340, 344 (5th Cir. 2023) (citing *Taylor v. Sturgell*, 553 U.S. 880, 907 (2008)); *see* FED. R. CIV. P. 8(c)(1).

[29] *See, e.g.*, *Mowbray v. Cameron Cnty.*, 274 F.3d 269, 281 (5th Cir. 2001) (res judicata); *OneBeacon Am. Ins. Co. v. Barnett*, 761 F. App'x 396, 399 (5th Cir. 2019) (collateral estoppel).

[30] *Energy Dev. Corp. v. St. Martin*, 296 F.3d 356, 363 (5th Cir. 2002) (per curiam).

turn to the merits.

B. First Amendment

We begin by addressing FDA's contention that the Warnings do not violate the First Amendment. We usually do not turn first to a constitutional issue where a challenge presents multiple pathways for review.[31] But "federal courts have emphasized the importance of resolving First Amendment cases at the earliest possible junction." *Green v. Miss U.S.A., LLC*, 52 F.4th 773, 800 (9th Cir. 2022). Further, the district court resolved only the constitutional issue.[32] Thus, we will do the same.

The outcome-determinative question for the First Amendment issue is whether the district court properly found that the Warnings do not receive *Zauderer*'s deferential scrutiny. The district court erred. The Warnings are both factual and uncontroversial, despite the emotional impact the graphics may have. Therefore, we reverse.

1. *Zauderer* and *Central Hudson*

The Warnings are government-compelled speech—not speech restrictions. Because of that, the many cases plaintiffs and their *amici* cite regarding prohibitions or restrictions on speech provide, at best, merely persuasive authority.[33] That said, government-compelled speech inherently reg-

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[31] *See Jean v. Nelson*, 472 U.S. 846, 854 (1985).

[32] *See also United Home Rentals*, 716 F.2d at 328 (Typically, "the initial review of the constitutionality of a state agency's interpretation of its own rules is a matter that the federal courts should undertake only when circumstances warrant it, and abstention would serve no purpose."). Here, however, not only do we address a federal agency's interpreting an act of Congress instead of a rule, but also the First Amendment challenge is the only one before us.

[33] For example, one of the *amici* cites ten speech-restriction cases but only two compelled-speech cases. Those two are *National Institute of Family & Life Advocates v.*

ulates speech on the basis of its content.[34] And, as plaintiffs point out, we generally review content-based regulations of speech under strict scrutiny unless they come within an exception such as the commercial speech exceptions of *Zauderer* or *Central Hudson*.

For decades, the Supreme Court has consistently applied *Central Hudson* and *Zauderer* to cases implicating regulation of commercial speech.[35] We, too, are no strangers to those frameworks.[36]

In *Central Hudson*, the Public Service Commission of New York had banned all advertising promoting the use of electricity, and Central Hudson Gas & Electric Corporation challenged the ban as a violation of its First Amendment rights. 447 U.S. at 558–59. The Court acknowledged that "[t]he First Amendment . . . protects commercial speech" because it "furthers the societal interest in the fullest possible dissemination of information." *Id.* at 561–62 (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–62 (1976)). But the government may still regulate commercial speech more than it does "other constitutionally guar-

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Becerra (*NIFLA*), 585 U.S. 755 (2018), and *303 Creative LLC v. Elenis*, 600 U.S. 570 (2023). But *303 Creative* is inapplicable because that case dealt not with disclosures about the *terms* under which the service was available, but instead with compelling those services. *See* 600 U.S. at 580; *cf. NetChoice, L.L.C. v. Paxton*, 49 F.4th 439, 485 (5th Cir. 2022) *cert. granted in part*, 144 S. Ct. 477 (2023). In other words, *303 Creative* was much more like *West Virginia Board of Education v. Barnette*, 319 U.S. 624 (1943), or *Wooley v. Maynard*, 430 U.S. 705 (1977), where the government compelled substantive speech, whereas this case is much more like *NetChoice* and *Zauderer*, where the government compelled certain terms. *NIFLA* is applicable, though, and we discuss it *infra*.

[34] *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573–74 (1995); *see also Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988).

[35] *See, e.g.*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010); *NIFLA*, 585 U.S. 755.

[36] *See, e.g.*, *NetChoice*, 49 F.4th at 485; *Chamber of Com. v. SEC*, 85 F.4th 760 (5th Cir. 2023).

anteed expression." *Id.* at 563 (citing *Ohralik v. Ohio State Bar Ass'n*, 463 U.S. 447, 456 (1978)). So, the Court applied a form of intermediate scrutiny—requiring narrow tailoring and a substantial government interest—to the Commission's rule and struck it down. *Id.* at 569–72.

Five years later, in *Zauderer*, the Court created a carve-out to *Central Hudson*'s rule for government-*compelled* commercial speech. The Court reviewed the discipline of an Ohio attorney who had published two newspaper advertisements. The Court began by explaining that "advertising . . . falls within those bounds" of commercial speech that "is entitled to the protection of the First Amendment, albeit to protection somewhat less extensive than that afforded 'noncommercial speech.'" *Zauderer*, 471 U.S. at 637 (citations omitted). And the Court applied *Central Hudson* to the speech restrictions. *Id.* at 638.

The Court applied a different standard, however, to compelled disclosures in advertising. It acknowledged that "in some instances[,] compulsion to speak may be as violative of the First Amendment as prohibitions on speech"[37] and that no State may "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein."[38] Yet speakers have no protected interests in false statements,[39] and Ohio had "prescribe[d] what shall be orthodox [only] in *commercial advertising*," not all speech. *Id.* at 651 (emphasis added). Further, the "prescription ha[d only] taken the form of a requirement that [Zauderer] include . . . purely factual and uncontroversial infor-

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[37] 471 U.S. at 638 (citing *Wooley*, 430 U.S. 705; *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241 (1974)).

[38] 471 U.S. at 651 (quoting *Barnette*, 319 U.S. at 642).

[39] *See id.* at 638 (citing *Friedman v. Rogers*, 440 U.S. 1 (1979)).

mation . . . ." *Id.* Thus, his limited rights in commercial advertising were "adequately protected" because his "interest in *not* providing any particular factual information in his advertising [wa]s minimal." *Id.* And the disclosure requirements were neither (1) "unjustified or unduly burdensome" nor (2) "[un]related to the State's interest in preventing deception of consumers." *Id.*; *see also id.* at 651 & n.14.

Then, in *Milavetz*, 559 U.S. at 249–50, the Court applied *Zauderer* to uphold the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005. The Bankruptcy Code's disclosure requirement was "directed at misleading commercial speech"; "the challenged provisions impose[d] a disclosure requirement rather than an affirmative limitation on speech"; and "the disclosures entail[ed] only an accurate statement . . . ." *Id.* (emphasis omitted). Therefore, the law did not violate the First Amendment.

Most recently in *NIFLA* in 2018, the Court distinguished *Zauderer*. It struck down a California law that required crisis-pregnancy centers to provide notices related to, among other things, the availability of state-sponsored abortion services. 585 U.S. 760–62, 765. Describing *Zauderer*, the Court did not refer to any requisite claimed state interest in preventing misleading speech. *Id.* at 768–69, 776–77.[40] Instead, the Court distinguished *Zauderer* by focusing on the controversial nature of abortion as well as the fact that the disclosures discussed state-provided services rather than compelled-speaker-provided services. *Id.* at 768–69.

Four years after *NIFLA*, we applied *Zauderer* in *NetChoice*. Describing our pre-enforcement review of a law requiring social media companies to publish three censorship disclosures as "controlled by . . . *Zauderer*," we

[40] Indeed, the Court assumed that the informational interest was substantial before it preliminarily enjoined the law for failing narrow tailoring. 585 U.S. at 776–78.

declared the disclosures to be factual and noncontroversial. 49 F.4th at 485. Then, we held that the state's interest in "enabling users to make an informed choice regarding whether to use [social media] Platforms" was sufficient to survive review under *Zauderer*. *Id.* (cleaned up).

Finally, just a few months ago, in *Chamber of Commerce*, we reviewed the SEC's ability to compel speech by publicly traded companies related to share buybacks. 85 F.4th at 766–67. Applying *Zauderer* and *NetChoice*, we ruled that the disclosure of a company's rationale for a stock buyback was purely factual and uncontroversial commercial speech. *Id.* at 768–72 (citing *NetChoice*, 49 F.4th at 485–88).

Distilling that precedent, *Zauderer* applies where the compelled speech is (1) purely factual and (2) uncontroversial. To survive *Zauderer* scrutiny, the warnings must (3) be justified by a legitimate state interest and (4) not unduly burdensome. FDA's Warnings meet all four requirements.

a. The Warnings Are Purely Factual.

Despite the myriad applications of *Zauderer*, neither the Supreme Court nor this court has expressly defined "purely factual . . . information." *Zauderer*, 471 U.S. at 651. The closest comes from the distinction between a statement of fact that "expresses certainty about a thing," and "a statement of opinion . . . [that] does not."[41] We have similarly described "'explain[ing]

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[41] *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 183 (2015); *see also generally Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 101 (1990). We recognize that "the language of an opinion is not always to be parsed as though we were dealing with language of a statute." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374 (2023) (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 341 (1979)). But the "difference between [a statement of fact and a statement of opinion] is so ingrained in our everyday ways of speaking and thinking" that the use of "factual" suggests little else. *Omnicare*, 575 U.S. at 183. With that ruling, we join the Sixth Circuit in its interpretation of *Zauderer*, *see Discount Tobacco*, 674 F.3d at 556–58, and the Second Circuit, *see Nat'l Elec.*

the reason' for [a company's] actions [as] a purely factual disclosure." *Chamber of Comm.*, 85 F.4th at 769 (quoting *NetChoice*, 49 F.4th at 446, 485). But, we have cautioned, the government may not demand a private party "undertake contextual analyses, weighing and balancing many factors . . . that depend on community standards," to determine the speech it must parrot. *Book People, Inc. v. Wong*, 91 F.4th 318, 340 (5th Cir. 2024).

Those interpretations closely mirror common usage as seen in several dictionaries. As a grammatical matter, both "purely" and "factual" describe "information." Therefore, we set our baseline understanding by defining "information"; and then we narrow it.

The Oxford English Dictionary ("OED") defines "information" as "[f]acts provided or learned about something" and as "[w]hat is conveyed or represented by a particular arrangement or sequence of things."[42] Similarly, Garner's Dictionary of Legal Usage ("Garner's") defines "information" through "knowledge," but as "a broader term, covering the full gamut ranging from all that is meant by knowledge to putative facts, unverified and unverifiable facts, and a collection of falsehoods."[43] Therefore, we define "information" quite broadly.

Zauderer narrows that baseline by requiring that the information be factual. Garner's defines "factual" as "of or involving facts" or as "true."[44]

Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114 n.5 (2d Cir. 2001).

[42] *Information*, Oxford English Dictionary, tinyurl.com/8f83y7dd (last visited Feb. 22, 2024).

[43] *Knowledge*, Garner's Dictionary of Legal Usage, tinyurl.com/38hcdcsu (last visited Feb. 22, 2024) (emphasis omitted).

[44] *See Fact (adj.); factual*, Garner's Dictionary of Legal Usage, tinyurl.com/2fyb6hjz (last visited Feb. 22, 2024). Garner's also defines "fact" as, *inter alia*, "an event, an occurrence, or a circumstance." *Fact (n.); factum*, Garner's Dic-

OED similarly explains that "factual" means (1) "[c]oncerned with what is actually the case rather than interpretations of or reactions to it" and (1.a) "actually occurring."[45] Applying those definitions, we understand "factual" to limit "information" to falsifiable material and inferences fairly drawn from it, rather than one's non-falsifiable "interpretations[,] . . . reactions," or opinions.

To reach this understanding, we reject the construction that plaintiffs and the district court proffer—that, to be factual, the information must be true. Despite that such a reading matches Garner's second definition, were we to adopt that interpretation, we would create surplusage: The adverb "purely" becomes entirely redundant in the phrase "purely factual information" if "factual information" already excludes any information that is not true and objective.[46] Therefore, instead of reading surplusage into the phrase, we adopt the more natural reading.[47]

Guided by that understanding of *Zauderer*, we must determine whether the Warnings are (1) statements composed of only (a) information supported by facts and (b) conclusions driven by those facts, and (2) not akin to unfalsifiable statements of opinion.[48]

TIONARY OF LEGAL USAGE, tinyurl.com/mrunrusp (last visited Feb. 22, 2024).

[45] *Factual*, OXFORD ENGLISH DICTIONARY, tinyurl.com/3v4k9y3y (last visited Feb. 22, 2024).

[46] *See Purely*, OXFORD ENGLISH DICTIONARY, tinyurl.com/yafbr6mh (last visited Feb. 22, 2024) (defining "purely" as "[e]ntirely; exclusively.").

[47] Additionally, if we understood "factual" to mean "true," we could only define "uncontroversial" as relevant to politics or disfavor. As explained below, we see no justification for that reading.

[48] We expressly refrain from suggesting that a factual statement is necessarily an accurate one. *Cf. Scott v. Harris*, 550 U.S. 372, 380 n.7 (2007). As we discuss *infra*,

Because plaintiffs challenge each component of the Warnings as well as the Warnings as a whole, we begin with the text. The Surgeon General's 2014 report found that cigarette smoking causes the negative health consequences identified in the textual warnings.[49] Without contesting the Surgeon General's report, plaintiffs allege that the updated textual warnings create Warnings that "misleadingly exaggerate smoking risks" and improperly "focus on conditions that less frequently arise from smoking." Yet they acknowledge that the 1984 (and currently used) "Surgeon General's warnings are purely factual[and] uncontroversial."

We cannot square those contentions. Consequences supported by scientific findings, even if exaggerated or non-modal, are still, by definition, factual. Thus, though the Rule does not use the TCA's exact language, we, like the Sixth Circuit, hold that the "factual content of the textual warnings is undisputed."[50] So, the crux of the dispute must center on the images.

We agree with the Sixth Circuit's reasoning and its examples of images that might be factual. The Warnings fall well within the ambit of those examples. The addition of images to the textual warnings makes no difference to the constitutional analysis of factuality.

In *Discount Tobacco*, the Sixth Circuit read *Zauderer*'s depiction of an IUD to "demonstrate[] that a picture can be accurate and factual." 674 F.3d

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accuracy is a matter of controversy. Instead, the "factual" nature of a statement turns on the certainty the statement expresses. *See Omnicare*, 575 U.S. at 183.

[49] *See* 85 Fed. Reg. at 15646, 15670, 15672–84; *see also supra* note 23 and accompanying text.

[50] *Discount Tobacco*, 674 F.3d at 558; *see also Altria Grp., Inc. v. Good*, 555 U.S. 70, 87–91 (2008) (suggesting that "statements of tar and nicotine content . . . shown to be accurate and fully substantiated by tests" are factual statements (cleaned up)).

at 560 (citing *Zauderer*, 471 U.S. at 647–49).[51] It then suggested several examples of images that it would consider factual.[52] For this 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." 85 Fed. Reg. at 15646. As one of the *amici* explained it, each of the images provides "a straightforward, science-based, objectively truthful depiction of the accompanying text." The images are no different from those a medical student might see in a textbook, and several are of exactly the type described by the Sixth Circuit as purely factual. We see no reason to split from our sister circuit.

Plaintiffs then claim the Rule is unlawful because it conveys an ideological or provocative message. They imply a requirement that is absent, and we join the Sixth Circuit in rejecting their imaginative, novel limitation. *See Discount Tobacco*, 674 F.3d at 569.

A fact does not become "value-laden" merely because the fact drives a reaction. But even if it did, ideological baggage has no relevance to the first *Zauderer* prong. Any number of factual messages are, of course, ideological.[53]

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[51] *See also Peel*, 496 U.S. at 106–07 (describing an attorney's statement as a "Certified Civil Trial Specialist by the National Board of Trial Advocacy" as "pos[ing] no greater potential of misleading consumers than . . . confusing a reader with an accurate illustration" and citing *Zauderer*, 471 U.S. 626); *Pub. Citizen Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 219 (5th Cir. 2011) ("A depiction of a scene or picture can be presented in a non-deceptive way in an attorney advertisement." (citing *Zauderer*, 471 U.S. at 647)).

[52] *See supra* part B.1 (citing *Discount Tobacco*, 674 F.3d at 559).

[53] *See Glickman v. Wileman Bros. & Elliot, Inc.*, 521 U.S. 457, 492 n.6 (1997) (Souter, J., dissenting). We offer the following example: "The Nazis committed genocide." That is a factual statement. It is also a statement that denounces the Nazi's actions and

Similarly, emotional response to a statement is irrelevant to its truth. That someone may have to declare bankruptcy is likely to engender strong emotions. But the Court never even discussed that aspect of the mandatory disclosures of *Milavetz*. *See* 559 U.S. at 249–50.

Further, unlike the images before the D.C. Circuit in *R.J. Reynolds*, these images *are* "meant to be interpreted literally." 696 F.3d at 1216. They 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. *Id.* Thus, at most, the emotional response of viewers is incidental to their retention of information about the health risks. Consequently, even if we adopted the D.C. Circuit's reasoning, the emotional impact of the Warnings does not abrogate their factual nature.

Plaintiffs and the district court next suggest that because the images may be subject to several interpretations, they cannot possibly have *one* factual meaning.[54] Plaintiffs take further issue with the FDA's lack of "testing to ensure the warnings have only one meaning." But when each image is paired with a fact-based, textual warning, any reasonable viewer interprets the image in light of the words. Each image *emphasizes* the factual meaning of the words it accompanies; it does not impart distinct, novel meaning. In other words, it provides context.[55]

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beliefs as morally repugnant. That is an ideological message. Though the government may not be able to compel Volkswagen to include that message in its advertising without justification, a court would likely still review any such attempt under *Zauderer*.

[54] In the abstract, they are right. To one viewer, Little Boy's atomic plume shows the greatest threat to human survival ever created. To another, it symbolizes the end of World War II. Regardless of the interpretation, though, it factually shows the result of dropping a nuclear bomb.

[55] *Cf. Milavetz*, 559 U.S. at 252 ("The required statement that the advertiser

In its analysis, the district court considered the possible different interpretations of the image bereft of the text. That was error. Consumers will see not just the image, but the image *with* the text. That context matters.

Finally, contrary to the district court's reasoning, we uncover no case-law requiring the government to choose only the most common side-effect or consequence of the disease or injury discussed in a warning.[56] Indeed, *Milavetz* forecloses the "single, objective meaning" approach to determining whether a compelled disclosure is factual. People may interpret "debt relief agency" in many ways, but disclosing that a business *is one* is still purely factual. *See* 559 U.S. at 251–52. Similarly, there is no requirement that cigarette manufacturers "undertake contextual analyses, weighing and balancing many factors to determine" the warning—the FDA did that for them. *Book People*, 91 F.4th at 339. Therefore, the Warnings are factual so long as FDA's claims are inferable from scientific observation.

Thus, the Warnings are factual under *Zauderer*.

b. The Warnings Are Uncontroversial.

Plaintiffs claim that the Warnings are not uncontroversial for the same reasons they are not factual. We review the cases discussed above and disagree.

In *NIFLA*, the Court found that the abortion-services notifications were controversial, 585 U.S. at 769, but, in *NetChoice*, we found that disclosures of social media censorship decisions were not controversial, 49 F.4th

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'help[s] people file for bankruptcy relief' gives meaningful *context* to the term 'debt relief agency.'" (emphasis added)).

[56] As FDA points out, it would "not [be] feasible . . . for a single warning to convey all the information that may be related to a particular health condition." 85 Fed. Reg. at 15684.

at 485. From these disparate results, we distill the following: A factual statement is "controversial" under *Zauderer* where the truth of the statement is not settled or is overwhelmingly disproven or where the inherent nature of the subject raises a live, contentious political dispute.[57] In other words, that the speaker does not like the message does not make it controversial; there must be something more. *See Chamber of Com.*, 85 F.4th at 770 (weighing the level of political controversy). If mere dislike sufficed, Zauderer would have prevailed, as he certainly did not want to drive away potential clients by telling them they might still be liable for costs. Similarly, if mere connection to a live, contentious, political issue sufficed, NetChoice would have prevailed.[58]

Yet, plaintiffs never suggest any good-faith debate that the Warnings are not truthful. As discussed in the section above, we evaluate the compelled speech's truthfulness as a matter of "controversy." But where, as here, neither party disputes the Warnings' claims and *amici* offer even more support for their factualness, any controversy must derive from the subject matter or the presentation of the Warnings.

Nevertheless, the assertion of controversy fails here too. Plaintiffs contend only that the Warnings are emotion-inducing and ideological. They do not assert that cigarette warnings are an inherent part of a national political debate. Instead, plaintiffs merely dislike the nature of the warnings. Yet, just as bankruptcy warnings, disclosure of stock buyback rationales, and explana-

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[57] *See Consol. Edison Co. of N.Y., Inc. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 530, 535 (1980); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n.*, 475 U.S. 1, 8–9 (1986); *see also Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1277–78 (9th Cir. 2023).

[58] Indeed, if mere dislike sufficed, the government could never compel any disclosure. If the speaker liked the disclosure, it would presumably already be making it. That proves too much.

tions of social media censorship decisions may induce emotions or be related to ideological and political issues while remaining uncontroversial, so too the Warnings.

Thus, the Warnings are uncontroversial under *Zauderer*.

2. The Rule Satisfies *Zauderer*.

Assured that the Warnings are both factual and uncontroversial, we now apply *Zauderer*'s deferential standard of review, under which the Warnings must be "reasonably related to the State's interest" and not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651.

Plaintiffs aver that the warnings are unjustified for two reasons. First, that FDA does not claim an interest in preventing deception, which plaintiffs contend *Zauderer* requires. Second, that even if *Zauderer* does not require an anti-deception interest, FDA still has not proven its informational interest sufficient or the Warnings effective.

a. FDA's Interest Is of the Type Subject to Zauderer *Scrutiny.*

Plaintiffs claim that, because *Zauderer* upheld the compelled speech as "reasonably related to the State's interest in preventing deception of consumers[,]" only *that* interest suffices. 471 U.S. at 651. In other words, anti-deception is a necessary interest, and that interest must independently justify the entire rule on *Zauderer* review. Yet, mirroring the TCA, the FDA justifies the Rule by claiming primarily that the government has an interest in "greater public understanding" of the risks of smoking. 85 Fed. Reg. at 15650; *see* TCA § 3(6). So, in plaintiffs' view, the government's interest is not cognizable under *Zauderer*. Once again, we conclude otherwise: *Zauderer* does not require the state to assert an anti-deception interest.

Plaintiffs' primary contention is that "the Supreme Court has never held that *Zauderer* applies outside the consumer-deception context." So, it

must not apply in any other context. Our sister circuits have read *Zauderer* differently, though. As the D.C. Circuit explained in *American Meat Institute*, "the principles articulated in *Zauderer* apply more broadly to factual and uncontroversial disclosures required to serve other government interests" than the prevention of deception. 760 F.3d at 21–23. The First,[59] Second,[60] Sixth,[61] and Ninth Circuits[62] have also taken that approach.

Chamber of Commerce and *NetChoice* also endorse that broader application of *Zauderer*. In *Chamber of Commerce*, we upheld the buyback disclosure law on the ground that the "SEC has a legitimate interest in promoting the free flow of commercial information"; we ruled that was "more than enough to satisfy this prong of *Zauderer*." 85 F.4th at 771. That analysis pointedly dropped the deception-of-consumers rationale from its description of *Zauderer*. In *NetChoice*, we similarly described *Zauderer* as mandating that "disclosure requirements . . . be reasonably related to a legitimate state interest, *like* preventing deception of consumers." 49 F.4th at 485 (emphasis added).

Further, the Supreme Court implicitly adopted that reasoning in *NIFLA* when it declined to "decide what type of state interest is sufficient to sustain a disclosure requirement . . . ." 585 U.S. at 776. Therefore, we follow the Supreme Court, finish the job started by *NetChoice* and *Chamber of Commerce*, and join our sister circuits' interpretation.

One of the *amici* suggests that in *Test Masters Educational Services, Inc.*

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[59] *See Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005).

[60] See *Sorrell*, 272 F.3d at 115.

[61] *See Discount Tobacco*, 674 F.3d at 556–58.

[62] See *CTIA—The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019).

v. Robin Singh Educational Services, Inc.,[63] this court based its holding on the interest of eschewing the "deception of consumers."[64] Thus, *amicus* contends, we are limited to applying *Zauderer* only to that interest. But no analysis accompanied our statement in *Test Masters*. Instead, like *Zauderer*, we merely concluded the government's interest in preventing deception sufficed, not that that interest was necessary.[65] The same can be said for *Public Citizen*, where we again accepted the interest in preventing deception as sufficient without deciding it was necessary. 632 F.3d at 227. Further, we see no way to adopt the *amicus*'s reading of *Public Citizen* without disregarding our acknowledgment that the government also had a "substantial interest in promoting the ethical integrity of the legal profession" as we upheld that case's disclaimer requirement. *Id.* at 228.[66]

In other words, our review uncovers both (1) in-circuit applications of *Zauderer* with non-consumer deception interests claimed by the state and

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[63] 799 F.3d 437 (5th Cir. 2015), *on reh'g*, No. 13-20250, 2015 WL 13768849 (5th Cir. Oct. 22, 2015).

[64] *See id.* at 453.

[65] *See id.* ("This standard applies because Singh's original posting was deceptive.").

[66] That same *amicus* also contends that we have applied heightened scrutiny to "compelled disclosures unrelated to preventing consumer deception," so we must do so here under *Hersh v. United States ex rel. Mukasey*, 553 F.3d 743, 764–68 (5th Cir. 2008). But that case only very briefly made mention of *Zauderer*. We neither distinguished *Zauderer* nor suggested it did not apply because we did not need to do so. In *Hersh*, the district court had found that the disclosure survived heightened scrutiny, so we had no need to determine the applicable level of scrutiny.

Allstate Ins. Co v. Abbott, 495 F.3d 151, 165 (5th Cir. 2007), presents a similarly distinguishable application. There, we cited *Zauderer* for the state's anti-deception interest. Next, we immediately turned to *Central Hudson*. In other words, we never explicitly ruled that *Zauderer* applies *only* to deceptive advertising; we held only that *Central Hudson* applies to restrictions on speech (as distinguished from compelled speech).

(2) persuasive out-of-circuit applications. Joining our sister circuits, we hold that *Zauderer* applies even when the government's claimed primary interest is not the prevention of consumer deception. The standard is not that *only* anti-deception interests suffice, but that *any* legitimate state interest suffices, and anti-deception is a legitimate state interest. *See Chamber of Com.*, 85 F.4th at 768. Increasing public understanding of the risks of smoking, particularly given the "long history of deception concerning consumer health risks in the cigarette industry," is a legitimate state interest, meeting that standard.[67]

b. FDA's Claimed Interest Justifies the Warnings.

Plaintiffs compare the Warnings to the disclosures struck down in *NIFLA* and claim that the Warnings are unjustified because (1) the interest is insufficient or too amorphous and (2) FDA has not proven the Warnings effective. We conclude otherwise.

We begin with the claimed interest in the images. FDA asserts that the images serve an informational interest. In *Zauderer*, the Court explained that "[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly." 471 U.S. at 647. The Warnings do exactly that—they "attract attention" and

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[67] 85 Fed. Reg. at 15645. Even if *Zauderer* required an anti-deception interest, FDA has sufficiently alleged, and has an interest in preventing, consumer deception related to tobacco marketing. Congress explicitly found that "[t]obacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors." TCA § 2(17). Further, FDA describes its interest in remedying the public's "*misperceptions* about the health risks caused by smoking" and the "long history of *deception* concerning consumer health risks in the cigarette industry." 85 Fed. Reg. at 15638, 15645 (emphases added); *see also generally Philip Morris*, 566 F.3d 1095. Finally, the Sixth Circuit took a similar approach in *Discount Tobacco*, and we see no reason to suggest it did so improperly. *See* 674 F.3d at 562–63.

"impart information."

Indeed, FDA justified the Warnings through an informational interest, specifically focusing on raising consumer awareness: the agency tested the Warnings' effectiveness in raising consumer awareness and then refined them based on those results. *See* 84 Fed. Reg. 42768–69. Consequently, the informational interest suffices under *Zauderer*, and FDA's selection of images in the Warnings serves that interest.

Next, we turn to the breadth of the claimed interest. In *NIFLA*, the Court explained that a compelled disclosure is justified only if it will "remedy a harm that is 'potentially real[,] not purely hypothetical,' and . . . 'extend[s] no broader than reasonably necessary.'"[68] Plaintiffs challenge that the current Surgeon General's warnings are sufficient, so the imposition of the new Warnings must inherently "extend" the First Amendment harm more "than reasonably necessary."

Not only did the Sixth Circuit reject that position in *Discount Tobacco*, *see* 674 F.3d at 563–64, but that claim also ignores FDA's significant evidence that consumers do not notice, much less internalize, the text-only warnings in the *status quo*.[69] The updated warnings serve to remedy the harm that

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[68] *NIFLA*, 585 U.S. at 776 (first quoting *Ibanez v. Fla. Dept. of Bus. & Pro. Regul., Bd. of Accountancy*, 512 U.S. 136, 146 (1994), then quoting *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

[69] *See* 85 Fed. Reg. at 15653–57; 84 Fed. Reg. at 42760–65. Plaintiffs inconsistently claim that the disclosure requirements are overly emotional and ideological such that they become non-factual speech, while also asserting that FDA's informational interest does not justify the Warnings because they will not be effective. In other words, plaintiffs suggest consumers will simultaneously notice and not notice the warnings. But, as an *amicus* explains, "disclosure requirements would serve little purpose if they could be invalidated on the ground that consumers might use the information provided in deciding whether to purchase and use the products or services at issue." Though we do not rely on that

buyers might (1) not know about tobacco's harms or (2) ignore the existing Surgeon General's warnings. In other words, FDA and Congress have well justified the extent of the new warnings.

Finally, we consider the effectiveness of the Warnings. Plaintiffs assert that alleged flaws in the FDA's studies should be reason to discount their results. At the current stage, though, we search only for the regulation's reasonable relation to the legitimate state interest.[70] Whether FDA's use of the studies survives APA review is a question we consider separately from our *Zauderer* review. FDA has sufficiently proven that the Warnings reasonably relate to and further its legitimate, and substantial, interest.[71]

Thus, for purposes of *Zauderer*, the legitimate state interest justifies the Warnings.

c. The Warnings Are Not Unduly Burdensome.

Plaintiffs challenge the Warnings as an undue burden by claiming that the size and content of the Warnings will make it nearly impossible to convey information to potential customers. Three fatally erroneous assumptions underlie plaintiffs' assertion:

First, plaintiffs conflate *Zauderer* and *Central Hudson*, describing *Zauderer* as merely an application of *Central Hudson*.[72] But those are different

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inconsistency in ruling that the Warnings are sufficiently justified, it does weaken plaintiffs' claim. *See also supra* note 15.

[70] *See Chamber of Commerce*, 85 F.4th at 771.

[71] As discussed above, that people already know smoking is dangerous does not mean that they know all the health consequences of smoking. Informing them of those is a legitimate state interest.

[72] To justify this reading, plaintiffs cite then-Judge Kavanaugh's concurrence in *American Meat Institute*. *See* 760 F.3d at 33. But that concurrence did not receive a majority

tests. That some speech fails *Central Hudson* does not mean that speech automatically fails *Zauderer*. Indeed, the Court applied *Central Hudson* in *Zauderer* when it addressed speech restrictions, but it then declined expressly to adopt *Central Hudson* in its analysis of compelled speech. *See Zauderer*, 471 U.S. at 651 & n.14. Further, the Supreme Court treats the two as distinct.[73] Thus we decline to merge these distinct tests into one.

Second, plaintiffs focus their claim of burden solely on the size of the warnings. Yet these Warnings are no larger than those upheld by the Sixth Circuit when it reviewed the TCA. *See Discount Tobacco*, 674 F.3d at 567. Even though FDA updated the Warnings from those Congress selected in the TCA, they have not changed the size of the Warnings. We decline to give RJR a new chance to relitigate this issue without any factual distinctions.

Third, and most fundamentally, we reject plaintiffs' claim that any burden is inherently undue. True, the Warnings impose a burden on plaintiffs.[74] But that alone does not offend the Constitution. Instead, we must inquire whether that burden is *undue*. In other words, the regulation cannot impose a burden excessive or disproportionate to the benefits gained.

We draw that balancing requirement both from the plain meaning of "undue"[75] and from precedent. In *NIFLA*, the Court weighed the disclosure

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vote of the D.C. Circuit, has never been adopted by the Supreme Court, and has never been accepted by this court.

[73] In *NIFLA*, the Court first concluded *Zauderer* did not apply. Then, it expressly admitted to uncertainty over the standard applied to compelled speech that does not receive *Zauderer* scrutiny: *Central Hudson* or strict scrutiny. *See NIFLA*, 585 U.S. at 773.

[74] Nor is that unique to the Warnings. Any compelled speech, particularly compelled speech with which the speaker disagrees, inherently imposes some burden.

[75] *See Undue*, Oxford English Dictionary, tinyurl.com/56jcsuhx ("Unwarranted or inappropriate because excessive or disproportionate.").

requirement and found it lacking. The requirements (1) were "wholly disconnected from California's informational interest"; (2) allowed for no consideration of "what the facilities say on site or in their advertisements"; and (3) "cover[ed] a curiously narrow subset of speakers." 585 U.S. at 777; *see also id.* at 777–79. Therefore, the burden outweighed any possible benefit.

In *NetChoice*, after deciding that *Zauderer* applied, we similarly turned to whether the disclosure requirements were unduly burdensome. 49 F.4th at 485. Our analysis focused on the possibility of chilling protected commercial speech. *Id.* at 486 (citing *Zauderer*, 471 U.S. at 651). We found that the one-and-done and the biannual transparency disclosure requirements would not possibly "burden the Platforms' protected speech," so they both survived *Zauderer* review. *Id.* Then, we upheld the complaint-and-appeal disclosure requirement because the burden of the disclosure was not so significant in the context of the "statute's plainly legitimate sweep" that it reached the level of an undue burden. *Id.* at 487 (quoting *Ams. for Prosperity Found. v. Bonta*, 141 S. Ct. 2373, 2387 (2021)). In other words, we balanced the harm and the benefit, found the harm was minimal and the benefit significant, and ruled the burden was constitutional.

Finally, in *Chamber of Commerce*, we similarly balanced the interests. We explained that the compelled disclosures were not unduly burdensome because they "neither burden[] issuers' protected speech nor drown[] out their message." 85 F.4th at 772. We found the balance tilted toward the SEC because it had imposed additional speech only "within the narrow confines of SEC filings . . . ." *Id.* (citing *NetChoice*, 49 F.4th at 486).

As explained earlier, FDA claims the Warnings directly alleviate information asymmetry regarding the harms tobacco causes and consumers' suboptimal awareness of and response to those harms. And the government has shown a significant benefit from the resultant reduction in those harms. *See*

TCA § 2; *see also* 84 Fed. Reg. at 42,779; *supra* part II.B.2.b.

On the other hand, plaintiffs claim two large burdens—that the government is infringing on their First Amendment rights and that they will suffer financial harm.

The scale tilts toward the benefits for two reasons.

First, plaintiffs can still speak on 80% of their advertisements, and they still control more than 50% of the total surface area of their cigarette packages. *See* 15 U.S.C. § 1333(a)(2), (b)(2). The remaining portions offer "ample room for manufacturers to distinguish their products from other products." 85 Fed. Reg. at 15647. Thus, we are not concerned that the brands will be "drown[ed] out" by the warnings such that plaintiffs would have no reason to speak at all. *Contra NIFLA*, 585 U.S. at 778. Though the Warnings will not produce "additional speech" in the same way the novel disclosures did in *NetChoice* or *Chamber of Commerce*, they also do not impose a disproportionate requirement that would "'effectively rule[] out' the possibility of having [an advertisement] in the first place." *NIFLA*, 585 U.S. at 778 (quoting *Ibanez*, 512 U.S. at 146). So, it is extremely unlikely that the Warnings will chill protected commercial speech. *See NetChoice*, 49 F.4th at 485.

Second, as mentioned earlier, plaintiffs have, at most, a minimal interest in not withholding useful and factual information from their customers. *See Zauderer*, 471 U.S. at 651. Any harm suffered purely because of an infringement on that minimal interest is limited.

Thus, the Warnings are not unduly burdensome under *Zauderer*.

* * * * *

In sum, because the Warnings are (1) purely factual and (2) uncontroversial, *Zauderer* scrutiny applies. Then, because the Warnings address a legitimate state interest, are justified, and are not unduly burdensome in light

of that interest and justification, the Warnings survive *Zauderer* scrutiny.

C. APA Claim

We turn to plaintiffs' contention that FDA issued the Rule in violation of the APA. The district court never reached the issue, granting summary judgment for plaintiffs solely on its finding that the Rule violated the First Amendment. We generally prefer not to resolve a complicated fact-intensive dispute without the benefit of the district court's reasoning, and the instant case is no exception. So we remand for consideration in the first instance.

Plaintiffs are right that "this Court may affirm . . . on any ground supported by the record and presented to the district court." *Wantou v. Wal-Mart Stores Tex., L.L.C.*, 23 F.4th 422, 430 (5th Cir. 2022). But we generally "will not reach the merits of an issue not considered by the district court" and we see no reason to stretch for them here.[76]

We recognize that an exception to that well-established rule arises where there are "special circumstances." *PHH*, 80 F.4th at 563 (citing *Man Roland, Inc. v. Kreitz Motor Exp., Inc.*, 438 F.3d 476, 483 (5th Cir. 2006)). But those circumstances are not present here. The extensive dispute in the district court, and the limited briefing on appeal, repudiate any suggestion that the "proper resolution is beyond any doubt."[77] *Id.* (quoting *Baker v. Bell*,

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[76] *PHH Mortg. Corp. v. Old Republic Nat'l Title Ins. Co.*, 80 F.4th 555, 563 (5th Cir. 2023) (quoting *Magnolia Island Plantation, L.L.C. v. Whittington*, 29 F.4th 246, 252 (5th Cir. 2022)); *see also Browning v. Kramer*, 931 F.2d 340, 345 (5th Cir. 1991) ("As a court for review of errors, we are not to decide facts or make legal conclusions in the first instance. Our task is to review the actions of a trial court for claimed errors.").

[77] Although, at oral argument, both sides requested that we decide the APA issue now, and though they briefed the merits of the APA dispute in the district court, the parties presented us with comparatively little on the subject on appeal. They spent a combined 11 pages of the 157 in their briefs on this issue, and the district court never addressed it in its order.

630 F.2d 1046, 1056 (5th Cir. 1980)). Further, after an adverse APA ruling by the district court, either party may still appeal, without any concern that "injustice might otherwise result." Thus, the case does not present the necessary "special circumstances" for us to resolve an issue "not passed on below." *Id.* Consequently, we remand for the district court to conduct an initial analysis of the APA claims.

* * * * *

We summarize our conclusions as follows:

When determining whether *Zauderer* applies, (1) images can be factual; (2) ideological or emotion-inducing statements are not *per se* controversial or non-factual; (3) "uncontroversial" means not subject to good-faith dispute about the accuracy of the factual statement; and (4) legitimate state interests other than the prevention of consumer deception are cognizable under *Zauderer*. For the reasons detailed above, the district court erred by finding *Zauderer* inapplicable to the FDA's newest Warnings.[78]

Applying *Zauderer*, the Warnings survive constitutional muster against the First Amendment challenge. We REVERSE and REMAND with direction for the district court to consider the merits of the APA challenge.

[78] Because we reverse on the First Amendment ruling, we pass no judgment on the district court's declination to sever or on its application of vacatur.

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

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March 21, 2024

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW

Regarding: Fifth Circuit Statement on Petitions for Rehearing or Rehearing En Banc

No. 23-40076 R J Reynolds Tobacco v. FDA
USDC No. 6:20-CV-176

Enclosed is a copy of the court's decision. The court has entered judgment under Fed. R. App. P. 36. (However, the opinion may yet contain typographical or printing errors which are subject to correction.)

Fed. R. App. P. 39 through 41, and Fed. R. App. P. 35, 39, and 41 govern costs, rehearings, and mandates. **Fed. R. App. P. 35 and 40 require you to attach to your petition for panel rehearing or rehearing en banc an unmarked copy of the court's opinion or order.** Please read carefully the Internal Operating Procedures (IOP's) following Fed. R. App. P. 40 and Fed. R. App. P. 35 for a discussion of when a rehearing may be appropriate, the legal standards applied and sanctions which may be imposed if you make a nonmeritorious petition for rehearing en banc.

Direct Criminal Appeals. Fed. R. App. P. 41 provides that a motion for a stay of mandate under Fed. R. App. P. 41 will not be granted simply upon request. The petition must set forth good cause for a stay or clearly demonstrate that a substantial question will be presented to the Supreme Court. Otherwise, this court may deny the motion and issue the mandate immediately.

Pro Se Cases. If you were unsuccessful in the district court and/or on appeal, and are considering filing a petition for certiorari in the United States Supreme Court, you do not need to file a motion for stay of mandate under Fed. R. App. P. 41. The issuance of the mandate does not affect the time, or your right, to file with the Supreme Court.

Court Appointed Counsel. Court appointed counsel is responsible for filing petition(s) for rehearing(s) (panel and/or en banc) and writ(s) of certiorari to the U.S. Supreme Court, unless relieved of your obligation by court order. If it is your intention to file a motion to withdraw as counsel, you should notify your client promptly, **and advise them of the time limits for filing for rehearing and certiorari**. Additionally, you MUST confirm that this information was given to your client, within the body of your motion to withdraw as counsel.

The judgment entered provides that Appellees pay to Appellants the costs on appeal. A bill of cost form is available on the court's website www.ca5.uscourts.gov.

Sincerely,

LYLE W. CAYCE, Clerk

Dantrell Johnson

By:_____
Dantrell L. Johnson, Deputy Clerk

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