APPENDIX

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APPENDIX A

United States Court of Appeals
for the Fifth Circuit

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 advertisements.[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.

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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).

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 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

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

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

[6] *Id.* § 4.

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.

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

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[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).

[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.

[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.
>
> WARNING: Cigarettes cause fatal lung disease.
>
> WARNING: Cigarettes cause cancer.

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[10] TCA § 2(15), (17), (18).

[11] *Id.* § 2(31).

[12] *Id.* § 2(14).

> 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

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[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.

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 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

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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)).

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).

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.

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[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.

[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.

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 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)).

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[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*.

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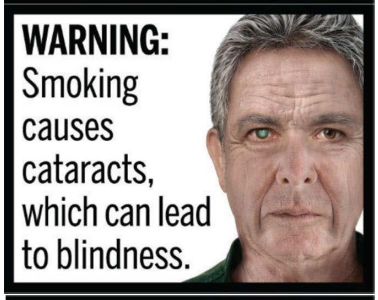
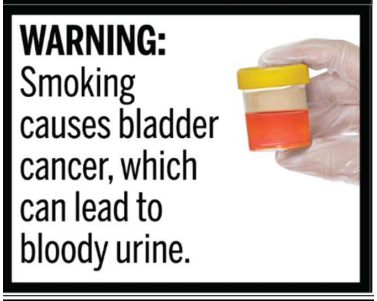
[20] *See Required Warnings for Cigarette Packaging and Advertisements*, 85 Fed. Reg. 15638 (Mar. 18, 2020) (codified at 21 C.F.R. §§ 1141.1–12). The FDA issued this rule only after litigious prompting. *See Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985, 2019 WL 1047149, at *3 (D. Mass. 2019).

[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).

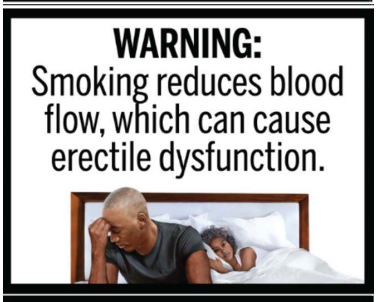

WARNING:
Smoking causes head and neck cancer.


WARNING:
Tobacco smoke causes fatal lung disease in nonsmokers.

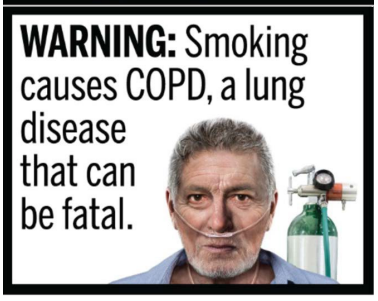

WARNING:
Smoking causes cataracts, which can lead to blindness.

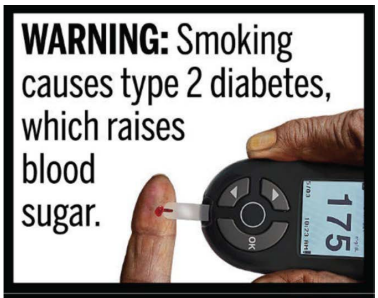

WARNING:
Smoking causes bladder cancer, which can lead to bloody urine.


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

[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

to make those changes derives from § 201 of the TCA, which allows the agency to "adjust the . . . text . . . of the cigarette 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 . . . .

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.

[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)).

Id. at 15695.[24]

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

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[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 warning statements.

Id. at 15695.

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 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

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

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

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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).

TCA as precluded, we would still need to resolve its challenge to the Rule. So, we 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

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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.

regarding prohibitions or restrictions on speech provide, at best, merely persuasive authority.[33] That said, government-compelled speech inherently regulates 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

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[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. 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).

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 guaranteed 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

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[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).

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 information . . . ." *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

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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)).

(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

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[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.

of a law requiring social media companies to publish three censorship disclosures as "controlled by . . . *Zauderer*," we 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] 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

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

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] 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-

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

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

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]

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[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*, 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.

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.

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[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)).

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 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

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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).

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] 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

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[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 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*.

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]

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 caselaw requiring the government to choose only the most common side-effect or consequence of the disease or injury discussed in a

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

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 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

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[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.

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

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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.

merely dislike the nature of the warnings. Yet, just as bankruptcy warnings, disclosure of stock buyback rationales, and explanations 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-

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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).

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. 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

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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.").

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 (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

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[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).

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

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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.

Warnings do exactly that—they "attract attention" and "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

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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

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. 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]

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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 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.

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 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

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[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 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.

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 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.

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[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.").

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' sub-optimal 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. WalMart 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]

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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*

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*, 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

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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.

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.

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[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

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

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

By: 
Dantrell L. Johnson, Deputy Clerk

Enclosure(s)

Mr. Austin Paganelli Anderson
Mr. Cory L. Andrews
Mr. Rohit Pranav Asirvatham
Ms. Lisa Schiavo Blatt
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Ms. Deva Roberts
Mr. Nicholas L. Schlossman
Mr. Mark Bernard Stern
Ms. Meaghan McLaine VerGow
Mr. Christian George Vergonis
Mr. Ryan Jeffrey Watson
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APPENDIX B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS

No. 6:20-cv-00176

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

v.

U.S. Food & Drug Administration et al.,
Defendants.

OPINION AND ORDER

Several motions are ready for resolution in this challenge to an FDA rule. First, the government asks the court to dismiss one plaintiff for lack of subject-matter jurisdiction and to then dismiss or transfer the case for improper venue in this district. For the reasons explained below, the government's argument as to jurisdiction is unpersuasive, and the government's argument as to venue is forfeited. Accordingly, the government's motion to dismiss or transfer (Doc. 36) is denied.

Second, both sides move for summary judgment and agree that no factual disputes require trial. As explained below, plaintiffs are entitled to judgment on their claim that the challenged rule is invalid under

the First Amendment. Accordingly, the court denies defendants' motion for summary judgment (Doc. 37) and grants in part plaintiffs' motion for summary judgment (Doc. 34).

Background

1. Plaintiffs sue to challenge an FDA rule on cigarette health warnings. Such warnings have a long history. For over 50 years, Congress has required health warnings on cigarette packages and advertising.[1] Section 4 of the Labeling Act of 1965 is the precursor of today's regime. It required that cigarette packages state: "Caution: Cigarette Smoking May Be Hazardous to Your Health."

Two decades later, Congress amended § 4 of the Labeling Act to require that cigarette packages and advertising include, on a rotating basis, one of four "Surgeon General's warnings":

- "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, [a]nd May Complicate Pregnancy."
- "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health."
- "SURGEON GENERAL'S WARNING: Smoking [b]y Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight."

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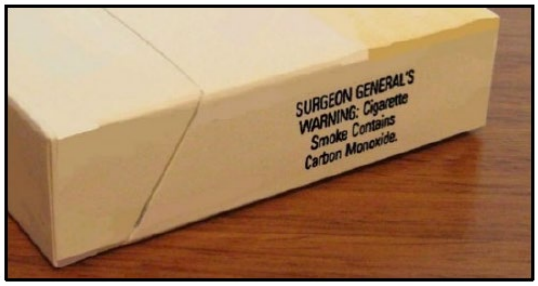
[1] Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 4, 79 Stat. 282, 283 (1965) (codified at 15 U.S.C. § 1333 (1970)).

- "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."[2]

Those warnings typically appear on the side panel of cigarette packages, as shown in the image below:[3]



In the 1990s, the FDA tried to impose additional restrictions on cigarette sales under its existing statutory authority. The Supreme Court, however, read those statutes as withholding authority for such regulations.[4] In response, Congress passed the Family Smoking Prevention and Tobacco Control Act of 2009,[5] which gives the FDA limited authority to regulate tobacco products. The Tobacco Control Act recites Congress's understanding that "tobacco products are inherently dangerous and cause cancer, heart disease,

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[2] Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 4, 98 Stat. 2200, 2201-02 (1984) (codified at 15 U.S.C. § 1333 (1988)).

[3] Institute of Medicine of the National Academies, *Ending the Tobacco Problem: A Blueprint for the Nation* 290 (2007) (Fig. 6-1), *available at* https://www.nap.edu/catalog/11795/ending-the-tobacco-problem-a-blueprint-for-the-nation.

[4] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137 (2000).

[5] Pub. L. No. 111-31, 123 Stat. 1776.

and other serious adverse health effects."[6] Congress expressed particular concern that more limited efforts to regulate tobacco products had "failed adequately to curb tobacco use by adolescents."[7]

Rather than banning tobacco products—which could foster a black market—the Tobacco Control Act creates measures aimed at reducing the usage and dangers of tobacco products. Among other things, the Act approves the FDA's 1990s restrictions on cigarette marketing, finding them "substantially related to accomplishing the public health goals" of the Act.[8] Specifically, Congress found that "[r]educing the use of tobacco by minors" by half would save over three million children from premature deaths,[9] and that advertising "often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors."[10]

The Tobacco Control Act also amends § 4 of the Labeling Act to replace the Surgeon General's warnings with new warnings that have both a textual and a graphic component.[11] Congress set out nine textual warnings—called "label statements"[12]—that must be displayed with equal frequency on a rotating

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[6] *Id.* § 2(2), 123 Stat. at 1777.

[7] *Id.* § 2(6), 123 Stat. at 1777.

[8] *Id.* § 2(30), 123 Stat. at 1778–79.

[9] *Id.* § 2(14), 123 Stat. at 1777.

[10] *Id.* § 2(17), 123 Stat. at 1778.

[11] *See id.* § 201 (codified at 15 U.S.C. § 1333).

[12] 15 U.S.C. § 1333(a)(1), (b)(2).

basis.[13] Congress then directed the Secretary of Health and Human Services to require, by rulemaking, that the label statements be accompanied by color graphics depicting the negative health consequences of smoking.[14]

Congress directed that the label statements must occupy the top half of the front and rear panels of cigarette packages.[15] And Congress directed that the label statements must occupy at least 20 percent of the area of cigarette advertising.[16]

Congress also specified type-size, format, and color requirements for the label statements.[17] But the type-size and format requirements—although not the color requirements—were made subject to adjustment by mandatory and optional rulemaking.[18]

Congress separately gave the Secretary authority to issue rules adjusting the type size, format, color graphics, and text of any label requirements "if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products."[19]

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[13] *Id.* § 1333(c)(2).

[14] *Id.* §§ 1332(9), 1333(d) (first of two subsections (d)).

[15] *Id.* § 1333(a)(2).

[16] *Id.* § 1333(b)(2).

[17] *Id.* § 1333(a)(2), (b)(2).

[18] *Id.* § 1333(b)(4) (*directing* the Secretary to provide for certain adjustments and *allowing* the Secretary to provide for further adjustments).

[19] *Id.* § 1333(d) (second of two subsections (d)).

Those amendments to § 4 of the Labeling Act were made in subsection (a) of § 201 of the Tobacco Control Act.[20] But those amendments were not effective immediately. Rather, Congress directed that the amendments "shall take effect 15 months after the issuance of the regulations required by subsection (a)" of § 201.[21]

Read literally, that provision creates a circularity. There are no regulations required by § 201(a) until § 201(a) takes effect as law. But the parties agree that "required by" should be read as meaning something like "required by § 201(a) were it in effect." The court agrees and adopts that reading to avoid an absurdity.

The parties also agree to another implied qualification: the 15-month countdown clock to the effectiveness of § 201(a)'s statutory amendments runs only if the contemplated regulations are not just *issued* but also *keep their effectiveness* throughout the countdown period. Thus, the parties agree that the Act's additional labeling requirements are "tied to *the effective date* of the graphic-warnings Rule."[22] On that view, a court's postponement of the effective date of the FDA's regulations also postpones the 15-months-after-rulemaking effective date of (i) the Tobacco Control Act's amendment to § 4 of the Labeling Act and (ii) related Tobacco Control Act provisions.[23] The

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[20] Pub. L. No. 111-31, § 201(a), 123 Stat. at 1845.

[21] *Id.* § 201(b), 123 Stat. at 1845.

[22] Doc. 30 at 4 n.1 (citations omitted; emphasis added). Citations to an ECF document ("Doc.") are to the page number added by ECF, not to the parties' assigned numbering.

[23] *See id.*

court accepts the parties' shared understanding of the effective date of the statutory provisions.

2. On June 22, 2011, the FDA issued a final rule specifying graphic health warnings.[24] The rule required that the Act's nine textual warnings be accompanied by graphics on the top half of the front and back panels of cigarette packs and the top fifth of advertisements.[25] As shown, the required graphics[26] included disembodied organs, a distressed baby, and a sutured corpse:

FDA's 2011 Graphics

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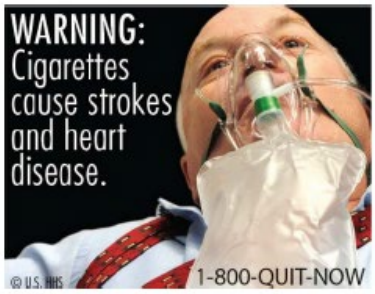
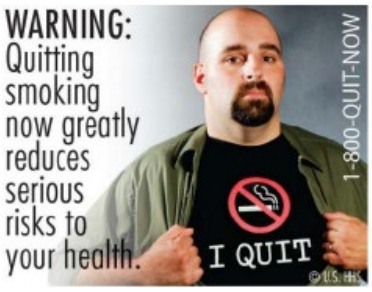
[24] *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011).

[25] *Id.* at 36,674.

[26] *Id.* at 36,629, 36,696; Complaint [Doc. 1] at 23-26, *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266 (D.D.C. 2012) (No. 1:11-cv-01482) (showing images).

FDA's 2011 Graphics





The FDA justified those graphics as reducing the consumption of cigarettes and thus improving public health:

> The warnings currently in use in the United States also fail to include any graphic component, despite the evidence in the scientific literature that larger, graphic health warnings promote greater understanding of the health risks of smoking and would help to reduce consumption. In proposing this regulation and preparing this final rule, we found substantial evidence indicating that larger cigarette health warnings including a graphic component, like those being required in this rule, would offer significant health benefits over the existing warnings.[27]

That regulatory approach follows the path of countries like Australia and Canada, which require cigarette packages to carry large warnings with stark graphic and textual components.[28]

3. Before the FDA's final rule issued in 2011, five cigarette manufacturers—including R.J. Reynolds—and one cigarette retailer sued the government to enjoin enforcement of some provisions of the Tobacco Control Act, including its requirement of graphic and textual health warnings.[29] The district court rejected those plaintiffs' argument that the Act's requirement was facially invalid as an unconstitutional compulsion

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[27] 76 Fed. Reg. at 36,629 (citations omitted).

[28] Institute of Medicine of the National Academies, *supra* note 3, at 292 (describing global approaches).

[29] *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

of and burden on private speech.[30] Graphics for the health warnings had not yet been specified by the FDA. But the court reasoned that a graphic component would not alter the neutral and uncontroversial nature of the required warnings, "at least as a general rule."[31]

The Sixth Circuit affirmed that aspect of the judgment.[32] It held that the Act's textual warnings should be judged under the free-speech standards set out by the Supreme Court in *Zauderer v. Office of Disciplinary Counsel*.[33] The textual warnings complied with those standards, the court held, because they were factual, uncontroversial, and reasonably related to preventing consumer deception (from past tobacco-industry deception).[34]

The Sixth Circuit then held that the Act's requirement of a graphic component to the warnings was not facially invalid. The court could imagine some set of graphics that might satisfy *Zauderer*, such as an illustration merely showing the warnings' text in a child's handwriting.[35] At the same time, the court noted that it was resolving only a facial challenge and that, by the time of its decision, specific images had

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[30] *Id.* at 528-32.

[31] *Id.* at 532.

[32] *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012).

[33] 471 U.S. 626 (1985).

[34] *Discount Tobacco*, 674 F.3d at 558, 562.

[35] *Id.* at 559-60, 564-66.

been chosen by the FDA and were "under review elsewhere."[36]

4. That separate review of the FDA's 2011 graphics took place in the District of Columbia. There, a group of tobacco companies sued and obtained on appeal a judgment vacating the 2011 rule.[37]

The vacatur of the 2011 rule, the parties agree, also postponed the effective date of the Tobacco Control Act's statutory amendments tied to that rulemaking.[38] That understanding leaves the Surgeon General's warnings applicable today, pursuant to the pre-Tobacco Control Act version of the Labeling Act.

The D.C. Circuit's vacatur of the FDA's 2011 rule rests on the First Amendment right to refrain from speaking.[39] That right requires scrutiny of state efforts to compel private speech or private subsidization of speech.[40] The FDA rule was such an effort, the D.C. Circuit held, as the FDA itself claimed to be making the top half of every cigarette package into "[a] mini billboard for the government's anti-smoking message."[41]

The parties disputed what standard of review applies to state action compelling a product's

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[36] *Id.* at 558.

[37] *R.J. Reynolds Tobacco Co. v. FDA*, Doc. 1391187, No. 11-5332, 696 F.3d 1205 (D.C. Cir. Aug. 24, 2012) (judgment).

[38] *See supra* notes 22-23 and accompanying text.

[39] *R.J. Reynolds*, 696 F.3d at 1211 (citing *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)).

[40] *Id.* at 1212.

[41] *Id.*

manufacturer to carry the government's speech. The agency argued for use of the less-stringent standard set out in *Zauderer*. But the D.C. Circuit viewed that standard as limited to disclosure requirements that are reasonably related to preventing consumer deception. On that view, the *Zauderer* standard was inapplicable to warnings based on public health.[42]

The D.C. Circuit also held that the FDA rule failed a second requirement for *Zauderer* treatment: that it compels only "purely factual and uncontroversial" information.[43] The court reasoned that many of the FDA's nine images could be misinterpreted as showing a common consequence of smoking, even though the government justified the images as symbolic rather than showing the nine most common consequences of smoking.[44] The court further held that the graphic warnings were not "purely" factual because they were primarily intended to evoke an emotional response or because they offered advocacy rather than factual information about health effects.[45]

After holding that the FDA rule did not qualify for *Zauderer* review, the D.C. Circuit turned to the general standard of review for commercial-speech

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[42] *Id.* at 1213. The D.C. Circuit has since overruled that aspect of its reasoning and held that *Zauderer* review applies to "factual and uncontroversial" compelled disclosures that serve government interests other than preventing consumer deception. *Am. Meat Inst. v. USDA*, 760 F.3d 18, 21-23 (D.C. Cir. 2014) (en banc) (overruling *R.J. Reynolds* on that point).

[43] *R.J. Reynolds*, 696 F.3d at 1216.

[44] *Id.*

[45] *Id.*

restrictions, which the Supreme Court set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*.[46] That standard requires the state to show that a regulation is narrowly tailored to achieve a substantial interest.[47]

The D.C. Circuit held that the FDA had to rely on the single interest asserted in the challenged rule: reducing the number of Americans, and particularly adolescents, who use tobacco products.[48] Yet no substantial evidence supported the government's argument that causing increased thoughts about quitting smoking would directly lead to an actual, material reduction in smoking.[49] It could just as well be true that causing more thoughts about quitting smoking would not actually overcome smoking's addictiveness.[50] The court apparently relied on the same reasoning about the resilience of the impulse to start smoking despite widespread knowledge of its health risks.

The D.C. Circuit dismissed the government's resort to an interest in "effectively communicating health information," standing alone.[51] A purely informational interest in education, the court reasoned, could not qualify as a substantial interest under *Central Hudson* because such an abstract

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[46] 447 U.S. 557 (1980).

[47] *Id.* at 564-65.

[48] *R.J. Reynolds*, 696 F.3d at 1218.

[49] *Id.* at 1219–21.

[50] *See id.*

[51] *Id.* at 1221.

interest can always be said to be directly advanced by more and more compelled disclosure.[52]

The D.C. Circuit thus held unconstitutional the FDA's attempt to force private companies to spread the government's antismoking message.[53] Relying on circuit precedent, the D.C. Circuit vacated the rule and remanded the rulemaking to the agency.[54]

5. On remand to the agency, the FDA spent years contemplating its future course of action. In 2016, several nonprofit organizations sued, claiming that the agency was unreasonably delaying the issuance of a new graphic-warning rule. A district court ordered the FDA to issue a final rule by March 15, 2020.[55]

On March 18, 2020, after receiving public comment on its proposed rule, the FDA issued a new final rule on cigarette health warnings. The rule requires that cigarette packaging and advertising display, with even frequency on a rotating basis, one of these eleven warnings:[56]

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[52] *Id.*

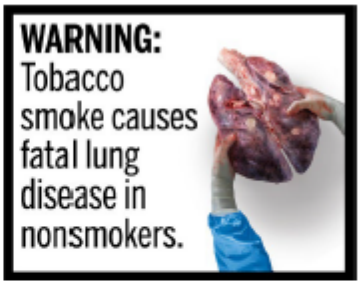
[53] *Id.* at 1221–22.

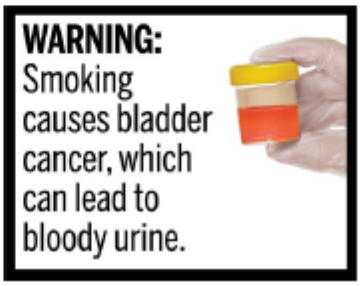
[54] *Id.* at 1222.

[55] *See Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985, 2019 WL 1047149, at *3 (D. Mass. 2019).

[56] 85 Fed. Reg. at 15,690–91; FDA, *Required Cigarette Health Warnings,* 2020, https://www.fda.gov/media/136157/download.

FDA's 2020 Graphics





FDA's 2020 Graphics

In adopting those eleven warnings, the rule does not simply provide graphics for the nine textual warnings

in the Act.[57] The rule omits two of the Act's warnings ("Cigarettes are addictive" and "Quitting smoking now greatly reduces serious risks to your health").[58] The rule then rephrases other warnings from the Act and splits one of the Act's warnings (on cancer) into two.

The rule also includes new warnings, not required by the Act, about three health outcomes (amputation, blindness, and erectile dysfunction).[59] Those additions are based in part on the intervening 2014 Surgeon General's report on smoking.[60] That report identified additional health conditions whose causal link to smoking was reported as established at the highest level of evidence.[61]

Regarding the D.C. Circuit's decision on the prior rule, the new rule disclaims that the government's "one true interest lies in reducing smoking rates."[62] Rather, the government justifies the new rule on an interest "in promoting greater public understanding of the negative health consequences of smoking."[63] That interest flows from the Tobacco Control Act, which allows changes to the graphic warnings to "promote

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[57] *See* 85 Fed. Reg. at 15,641–42 (asserting authority to do so).

[58] *See* 15 U.S.C. § 1333(a).

[59] *See* 85 Fed. Reg. at 15,680–84.

[60] *Id.* at 15,640.

[61] *See id.*; U.S. Dept. of Health & Human Servs., The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General (2014).

[62] 85 Fed. Reg. at 15,644.

[63] *Id.* at 15,650.

greater public understanding of the risks associated with the use of tobacco products."[64]

The rule then attempts to tie the chosen graphics to the government's interest in increasing public understanding. The rule contends that the new warnings will be noticed whereas the Surgeon General's warnings are not: "[T]here is considerable evidence that the Surgeon General's warnings go largely unnoticed and unconsidered by both smokers and nonsmokers . . . [and] have been described as 'invisible. ...'"[65]

The warnings required by the new rule must occupy the top 50 percent of the front and rear panels of cigarette packages and the top 20 percent of cigarette advertisements.[66] That would result in an appearance as follows:[67]

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[64] 15 U.S.C. § 1333(d) (second of two subsections (d)).

[65] 85 Fed. Reg. at 15,640.

[66] *Id.*

[67] U.S. Food & Drug Admin., *FDA Proposes New Health Warnings for Cigarette Packs and Ads* (May 1, 2020), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/fda-proposes-new-health-warnings-cigarette-packs-and-ads.

6. The new rule applies to manufacturers and retailers alike. The rule deems it unlawful conduct to make, package, sell, advertise, or offer for sale cigarettes without the specified warnings.[68] Retailers and manufacturers alike engage in activities on that list. Manufacturers make, package, and advertise cigarettes and sell them to retailers. Retailers too advertise and sell cigarettes.

Retailers may be penalized for their unlawful conduct if they fall outside an enforcement safe harbor in the rule. If a retailer sells or advertises cigarettes without a required warning, the retailer may face a term of imprisonment, a fine, and an injunction if either (i) the retailer materially altered the supplied packaging or advertising or (ii) the supplier did not hold a license or permit.[69]

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[68] 85 Fed. Reg. at 15,709 (21 C.F.R § 1140.10(c), (d)).

[69] *Id.* (21 C.F.R § 1141.1(c)–(d)); *see* 15 U.S.C. §§ 1338–39; 18 U.S.C. § 3581(b).

In addition to that enforcement mechanism, a noncompliant retailer may have its personal property seized and destroyed regardless of the safe harbor from other penalties. Failure to display the warnings makes cigarettes "misbranded" under the rule, which allows the government to seize and condemn them.[70]

7. Plaintiffs in this case are four cigarette manufacturers and five cigarette retailers. One of the retailer plaintiffs is Neocom, which resides in and sells cigarettes in this district. One of the manufacturer plaintiffs is R.J. Reynolds, which is bound by the *res judicata* effect of the Sixth Circuit's judgment on its facial challenge to the Tobacco Control Act.[71] The other plaintiffs are not.

Plaintiffs claim that (i) the rule and the Act's requirements for compelled warnings violate the First Amendment; (ii) the rule violates the Administrative Procedure Act; and (iii) the rule violates the Tobacco Control Act's own requirements for both the text and the graphics of the health warnings.

Early in the case, the parties jointly moved for a postponement of the rule's effective date, which the court granted. The court has extended that postponement while it considered pending motions. Three motions are now ripe for resolution:

(1) the government moves to dismiss plaintiff Neocom for lack of Article III standing;

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[70] 85 Fed. Reg. at 15,709 (21 C.F.R § 1141.12) (citing 21 U.S.C. § 387c); 21 U.S.C. § 334(a)(2)(E), (g).

[71] *See supra* note 35.

(2) the government moves to dismiss or transfer the case based on improper venue; and

(3) each side moves for summary judgment, with plaintiffs seeking a declaratory judgment, an injunction, and vacatur of the rule.

Analysis

For the reasons set forth below, the court denies the government's motion to dismiss plaintiff Neocom. *See infra* Part I. The court also denies the government's motion to dismiss or transfer the case based on venue. *See infra* Part II. Finally, the court denies the government's motion for summary judgment and grants plaintiffs' motion for summary judgment as to their First Amendment challenge to the rule. *See infra* Part III.

I. The court has jurisdiction to resolve Neocom's claims because they track the manufacturer plaintiffs' claims.

The government contends that "Neocom lacks Article III standing, and the Court lacks subject-matter jurisdiction over its claim."[72] At oral argument, the government confirmed that it seeks Neocom's dismissal on standing grounds regardless of how the government's defense of improper venue is resolved.

Because the government asserts the defense of lack of subject-matter jurisdiction, its motion to dismiss is governed by Federal Rule of Civil Procedure 12(b)(1), although its motion strangely fails to cite that rule. Such a motion should be granted "only if it appears

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[72] Doc. 36 at 17.

certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle [the] plaintiff to relief."[73]

The government admits that the manufacturer plaintiffs have Article III standing to bring their claims and that their claims arise under the Constitution and laws of the United States.[74] The court agrees that it has constitutional and statutory subject-matter jurisdiction over the manufacturers' claims.[75]

The five retailer plaintiffs allege the same legal defects in the same statute and same rule as do the manufacturer plaintiffs whose standing is established. Does that end the analysis?

The Supreme Court, for its part, has repeatedly ended its standing analysis there. In *Rumsfeld v. FAIR*, for instance, the Court stated that it could "limit its discussion" to the one plaintiff whose standing was established.[76] In *Watt v. Energy Action Educational Foundation*, the presence of one plaintiff with standing allowed the Court to "not consider the standing of the other plaintiffs."[77] Several other Supreme Court decisions follow such a "need not

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[73] *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001).

[74] Doc. 36 at 6.

[75] U.S. Const. art. III, § 1; 28 U.S.C. § 1331.

[76] 547 U.S. 47, 52 n.2 (2006).

[77] 454 U.S. 151, 160 (1981).

consider" approach after finding one plaintiff with standing to raise a particular legal argument.[78]

Explaining that approach, the Supreme Court in *Doe v. Bolton* stated that "nothing is gained or lost by the presence or absence of" additional plaintiffs past the first with standing.[79] Of course, that statement is not true in its broadest sense. An additional plaintiff's presence in a case will, under *res judicata*, bind that plaintiff to the judgment in that case. That is a very important thing "gained or lost" by being in court or not. Its importance is shown by the frequent litigation over using a class action to bind many plaintiffs to a single judgment.

The presence or absence of an additional plaintiff can also affect defenses such as improper venue. And it can affect discretionary transfer decisions based on the location of parties, witnesses, and evidence. All to say, at least some things are gained or lost by the presence or absence of additional plaintiffs.

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[78] *Horne v. Flores*, 557 U.S. 433, 446 (2009) (when one plaintiff has standing, "we need not consider whether the Legislators also have standing"); *Bowsher v. Synar*, 478 U.S. 714, 721 (1986) (holding that the Court "need not consider the standing issue as to" other plaintiffs when one plaintiff has Article III standing) (citing *Sec'y of the Interior v. California*, 464 U.S. 312, 319 n.3 (1984) ("Since the State of California clearly does have standing, we need not address the standing of the other respondents, whose position here is identical to the State's.")); *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 264 n.9 (1977) (noting that, because at least one plaintiff had standing, the Court "need not consider whether other . . . plaintiffs have standing").

[79] 410 U.S. 179, 189 (1973).

So perhaps the Supreme Court's reasoning should be understood as limited to a tribunal that can decide legal questions on which it grants review, as opposed to entire cases.[80] In deciding legal questions, truly nothing may be gained or lost by the presence in the case of additional plaintiffs. But a district court enters judgments adjudicating whether specific parties are entitled to specific types of relief.[81] So it does seem strange to contemplate a district court issuing a judgment awarding (or denying) relief to a party that does not have a cognizable legal stake in the case that gives it standing to sue.

The Supreme Court's approach may also reflect the fact that its holdings on matters of federal law bind all parties nationwide—if not as a matter of *res judicata*, then as a matter of *stare decisis*. So perhaps the Supreme Court's one-good-plaintiff approach to standing should not apply in the different setting of a circuit court (whose rulings do not have nationwide precedential effect) or a district court (whose rulings do not have even local precedential effect).

Whatever the merits of that debate, this court is bound by the rulings of the Fifth Circuit, which has not attached significance to those unique aspects of the Supreme Court. The Fifth Circuit holds that the presence of one party with standing is sufficient to authorize judicial relief as to all parties challenging

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[80] *See generally* Ben Johnson, *The Origins of Supreme Court Question Selection*, 122 Colum. L. Rev. 793 (2022).

[81] *See* Fed. R. Civ. P. 8(b) (directing that a party's pleading must contain a "demand for the relief sought"); Fed. R. Civ. P. 54(c) (directing that judgments must grant the "relief to which each party is entitled").

the same defendant's action on the same legal theory—what the Fifth Circuit calls the same "claim."[82]

That rule controls here. The manufacturer plaintiffs undeniably have standing to raise each of their challenges to the Tobacco Control Act and the FDA rule. And plaintiff Neocom challenges the same statute and rule on the same legal theories. Under binding circuit precedent, those facts confirm that awarding Neocom relief on its claims is within the Article III "case or controversy" entrusted to this court's jurisdiction. So the court need not consider Neocom's standing.

II. The government's venue defense is waived.

The government moves for dismissal of this action based on the defense of improper venue. But, prior to that request, the government made a substantive motion that failed to object to venue.[83] Plaintiffs argue

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[82] *Brackeen v. Haaland*, 994 F.3d 249, 291 (5th Cir. 2021), *cert. granted*, 142 S. Ct. 1205 (Feb. 28, 2022); *Texas v. United States*, 50 F.4th 498, 514 (5th Cir. 2022). This court was aware of those cases in waiting for an opportunity for the Fifth Circuit and the Supreme Court to clarify the law on this matter and the matter discussed below in Part III.F.2, which might work to the FDA's advantage. But the FDA has indicated its desire for a ruling at this time. Doc. 101.

[83] The parties relied (Doc. 30 at 2) on 5 U.S.C. § 705, which authorizes "the reviewing court" to issue "appropriate process" to prevent irreparable injury and preserve the status quo during judicial review of agency action.

that the government's litigation conduct waived or forfeited any venue defense.[84] The court agrees.

In response to plaintiffs' waiver argument, the government counters only that its venue defense was raised in a Rule 12(b)(3) motion to dismiss filed by the deadline for an answer to the complaint.[85] Such a motion does indeed avoid a deemed waiver under Rule 12(h). But application of Rule 12(h) is not the only way that a venue defense can be waived.

As noted in the treatise *Federal Practice & Procedure*, "Even in situations in which a motion under Rule 12(b)(3) would be appropriate, the defendant may waive his right to obtain a dismissal for lack of venue [when] the defendant interposes a pre-answer motion that fails to object to venue."[86] Numerous decisions of the Fifth Circuit and other circuits have so held with respect to the defenses of improper venue and lack of personal jurisdiction.[87]

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[84] Doc. 48 at 19.

[85] Doc. 70 at 106.

[86] 5B Charles Alan Wright et al., Fed. Prac. & Proc. Improper Venue § 1352 (3d ed.).

[87] *See, e.g.*, *Heyward v. Pub. Hous. Admin.*, 238 F.2d 689, 695 (5th Cir. 1956) ("[The defendant] by filing the motion for summary judgment and thus putting at issue the merits of the case effectively waived whatever objection to venue as it may have had."); *Rubens v. Ellis*, 202 F.2d 415, 417 (5th Cir. 1953) ("Even if the venue was improperly laid . . . . that irregularity . . . could be, and was, waived . . . because [the defendant] . . . sought the aid of the New Mexico court."); *Bel-Ray Co. v. Chemrite (Pty) Ltd.*, 181 F.3d 435, 443 (3d Cir. 1999) ("In particular, where a party seeks affirmative relief from a court, it normally submits itself to

That waiver principle was applied on remarkably similar facts in *Marquest Medical Products, Inc. v. EMDE Corp.*[88] There, the defendants objected to venue and personal jurisdiction after waiting six to ten weeks from service of the complaint and after they had "submitted to an order of th[e] court by their stipulation which restrains them from acting as was requested by [the plaintiff]."[89] Although the defendants "avoided actual argument on the probability of success or failure of the merits" by stipulating to an injunction, the motion for that relief still called on the court to assess the likely merits of the controversy:

> [I]n adopting the stipulated agreement I considered the propriety of the mutual injunctions in light of the facts and law in this case, albeit not determining the ultimate resolution of the litigation. Preliminary matters such as personal jurisdiction or venue should be

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the jurisdiction of the court with respect to the adjudication of claims arising from the same subject matter."); *Peterson v. Highland Music, Inc.*, 140 F.3d 1313, 1318 (9th Cir. 1998) ("Rule 12(h)(1) specifies the minimum steps that a party must take in order to preserve a defense. It does not follow, however, that a party's failure to satisfy those minimum steps constitutes the only circumstance under which the party will be deemed to have waived a defense."); *Manchester Knitted Fashions, Inc. v. Amalgamated Cotton Garment & Allied Indus. Fund*, 967 F.2d 688, 692 (1st Cir. 1992) ("[I]f a defendant interposes a pre-answer motion that fails to object to venue . . . he effectively has waived his right to obtain a dismissal on the ground of lack of venue.") (citations omitted).

[88] 496 F. Supp. 1242 (D. Colo. 1980).

[89] *Id.* at 1245.

> raised and disposed of before a court considers the merits or quasi-merits of a controversy.[90]

The defendants could not simply raise a venue challenge and "walk away" from the court's order that considered likelihood of merits success after stipulating to that very order and thus gaining "the presumed advantages which they obtained."[91]

Likewise here. The government joined in a motion for injunctive relief, gaining thereby some perceived advantage such as avoiding potential accelerated consideration of a temporary restraining order.[92] Granting that injunctive relief required this court to consider whether plaintiffs presented a substantial case on the merits.[93] The court did so. It found relief

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[90] *Id.* at 1246 (citations omitted).

[91] *Id.*

[92] The FDA might have itself acted to postpone the rule's effective date. Had it done so, however, that agency action might then have been challenged in court. *See, e.g.*, *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 21 (D.D.C. 2012) (invalidating an agency's stay of a rule's effectiveness when the agency failed to apply the four-part equitable test for a stay). Here, the FDA avoided such potential litigation by joining plaintiffs in moving the court to postpone the rule's effectiveness. In doing so, the FDA was not merely memorializing an internal agency action. Rather, it was seeking judicial relief that would not be subject to challenge in separate litigation.

[93] The judicial process "appropriate" under 5 U.S.C. § 705 is determined by the traditional "balancing process which attends the grant of injunctive relief." *Sampson v. Murray*, 415 U.S. 61, 80 (1974); *id.* at 68 n.15 (citing *Scripps-Howard Radio v. FCC*, 316 U.S. 4, 9–17 (1942)). As explained in *Scripps-Howard*: "A stay is not a matter of right, even if irreparable injury might otherwise result to the appellant. It is an exercise of judicial

appropriate considering the likelihood of success on the merits, irreparable injury, and the other equitable factors bearing on a stay.[94]

To be sure, a defendant need not raise a venue defense at the earliest conceivable moment in a case, such as the day of its filing or service of process. But the government here had ample time and resources to assess venue before it joined plaintiffs in moving to postpone the rule's effectiveness and proposing that the court move directly to cross-motions for summary judgment. Indeed, the government relied on a statute authorizing a stay by "the reviewing court"[95]—again intimating that this court's review is authorized. The reasoning of *Marquest Medical Products* thus has substantial persuasive force here.

Also persuasive is *Manchester Knitted Fashions, Inc. v. Amalgamated Cotton Garment and Allied*

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discretion." 316 U.S. at 10 (quoting *Virginia Railway v. United States*, 272 U.S. 658, 672 (1926)). The Fifth Circuit, citing the same *Virginia Railway* passage, has confirmed that a stay of agency action pending judicial review "is not a matter of right." *Texas v. EPA*, 829 F.3d 405, 424 (citing *Virginia Railway*, 272 U.S. at 672). A stay "appropriate" under § 705 requires satisfaction of the well-known test that considers the likelihood of success on the merits, injury to the plaintiff, injury to the defendant, and the public interest. *Id.* at 424, 435 (citing 5 U.S.C. § 705). *Accord, e.g.*, *Ohio ex rel. Celebrezze v. Nuclear Reg. Comm'n*, 812 F.2d 288, 290 (6th Cir. 1987) (holding that a § 705 stay is based on a balancing of the traditional four factors relevant to injunctive relief); *D.C. v. USDA*, 444 F. Supp. 3d 1, 15 (D.D.C. 2020) ("The factors governing issuance of a preliminary injunction also govern issuance of a § 705 stay.").

[94] Doc. 33 at 1–2. The court also adopted the parties' requested briefing schedule. *Id.* at 3–4.

[95] Doc. 30 at 2 (citing 5 U.S.C. § 705).

Industries Fund.[96] There, the defendants objected to venue for the first time almost nine weeks after service of the complaint and almost four weeks after they stipulated to a court order enjoining their conduct.[97] The court noted that the defendants had over one month to assess venue before entering into their stipulation to injunctive relief, which was "certainly adequate time to sufficiently apprise them of any question as to venue."[98] The court also explained that the defendants "submitted to the jurisdiction of the court by twice requesting hearings on the plaintiff's motions for a temporary restraining order and for a preliminary injunction."[99] The First Circuit then "agree[d] fully" with the district court's waiver ruling, reasoning that the defendant, by stipulating to a temporary injunction pending litigation and then requesting a hearing on further injunctive relief sought by the plaintiff, waived the venue defense.[100]

The same reasoning applies here. The government first objected to venue over 12 weeks after service of the complaint[101] and over 8 weeks after it stipulated to a court order staying the rule's effectiveness.[102] Both delays are longer than in *Manchester Knitted*. The government had adequate time to apprise itself of

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[96] 1990 WL 383798 (D.N.H. Nov. 30, 1990).

[97] *Id.* at *3.

[98] *Id.*

[99] *Id.*

[100] *Manchester Knitted Fashions*, 967 F.2d at 692.

[101] *See* Docs. 21–25.

[102] *See* Doc. 30.

any question as to venue before requesting § 705 relief from this court. And, similar to *Manchester Knitted*, the government here not only moved for injunctive relief but also asked for a hearing on its forthcoming motion for summary judgment.

The court has the duty and discretion to manage the adjudicative process to conserve judicial resources, and that end is advanced when venue issues are raised and disposed of before the court considers the merits of the controversy.[103] Applying those principles here, the court holds that the government's venue defense is waived.

III. Plaintiffs are entitled to summary judgment on their First Amendment challenge to the FDA rule.

The parties agree that no issues of fact require a trial and that the case is ripe for resolution on the cross-motions for summary judgment. The court concludes that the label statements required by the FDA rule do not qualify for First Amendment scrutiny under *Zauderer* because they are not purely factual and uncontroversial. The court then concludes that the compelled labels do not survive scrutiny under *Central Hudson*'s test for commercial-speech regulations generally.

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[103] *See United States v. Ziegler Bolt & Parts Co.*, 111 F.3d 878, 882 (Fed. Cir. 1997) (explaining abuse-of-discretion appellate review on this issue: "This court places waiver within the discretion of the trial court, consistent with its broad duties in managing the conduct of cases pending before it.").

A. *Zauderer* is a limited relaxation of *Central Hudson*'s framework for commercial-speech regulations.

A requirement to include warnings on a product's package or advertisements regulates commercial speech—speech inextricable from the commercial transaction that it proposes.[104] In *Central Hudson*,[105] the Supreme Court laid out a four-part framework for First Amendment review of commercial-speech regulations:

(1) The commercial speech must be protected constitutionally, as opposed to "forms of communication more likely to deceive the public than to inform it" and "commercial speech related to illegal activity."[106]

(2) The state "must assert a substantial interest" to be achieved by a regulation.[107]

(3) The restriction must "directly advance" the state interest, as opposed to providing only "remote" support.[108]

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[104] *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

[105] 447 U.S. at 561–66.

[106] *Id.* at 563–64.

[107] *Id.*

[108] *Id.* (giving the example that a restriction on advertising has only a remote connection to deterring shoddy professional work).

(4) The restriction must be "narrowly drawn"[109] in that "it is not more extensive than is necessary."[110]

As an example of a "narrower restriction" that could serve a given state interest, *Central Hudson* noted the potential to require "limited supplementation" of commercial speech, as "by way of warning."[111]

Five years later, in *Zauderer*, the Supreme Court confronted "three separate forms of regulation" of commercial speech: two prohibitions and one disclosure requirement for certain types of attorney advertising.[112] The Court reviewed the two prohibitory regulations under the *Central Hudson* test, confirming along the way that images in advertisements "are entitled to the First Amendment protections afforded verbal commercial speech."[113]

Turning to the third regulation, which required disclosures, *Zauderer* rejected the call for "precisely the same inquiry" as for the prohibitions of speech.[114] *Zauderer* acknowledged that a disclosure rule may require speakers to "provide somewhat more information than they might otherwise be inclined to present."[115] But *Zauderer* viewed that requirement as materially different than a rule that wholly prevents

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[109] *Id.*

[110] *Id.* at 566.

[111] *Id.* at 565.

[112] 471 U.S. at 638.

[113] *Id.* at 647.

[114] *Id.* at 650.

[115] *Id.*

commercial speakers "from conveying information to the public" because one type of regulation keeps information out of the marketplace, whereas the other adds information to the marketplace.[116]

At the same time, *Zauderer* recognized First Amendment principles that limit the state's power to compel disclosures. Specifically, the Court cited its compelled-speech decisions such as *Wooley v. Maynard*[117] and *West Virginia State Board of Education v. Barnette*,[118] which reject the idea "that a Bill of Rights which guards the individual's right to speak his own mind, left it open to public authorities to compel him to utter what is not in his mind."[119] That principle applied, but had lesser force, for two reasons:

(1) the speech compelled in *Zauderer* was "in commercial advertising,"[120] which is more susceptible to restrictions than is personal or political speech, and

(2) the state in *Zauderer* required the advertising to contain "accurate," "purely factual," and "uncontroversial information about the terms under which [the advertiser's] services will be available."[121]

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[116] *Id.*

[117] 430 U.S. 705 (1977).

[118] 319 U.S. 624 (1943).

[119] *Id.* at 633.

[120] 471 U.S. at 651.

[121] *Id.* at 651 & n.14.

If those two requirements are met, *Zauderer* provides a standard of review more lenient than *Central Hudson*'s. Specifically, *Zauderer* rejects a "strict 'least restrictive means' analysis" under which disclosure rules "must be struck down if there are other means by which the State's purposes may be served."[122] *Zauderer* requires only a "less exacting" tailoring inquiry that asks whether disclosure requirements are "reasonably related" to the state's interest.[123] *Zauderer* also requires that a disclosure requirement is not "unjustified or unduly burdensome."[124] In contrast, "[u]njustified or unduly burdensome disclosure requirements offend the First Amendment by chilling protected speech."[125]

This court need not decide whether a third prerequisite for *Zauderer* review exists: that the state's interest in a compelled disclosure is to prevent consumer deception. *Zauderer* recognized that the government's interest there was preventing potential consumer deception.[126] And *Zauderer* stated its holding in those terms, ruling "that an advertiser's rights are adequately protected as long as disclosure

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[122] *Id.* at 651 n.14.

[123] *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010).

[124] *Id.*

[125] *Id.* at 250. Because failing this test makes a government regulation "offend the First Amendment," *id.*, as opposed to just making it ineligible for a relaxed standard of review, the court has classified this requirement as part of the *Zauderer* standard of review itself, not just a prerequisite for that standard of review.

[126] 471 U.S. at 651.

requirements are reasonably related to the State's interest in preventing *deception of consumers*."[127]

But parts of *Zauderer*'s reasoning focused generally on the constitutional value of a freedom not to disclose facts in commercial advertising.[128] So several courts of appeals have held that *Zauderer* review is available for commercial disclosure requirements that advance state interests other than preventing consumer deception.[129] The Fifth Circuit has not decided that issue. Neither must this court decide that issue to resolve this case, as *Zauderer* review is unavailable for the independent reason explained below.

B. The rule's graphics are not inherently "accurate" and "purely factual and uncontroversial."

The parties agree that the disclosures required by the FDA rule would occur in commercial speech. So the first requirement for *Zauderer* review is met. But to allow *Zauderer* review, a compelled disclosure must also be of "accurate," "purely factual," and "uncontroversial" information.[130] That second requirement is not met here.

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[127] *Id.* (emphasis added).

[128] *Id.* at 650–52.

[129] *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019); *Discount Tobacco*, 674 F.3d at 556–57; *Am. Meat Inst.*, 760 F.3d at 22; *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 114–15 (2d Cir. 2001) (Walker, J.). *See also Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 (1st Cir. 2005).

[130] *Zauderer*, 471 U.S. at 651 & n.14.

For expression to be "purely factual," it must be information with an objective truth or existence.[131] That is how the law understands a "factual" assertion in general.[132] And only if a message is uncontroversial and objectively accurate can its compulsion fall within *Zauderer*'s carve out for disclosures that do not "prescribe what shall be orthodox" in matters of controversy.[133]

Verbal statements can usually be classified by courts as either purely factual or as value-laden opinion. Courts have thus found *Zauderer* applicable to many verbal disclosures, such as those stating what services are provided and their cost,[134] what country

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[131] *See* Lawrence Solum, Legal Theory Lexicon: Fact and Value, https://lsolum.typepad.com/legaltheory/2019/07/legal-theory-lexiconfact-and-value.html (July 7, 2019) (noting that, in "popular culture, the idea is that factual assertions or beliefs are, in principle, demonstrably true or false," although the "relationship between fact and value is a deep and complex topic" in philosophy).

[132] *E.g.*, Fed. R. Evid. 104(b) (referring to whether "a fact exists" or not); Fed. R. Evid. 401(a) (referring to whether the existence of "a fact" is "more or less probable" in light of given evidence than without it); Fed. R. Evid. 1008 (assigning a court the role of finding whether "the factual conditions" of admissibility are established or not).

[133] *Zauderer*, 471 U.S. at 651 (quoting *Barnette*, 319 U.S. at 642); *accord Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (rejecting *Zauderer* review where an image's message was "non-factual" and "opinion-based").

[134] *Milavetz*, 559 U.S. at 233; *Zauderer*, 471 U.S. at 652.

food comes from,[135] and how much of a chemical is in a product.[136]

But imagery can be more prone to ambiguous interpretation. Sometimes, that is even its artistic value.[137] This reality can make it harder for courts to ascertain whether an image has a single, objective meaning that could make it "purely factual."

That is the case here. Take, for instance, this warning required by the FDA rule:

Its verbal aspect makes a falsifiable claim—that smoking causes head and neck cancer. But it is unclear how a court would go about determining whether its graphic aspect is "accurate" and "factual" in nature. The image may convey one thing to one person and a different thing to another. One person might view the image as showing a typical representation of the sort of neck cancer caused by

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[135] *Am. Meat Inst.*, 760 F.3d at 21–26.

[136] *Sorrell*, 272 F.3d at 107, 113–16.

[137] *Cf. Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557, 569 (1995) (noting the painting of Jackson Pollock as an example of expression without a "narrow, succinctly articulable message").

smoking before a person could seek medical treatment. Another person might view the image as showing a stylized, exaggerated representation of neck cancer, perhaps in an effort to provoke repulsion. Others might interpret the depicted person's gaze, in conjunction with the text, as expressing regret at her choice to smoke or the message that smoking is a mistake. All of those interpretations would be at least reasonable.

The imagery in the warnings here is provocative. As to each warning, it is not beyond reasonable probability that consumers would take from it a value-laden message that smoking is a mistake.[138] For that reason alone, the graphics make all of the warnings here not "purely factual" and "uncontroversial" within the meaning of *Zauderer*.[139]

But that is just one possible interpretation of the graphic warnings. This highlights a broader problem. It is not apparent—and the FDA has not made a

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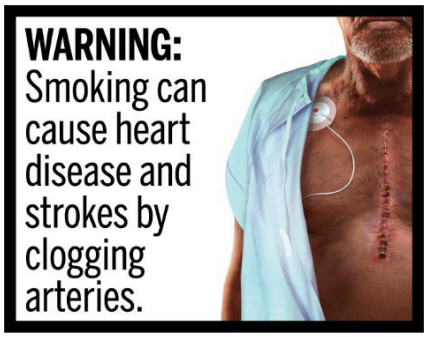
[138] The court does not hold that all conceivable imagery in a disclosure is necessarily value-laden. For example, a map showing on which continent food was farmed, next to a disclosure naming that continent, would seem purely factual. And perhaps a stylized icon could be mere shorthand for factual information, such as a symbol denoting the presence of a given chemical in a product.

[139] Notably, in rejecting a facial challenge to the Tobacco Control Act's requirement of a graphic component to health warnings, the Sixth Circuit reasoned that the graphics could "merely be[] words" and offered the example of "handwriting"—not provocative, photorealistic images. *Discount Tobacco*, 674 F.3d at 559. Thus, as to plaintiff R.J. Reynolds, preclusion principles do not bar the court's ruling as to the different graphic warnings at issue here.

record-based showing—that each image-and-text pairing conveys only one, unambiguous meaning that is factually correct. For example, take the heart-disease warning:



Consumers may reasonably interpret the image in this warning as indicating that open-heart surgery, whose scars are shown, is the most common treatment for heart disease. But the court has no evidence of that assertion's truth. Indeed, commenters notified that FDA that in-patient interventions for heart disease are 2.5 times more common than open-heart surgery.[140] The FDA did not disagree. It responded only that open-heart surgery is a "common" and "typical[]" treatment, without disagreeing that non-surgical treatment is 2.5 times more common or typical.[141] Neither does the FDA's cited source disprove that statistic.[142]

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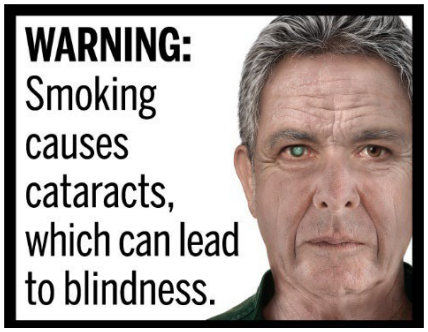
[140] 85 Fed. Reg. at 15,677.

[141] *Id.* at 15,678.

[142] Manesh R. Patel et al., *ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in*

Alternatively, the image could be reasonably understood as conveying that open-heart surgery is the best treatment for heart disease, even if not the most common. But that message would seem opinion-based, as opposed to a purely factual disclosure about an advertiser's product. At the least, nothing in the administrative record establishes the objective truth of that claim.

The same point about consumer misinterpretation applies, for example, to the cataracts warning:



For one, the warning does not indicate whether it shows cataracts or blindness, both of which are mentioned. That alone creates a reasonable possibility of misinterpretation by some consumers.

Moreover, even if the warning's text were limited to cataracts, without mentioning blindness, some consumers may reasonably interpret the image as depicting the most common result of cataracts. But the court has no evidence of that depiction being accurate. To the contrary, commenters told the FDA

Patients with Stable Ischemic Heart Disease, 69:17 J. of the Am. College of Cardiology 2212 (2017), https://doi.org/10.1016/j.jacc.2017.02.001.

that cataracts in the United States are typically treated long before they progress to the stage shown.[143] The FDA did not disagree. It responded only that "underserved populations may face barriers to receiving cataract surgery."[144] That may be. But it does not establish the accuracy of this reasonable interpretation of the warning as depicting the most common result of cataracts.[145]

Those two examples show a problem that exists with each of the graphic warnings required by the FDA rule. Because of their capacity for multiple reasonable interpretations, consumers may perceive expression whose truth has not been established by the record. So the court cannot deem the warnings "purely factual and uncontroversial" and objectively "accurate" as required to allow relaxed *Zauderer* review.[146] Accordingly, the court need not reach plaintiffs' alternative argument that, even if *Zauderer* review applies, the warnings would fail that review as unjustified and unduly burdensome.

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[143] 85 Fed. Reg. at 15,684; *accord* Doc. 1-5 at 327.

[144] 85 Fed. Reg. at 15,684.

[145] The FDA also justified its warnings based on the tobacco industry's "decades of deception" and concerted attempt to "misl[ead] its own customers." Doc. 37 at 6 (citing *United States v. Phillip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006)). But that is not an argument about whether the warnings here are "purely factual and uncontroversial" for purposes of *Zauderer*.

[146] *Zauderer*, 471 U.S. at 651 & n.14.

C. The FDA rule does not meet *Central Hudson*'s narrow-tailoring requirement.

The parties dispute whether intermediate scrutiny or strict scrutiny applies to a compelled advertising disclosure that does not qualify for relaxed *Zauderer* review. *Central Hudson* addressed only a "prohibition" of speech, not an involuntary conveyance of speech.[147] And *Zauderer* itself recognized the Court's earlier suggestion that "involuntary affirmation could be commanded only on even more immediate and urgent grounds than silence."[148]

The Fifth Circuit has not decided which standard applies. But a commercial compelled disclosure outside *Zauderer*'s ambit must at least satisfy intermediate scrutiny, even if more is required. So the court turns now to that standard.

Central Hudson review first asks if a regulation serves a substantial state interest. The Tobacco Control Act's stated purpose for its health warnings is that "the public may be adequately informed about any adverse health effects of cigarette smoking."[149] The FDA likewise relies on "the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking"[150] and cites evidence that consumer awareness of the health risks of smoking is a substantial problem.[151]

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[147] 447 U.S. at 540.

[148] 471 U.S. at 650 (quoting *Barnette*, 319 U.S. at 633).

[149] 15 U.S.C. § 1331(1).

[150] 85 Fed. Reg. at 15,638.

[151] 85 Fed. Reg. at 15,655.

Promoting public understanding of the dangers of smoking is also the state interest behind the current regime of "Surgeon General's Warnings,"[152] which plaintiffs do not question under *Central Hudson*. So one might assume that the same interest qualifies as substantial here. Because the FDA rule fails *Central Hudson* review for an independent reason, however, the court need not decide the parties' arguments about (i) whether the conceptual nature of that interest is disqualifying or (ii) the extent of record evidence needed to qualify that interest as substantial.

As noted, *Central Hudson* review requires not only a substantial state interest, but also that a commercial-speech regulation is "'narrowly drawn"'[153] to that interest, in that "it is not more extensive than is necessary."[154] That formulation has similarities to the test set out in *Wooley v. Maynard* for review of government compulsion of speech: "even though the governmental purpose be legitimate and substantial, that purpose cannot be pursued by means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved."[155] Both ask whether a

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[152] Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 2, 98 Stat. at 2202 (1984) (stating Congress's purpose to make "Americans more aware of any adverse health effects of smoking" and "enable individuals to make informed decisions about smoking").

[153] 447 U.S. at 565 (quoting *In re Primus*, 436 U.S. 412, 438 (1978)).

[154] *Id.* at 566.

[155] 430 U.S. at 716 (quotation marks omitted).

narrower alternative would achieve the government's interest.

Here, the government has not shown that compelling these large, graphic warnings is necessary in light of other options. Rather than taking over half of a package's face, the government may take advantage of other strategies such as increasing funding for anti-smoking advertisements in various forms of media, increasing funding for speakers and school instruction, and increasing anti-smoking resources in the government's own communications. Deeming those alternatives as more narrowly drawn means to achieve the government's interest follows from the Supreme Court's recent decision in *NIFLA*, which held that a compelled disclosure failed this requirement because the state could have informed people of the desired information with a "public-information campaign" involving steps such as postings on public property and in private advertisements.[156]

Increasing resources for such a public-information campaign not only is less burdensome of private speech but also offers the ability to target particular groups in different channels of communication with different messages. Indeed, the FDA has touted such public-information campaigns as highly successful in educating youth about the dangers of smoking.[157]

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[156] *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2376 (2018).

[157] In 2019, for example, the Acting Commissioner of Food and Drugs issued a press release describing the FDA's "highly successful" public-information campaigns, which "are yielding

Notwithstanding those campaigns, the FDA argues that "millions of Americans may pick up smoking, or continue to smoke, without knowing many of the serious risks to which they are exposing themselves and their loved ones."[158] That is legitimate cause for concern. But *NIFLA* held that, "regardless, a tepid response does not prove that an advertising campaign is not a sufficient alternative" as a First Amendment matter.[159] *NIFLA* reasoned that the constitutional line is principled, not pragmatic: "The First Amendment does not permit the State to sacrifice speech for efficiency."[160] That reasoning controls today.

The FDA also cannot argue that less burdensome warnings on cigarette packages and advertisements would not achieve the government's interest, for the FDA did not test the efficacy of "smaller or differently placed warnings."[161] The FDA explains that it did not consider such warnings because "the statute sets forth the requirements with regard to size and placement of

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tremendous results." Norman E. "Ned" Sharpless, *Statement on New Results Demonstrating Continued Success of the Agency's Youth Smoking Prevention Efforts and Significant Public Health Cost Savings* (Aug. 20, 2019), www.fda.gov/news- events/press-announcements/statement-new-results-demonstratingcontinued-success-agencys-youth-smoking-prevention-efforts-and.

[158] Doc. 37 at 60.

[159] *Id.* (quotation marks omitted).

[160] *Id.* (quoting *Riley v. Nat'l Fed. of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988)) (quotation and alteration marks omitted).

[161] 85 Fed. Reg. at 13,650.

the warnings."[162] But the First Amendment limits congressional action as much as agency action. So the lack of any such consideration in the record counts against the government.[163]

For all of those reasons, *Central Hudson*'s narrow-tailoring requirement is not met here. Accordingly, the FDA rule exceeds First Amendment limits. That holding "in no way disparages the national interest"[164] in reducing smoking, particularly among youth. But when that goal is pursued by mandating commercial disclosures that are not purely factual and uncontroversial, the First Amendment requires at least that such a regulation "be no more extensive than is necessary to serve the state interest."[165] In this case, as in *Central Hudson*, that requirement is not met.

D. Plaintiffs' other claims need not be resolved.

Notwithstanding the general doctrine of constitutional avoidance, "federal courts have emphasized the importance of resolving First

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[162] *Id.*

[163] *See, e.g.*, *Ent'mt Software Ass'n*, 469 F.3d at 652 & n.13 (noting that the government "has failed to even explain why a smaller [warning] would not suffice" and holding that a sticker covering less than 10% of a package "*literally* fail[ed] to be narrowly tailored"); *Am. Beverage Ass'n v. City and Cty. of San Francisco*, 916 F.3d 749, 756–57 (9th Cir. 2019) (holding that a warning that occupied 20% of advertisements for sugar-sweetened beverages—far less space than here—was "unduly burdensome").

[164] *Central Hudson*, 447 U.S. at 571.

[165] *Id.*

Amendment cases at the earliest possible junction."[166] Indeed, the district court that considered the FDA's first graphic-warnings rule resolved the case on First Amendment grounds rather than deciding the Administrative Procedure Act claims.[167] So this court will "follow a well-trodden path by reaching and deciding a dispositive First Amendment issue that will avoid forcing the parties through unnecessary" litigation over statutory issues.[168] The court thus expresses no opinion on plaintiffs' non-First Amendment claims.

E. Severance is inappropriate.

The government argues that, if the court credits plaintiffs' First Amendment claim, the court should sever and declare invalid only certain aspects of the warnings. But while the Tobacco Control Act expresses a general preference for severance, the Act directs that text and graphics be tied together in health warnings.

Section 5 of the Act is the general severability provision. It directs that if "any provision" of the Act or regulations promulgated under the Act "is held to be invalid," then the remainder of the Act or any such regulations "shall not be affected and shall continue to

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[166] *Green v. Miss U.S.A., LLC*, 52 F.4th 773, 2022 WL 16628387, at *57 (9th Cir. 2022) (collecting cases).

[167] *R.J. Reynolds Tobacco Co. v. FDA*, 823 F. Supp. 2d 36, 39–40 n.3 (D.D.C. 2011) ("Because plaintiffs prevail on their First Amendment claim, an analysis of the APA claim is unnecessary."); *see also id.*, Mem. in Supp. of Pls.' Mot. for Summ. J. and Perm. Inj. at 49–55 (filed Aug. 9, 2011) (argument on the arbitrary-and-capricious and notice-and-comment APA claims).

[168] *Green*, *supra* note 166, at *57.

be enforced to the fullest extent possible."[169] Consistent with that direction, today's ruling does not affect many provisions of the Tobacco Control Act, such as its provisions on agency authority over "tobacco products"[170] or on penalties for regulatory violations.[171] Even the Act's provisions on health warnings are not held facially invalid but, rather, are held invalid only as applied in the specific health warnings in the challenged rule and on the administrative record presented here.

The Act, however, does not allow the court to "sever" the FDA's warnings by simply deleting their graphical component. To the contrary, the Act directs that graphics and text must accompany each other in the new warnings.[172] That linkage presumably underlies Congress's direction about the size of the warnings. And the Act directs that its requirement of new warnings will not go into effect until the accompanying graphics are specified by rule.[173] "As a fundamental rule of statutory interpretation, specific provisions trump general provisions."[174] So the Act's specific direction that health warnings must include both graphics and text, which become effective only as a

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[169] Tobacco Control Act § 5, 123 Stat. at 1782.

[170] *E.g.*, *id.* § 101, 123 Stat. at 1782–1830.

[171] *E.g.*, *id.* § 102(q), 123 Stat. at 1839–40.

[172] 15 U.S.C. § 1333(d) (first of two subsections (d)).

[173] *See supra* note 21 and accompanying text.

[174] *Navarro-Miranda v. Ashcroft*, 330 F.3d 672, 676 (5th Cir. 2003).

whole, controls. The court thus rules on each warning as a whole.

F. The court issues the remedies of a declaratory judgment and vacatur of the FDA rule.

1. The Declaratory Judgment Act allows a reviewing court to "declare the rights and other legal relations of any interested party seeking such declaration."[175] Any such declaration "shall have the force and effect of a final judgment or decree."[176] If necessary, a court may later grant an injunction to enforce its declaratory judgment.[177]

The government offers no argument against declaratory relief if the court credits any of plaintiffs' claims.[178] And the court finds it proper to exercise its discretion to issue such relief.[179] The court will therefore issue a final judgment declaring that enforcement against plaintiffs of the FDA rule would be contrary to constitutional right under the First Amendment. It is "anticipated that [defendants] would respect the declaratory judgment,"[180] so the court chooses not to issue an injunction at this time.[181] Plaintiffs may, of course, seek an injunction should

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[175] 28 U.S.C. § 2201(a).

[176] *Id.*

[177] *Id.* § 2202; *Powell v. McCormack*, 395 U.S. 486, 499 (1969).

[178] *See* Doc. 37 at 83–88; Doc. 67 at 37.

[179] *See Sherwin-Williams Co. v. Holmes Cty.*, 343 F.3d 383, 388 (5th Cir. 2003).

[180] *Poe v. Gerstein*, 417 U.S. 281, 281 (1974).

[181] *See Morrow v. Harwell*, 768 F.2d 619, 627 (5th Cir. 1985).

defendants threaten to depart from the declaratory judgment.

2. The next question is whether to vacate the FDA rule. The court understands vacatur (or vacation[182]) of an agency rule as relief beyond just a court order that the defendants not enforce the rule as to cause irreparable harm to the plaintiffs. Such an order would simply be an injunction.[183]

Rather than operating *in personam* on defendants by ordering them not to take action, vacatur operates *in rem* on the agency rule itself. Vacatur of an agency rule nullifies and revokes the rule, rendering it devoid of legal effect in the same way that an appellate vacatur acts on a district-court judgment.[184]

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[182] Some writers prefer "vacation" whereas others prefer "vacatur." Both terms appear to be accepted by lexicographers.

[183] Preventing irreparable injury to a plaintiff may require enjoining a rule's enforcement as to all parties that it governs if those parties' conduct under the rule causes the plaintiff's irreparable injury. *See, e.g.*, *Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015) (upholding nationwide injunction given freedom of movement across the country of persons found to impose pocketbook injury on plaintiffs as a result of the agency action), *aff'd by an evenly divided Court*, 579 U.S. 547 (2016) (per curiam). But such a remedy is still an injunction against enforcement of agency action; the remedy applies nationwide because the irreparable injury to plaintiff would flow from nationwide enforcement of the agency action. That is not the same as acting on an agency rule itself. And here, of course, there is no claim that enforcement of the FDA rule as to parties other than plaintiffs would cause irreparable injury to plaintiffs.

[184] *See* Merrick B. Garland, *Deregulation and Judicial Review*, 98 Harv. L. Rev. 505, 574 (1985) (stating that "vacating [an agency] order alone returns the matter to the status quo ante" by

The practical effect of vacatur will vary by the nature of the vacated agency action. When the agency action is adjudication of a dispute between the government and a private party,[185] vacatur of an agency ruling for the government affords relief only to the private party.[186] When the agency action is a rulemaking,[187] vacatur of that action nullifies the rule for all whom it would otherwise bind. If a rule had nationwide force, the rule's vacatur would be nationwide.

The government complains that nullifying a rule's legal effect on all whom it binds would deprive the government of the benefit of any victory in separate lawsuits by different plaintiffs challenging the same rule. That point has some force. As the government notes,[188] the APA does not answer the question: set aside as to whom? Indeed, the APA does not mention "vacating" an agency rule at all. So where is that relief authorized?

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undoing the "effect" of the agency order); *see also, e.g.*, Jonathan F. Mitchell, *The Writ of Erasure Fallacy*, 104 Va. L. Rev. 933, 1012 (2018) (contrasting vacatur of a rule with an injunction against its enforcement: "courts may formally vacate an agency's rule or order, rather than merely enjoin officials from enforcing it"); Ronald M. Levin, *"Vacation" at Sea: Judicial Remedies and Equitable Discretion in Administrative Law*, 53 Duke L.J. 291, 299 (2003) (describing vacation of a rule as "nullification" of the rule).

[185] *See* 5 U.S.C. § 554 (procedure for adjudications).

[186] A vacatur in those circumstances would not seem to present the Article III debate described below.

[187] *See* 5 U.S.C. § 553 (procedure for rulemaking).

[188] Doc. 67 at 37 n.30.

The APA does have a provision on the form of judicial review. That provision, 5 U.S.C. § 703, allows judicial review in either a special statutory review proceeding (not applicable here) or in "any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction." The previous provision of the APA, 5 U.S.C. § 702, requires that "any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance." Neither provision mentions a remedy of vacatur that acts on an agency rule itself.

The APA also has a provision, 5 U.S.C. § 705, on judicial relief pending review. That provision allows a court to postpone the effective date of agency action "to the extent necessary to prevent irreparable injury." Similarly, under circuit precedent, such relief turns on the extent of any irreparable injury to the plaintiff absent a stay pending review and the extent of any injury to the defendant from a stay pending review.[189] So this provision seems to allow judicial relief only as needed to prevent irreparable injury shown by a party in litigation, as opposed to postponing a rule's legal effect on all parties regardless of their likelihood of irreparable injury.

That leaves a textual analysis of the APA with its provision on the scope of judicial review. That provision, 5 U.S.C. § 706, directs a reviewing court to issue two forms of relief: (1) compel agency action if certain criteria are met and (2) "hold unlawful and set

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[189] *See supra* note 93 (discussing this provision).

aside agency action, findings, and conclusions" that meet other criteria like, as relevant here, infringing constitutional rights.

This provision too does not mention "vacatur." But it does direct a court to "set aside" the specified agency actions. That term could mean two things—a rule of decision or a form of relief. Does it simply mean setting aside the agency action in deciding a claimant's case? That is what courts do in the analogous context of holding a statute unconstitutional; courts simply refuse to enforce the statute in the case at hand.[190] Or does that term mean setting aside the agency action from legal effectiveness in any case or controversy, involving any party? That is the effect of vacatur.

In favor of the former view, researchers have argued that the remedy of vacatur was unknown to Congress and to the courts at the time of the APA's enactment and that universally nullifying a rule's legal effect exceeds Article III limits.[191] A leading treatise, moreover, refers to the APA's direction that a court

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[190] Mitchell, *supra* note 184, at 972 ("[A] federal court has no authority to render a duly enacted statute invalid or 'void'; its powers extend only to resolving the cases and controversies described in Article III.").

[191] *See* John C. Harrison, *Vacatur of Rules Under the Administrative Procedure Act*, Yale J. on Reg. Bull. (forthcoming 2022), *available at* https://ssrn.com/abstract=4247173; John C. Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*, 38 Yale J. on Reg. Bull. 1, 6–9 (2020); Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417, 420–21, 451–52 (2017).

"set aside" agency action as "functionally similar" to an injunction.[192]

Moreover, if "set aside" were to have its broader meaning, one might expect to see courts vacating agency rules not only in pre-enforcement challenges like this one but also in civil and criminal enforcement actions brought by the government. After all, § 706 does not distinguish between pre-and post-enforcement judicial review of agency action. Yet attention has not been called here to that practice, which would seem inconsistent with the government's traditional choice not to appeal some losses as to preserve its ability to litigate the same legal issue in another case.

But arguments for the broader understanding of "set aside" also have force. First, that is a linguistically plausible reading of the term.[193] Second, in some circumstances, a pragmatic argument might be made for that broader view. For some types of rules, it might be unadministrable or counterproductive to allow a rule's enforcement as to some parties but enjoin it as to others.

Third, the APA's provision on the scope of judicial review allows courts to compel agency action, including rulemaking, if unreasonably delayed.[194]

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[192] 33 Charles Alan Wright et al., Fed. Prac. & Proc. Judicial Review § 8307 (2d ed.).

[193] *See, e.g.*, *Set Aside*, Black's Law Dictionary (11th ed. 2019) (giving a definition of "set aside" that refers to vacatur, at least of a court order: "(Of a court) to annul or vacate (a judgment, order, etc.)").

[194] 5 U.S.C. § 706(1).

That is understood to allow a court to compel rulemaking that will bind nationwide, even on persons not represented in that court. That scope, in turn, may suggest a similarly broad meaning of "set aside" in the same APA provision.

Fourth, other areas of the law feature federal courts vacating legal commands as such, rather than just enjoining their enforcement by named parties. Most analogously, federal appellate courts vacate judgments, injunctive orders, and consent decrees entered by federal district courts. That analogy breaks down somewhat because, unlike district courts, agencies are not acting under Article III's power to resolve cases and controversies between identified parties. The federal courts' Article III power may not allow them to nullify a rule that an agency issues outside the constraints of Article III. But perhaps Article III is not the only source of federal courts' power to vacate agency rules. If Congress can delegate its Article I lawmaking authority to Article II agencies, unmentioned in the Constitution and staffed by unelected officials, then perhaps Congress can delegate to the Article III judiciary the authority to veto agency rules that violate §706's standards.[195]

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[195] Congress has occasionally conscripted the federal judiciary into functions outside traditional Article III dispute resolution. For example, in the Invalid Pensions Act of 1792, Congress instructed the federal circuit courts to review claims for pensions by veterans of the Revolutionary War. To address the concerns of some Justices of the Supreme Court that such a duty was unconstitutional, Chief Justice Jay and Justice Cushing adjourned court and then "regard[ed] themselves as being . . . commissioners, to execute the business of this act in the same

Another example may be judicial approval of funding requests under the Criminal Justice Act. Judges perform that function, using the dockets used for Article III cases. But a federal judge's funding decision may be susceptible to veto by a non-judicial officer, which may provide another example of Congress entrusting the judiciary with tasks outside traditional Article III dispute resolution. *See* 18 U.S.C. § 3006A(i); *Ayestas v. Davis*, 138 S. Ct. 1080, 1091 (2018) (collecting cases interpreting the CJA that way); *see, e.g.*, *United States v. Gast*, 297 F. Supp. 620, 621–22 (D. Del. 1969) (noting that a Comptroller General's Opinion prevented CJA funding that district judges approved); Subcomm. on Constitutional Rights, S. Comm. on the Judiciary, *The Criminal Justice Act in the Federal District Courts* 213, 90th Cong. (Comm. Print 1968) (detailing Administrative Office rejections of judge-approved funding).

In any event, even if it is idiosyncratic in the law for judicial relief to operate on a thing (such as an agency rule) as opposed to a party's actions (such as enforcement of a rule), that does not make it altogether unique. In an *in rem* action, jurisdiction and remedies proceed on the legal fiction that a court is imposing liability on a thing.[196] And judicial relief that operates on an offending rule may have some common-law analogues, such as the quashing order in U.K. practice, which invalidates administrative

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court room, or chamber." *Hayburn's Case*, 2 U.S. (2 Dall.) 409, 414 (1792); *see also United States v. Ferreira*, 54 U.S. (13 How.) 40, 53 (1851).

[196] *See, e.g.*, *Cargill B.V. v. S/S Ocean Traveller*, 726 F. Supp. 56, 61 (S.D.N.Y. 1989).

measures that are *ultra vires* or suffer from a facial error of law.[197]

Finally, the D.C. Circuit has held for decades that vacatur of an agency rule is authorized by § 706 of the APA: "When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed."[198] Of course, even the remedial practice of circuit courts that routinely hear certain types of cases does not always carry the day.[199] But that is precisely the relief awarded by the D.C. Circuit upon review of the FDA's prior rule on cigarette health warnings.[200]

Ultimately, the debate is resolved at this stage by Fifth Circuit precedent, which is binding here. That precedent treats "set aside" in § 706 of the APA as meaning the remedy of vacatur. For example, in *Chamber of Commerce v. Department of Labor*,[201] the Fifth Circuit relied on the APA's "set aside" language to vacate an agency rule *in toto*. Likewise, in *Community Financial Services Association v.*

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[197] *See* Her Majesty's Treasury v. Ahmed and Others [2010] UKSC 5 (noting that a quashing order indicates that the offending measure is *ultra vires* and "of no effect in law").

[198] *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998).

[199] *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391–94 (2006) (reversing the Federal Circuit's rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances).

[200] *See supra* note 37.

[201] 885 F.3d 360, 388 (5th Cir. 2018).

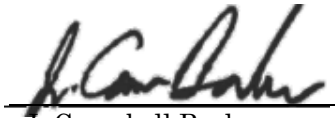
CFPB,[202] the court rendered judgment vacating a rule that exceeded the agency's authority. Similarly, in *Southwestern Electric Power Co. v. EPA*,[203] the Fifth Circuit vacated portions of a rule held to be unlawful. Consistent with that circuit precedent, this court will vacate the challenged rule.

Conclusion

For the reasons explained above, plaintiffs' motion for summary judgment on their First Amendment claim is granted. The court will grant plaintiffs (1) a declaratory judgment and (2) vacatur of the FDA rule. Vacatur of the rule resolves all of plaintiffs' pleaded injuries given defendants' agreement that the relevant Tobacco Control Act provisions do not take effect if the rule is vacated. So this court need not consider plaintiffs' other claims.

The court denies defendants' motion to dismiss and cross-motion for summary judgment. All other pending motions are denied as moot. A final judgment will issue forthwith.

So ordered by the court on December 7, 2022.



J. Campbell Barker
United States District Judge

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[202] 51 F.4th 616, 643–44 (5th Cir. 2022), petition for cert. filed, No. 22–448 (filed Nov. 14, 2022).

[203] 920 F.3d 999, 1033 (5th Cir. 2019).

APPENDIX C

United States Court of Appeals for the Fifth Circuit

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

ON PETITION FOR REHEARING EN BANC

Before SMITH, ELROD, and GRAVES, *Circuit Judges*.

PER CURIAM:

Treating the petition for rehearing en banc as a petition for panel rehearing (5TH CIR. R. 35 I.O.P.), the petition for panel rehearing is DENIED. Because no member of the panel or judge in regular active service requested that the court be polled on rehearing en banc (FED. R. APP. P. 35 and 5TH CIR. R. 35), the petition for rehearing en banc is DENIED.

APPENDIX D

U.S.C.A. CONST. AMEND. I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

APPENDIX E

15 U.S.C. § 1333

(a) Label requirements

(1) In general

It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

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.

(2) Placement; typography; etc.

Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word "WARNING" shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

(3) Does not apply to foreign distribution

The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import

cigarettes for sale or distribution within the United States.

(4) Applicability to retailers

A retailer of cigarettes shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) Advertising requirements

(1) In general

It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2) Typography, etc.

Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least

20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital "W" of the word "WARNING" in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by

3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3) Matchbooks

Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) Adjustment by Secretary

The Secretary may, through a rulemaking under section 553 of Title 5, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text,

format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) Marketing requirements

(1) Random display

The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(2) Rotation

The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or

retailer to, and approved by, the Secretary.

(3) Review

The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(4) Applicability to retailers

This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

(d) Graphic label statements

Not later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color graphics depicting the negative

health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) 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.

(d) Change in required statements

The Secretary through a rulemaking conducted under section 553 of Title 5 may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

(e) Tar, nicotine, and other smoke constituent disclosure

(1) In general

The Secretary shall, by a rulemaking conducted under section 553 of Title 5, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure

shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

(2) Resolution of differences

Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

(3) Cigarette and other tobacco product constituents

In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of Title 5, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement.

Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

(4) Retailers

This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.

APPENDIX F

21 C.F.R. § 1141.1

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of required warnings on cigarette packages and in advertisements for cigarettes.
(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.
(c) A cigarette retailer will not be in violation of § 1141.10 for packaging that:

(1) Contains a warning;
(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, or distributor; and
(3) Is not altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) or this part.

(d) Section 1141.10(d) applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under § 1141.10 for advertising. However, this paragraph (d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain

a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act or this part.

21 C.F.R. § 1141.3

§ 1141.3 Definitions.

For purposes of this part:

Cigarette means—

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and rear panel mean the two largest sides or surfaces of the package.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.

Package or packaging means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

21 C.F.R. § 1141.5

§ 1141.5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the source listed in paragraph (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993;
1-888-463-6332. You may also obtain the material at https://www.fda.gov/cigarette-warning-files.

(1) "Required Cigarette Health Warnings, 2020", IBR approved for § 1141.10.

(2) [Reserved]

21 C.F.R. § 1141.10

§ 1141.10 Required Warnings.

(a) Required warnings. A required warning must include the following:

(1) One of the following textual warning label statements:

(i) WARNING: Tobacco smoke can harm your children.

(ii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

(iii) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.

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

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

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

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

(viii) WARNING: Smoking causes head and neck cancer.

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

(x) WARNING: Smoking during pregnancy stunts fetal growth.

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

(2) A color graphic to accompany the textual warning label statement.

(b) Accurately reproduced. Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5.

(c) Packages. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping.

(2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels.

(3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(d) Advertisements. It is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.

(2) The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

(3) The text in each required warning must be in the English language, except as follows:

(i) In the case of an advertisement that appears in a non–English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the

required warning must appear in the same language as that principally used in the advertisement.

(4) For English-language and Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5.

(5) For non–English-language warnings, other than Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5, including the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English language version. The inserted textual warning label statement must comply with the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act, including area and other formatting requirements, and this part.

(e) Irremovable or permanent warnings. The required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be

removed to access the product within the package.

(f) Sale or distribution. No person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part, except as provided by § 1141.1(c) and (d).

(g) Marketing requirements—

(1) Random display. The required warnings for packages specified in paragraph (a) of this section must be randomly displayed in each 12–month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) Rotation. The required warnings for advertisements specified in paragraph (a) of this section must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributer, retailer to,

and approved by, the Food and Drug Administration.

(3) Review. The Food and Drug Administration will review each plan submitted under this section and approve it if the plan:

(i) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

(4) Record retention. Each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA–approved plan under section 4 of the Federal Cigarette Labeling and Advertising Act and this part must maintain a copy of such FDA–approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA–approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

21 C.F.R. § 1141.12

§ 1141.12 Misbranding of cigarettes.

(a) A cigarette will be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette will be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(b) A cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of

the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.