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

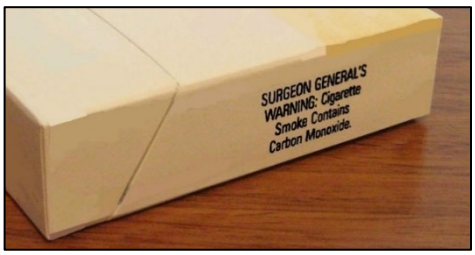
1. Plaintiffs sue to challenge an FDA rule on cigarette health warnings. Such warnings have a long history. For over 50 years, Congress has required health warnings on cigarette packages and advertising.[1] Section 4 of the Labeling Act of 1965 is the precursor of today's regime. It required that cigarette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

[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)).

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."
- "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

[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.

Tobacco Control Act recites Congress's understanding that "tobacco products are inherently dangerous and cause cancer, heart disease, 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 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

[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).
[13] *Id.* § 1333(c)(2).
[14] *Id.* §§ 1332(9), 1333(d) (first of two subsections (d)).
[15] *Id.* § 1333(a)(2).

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]

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

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[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)).

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

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

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 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

[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.

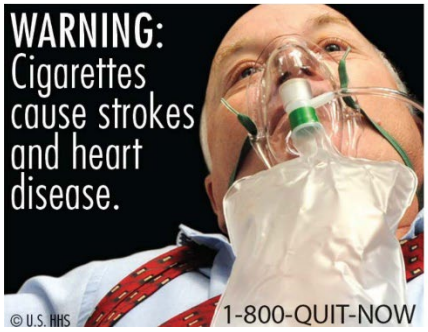
[23] *See id.*

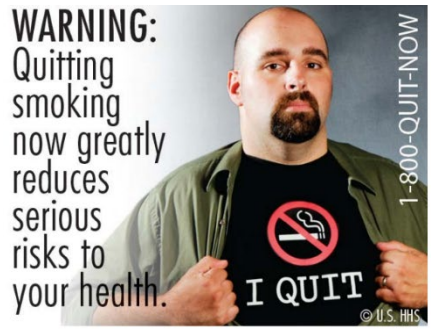
[24] *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011).

[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 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]

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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).

[30] *Id.* at 528–32.

[31] *Id.* at 532.

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 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

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[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.

[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)).

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 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

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[40] *Id.* at 1212.

[41] *Id.*

[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.*

for commercial-speech 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 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 anti-smoking message.[53] Relying on circuit precedent, the D.C. Circuit vacated the rule and remanded the rulemaking to the agency.[54]

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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.
[52] *Id.*
[53] *Id.* at 1221–22.
[54] *Id.* at 1222.

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]

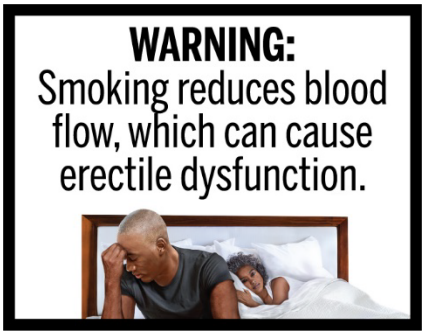
On March 18, 2020, after receiving public comment on its proposed rule, the FDA issued a new final rule on cigarette health warnings. The rule requires that cigarette packaging and advertising display, with even frequency on a rotating basis, one of these eleven warnings:[56]

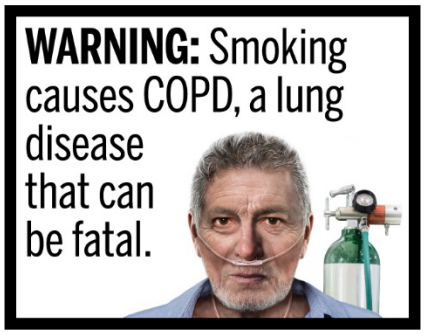
FDA's 2020 Graphics

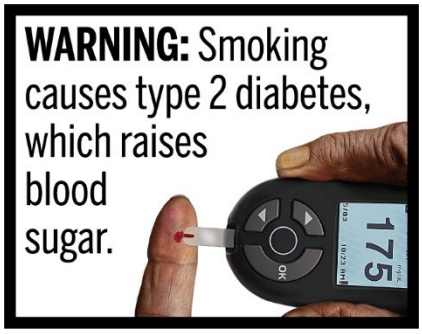
[55] *See Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985, 2019 WL 1047149, at *3 (D. Mass. 2019).

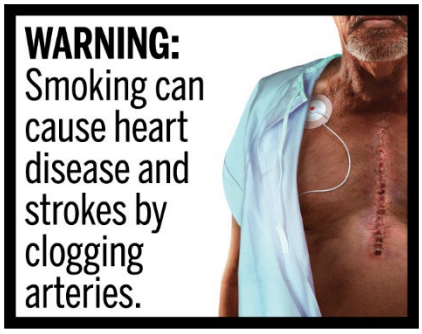
[56] 85 Fed. Reg. at 15,690–91; FDA, *Required Cigarette Health Warnings,* 2020, https://www.fda.gov/media/136157/download.

FDA's 2020 Graphics









In adopting those eleven warnings, the rule does not simply provide graphics for the nine textual warnings in the Act.[57] The

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

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 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]

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[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.

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

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

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]

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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[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.

[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;

(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

[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.

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 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

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[72] Doc. 36 at 17.
[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).

allowed the Court to "not consider the standing of the other plaintiffs."[77] Several other Supreme Court decisions follow such a "need not 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.

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

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

[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).

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

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 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"

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[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").

[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.

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 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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[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.

[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

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 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]

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affirmative relief from a court, it normally submits itself to 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.

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

[91] *Id.*

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 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

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[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 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.

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 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 any

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

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.

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:

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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.").

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

[105] 447 U.S. at 561–66.

(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]

(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

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[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).
[109] *Id.*
[110] *Id.* at 566.
[111] *Id.* at 565.
[112] 471 U.S. at 638.
[113] *Id.* at 647.
[114] *Id.* at 650.

information than they might otherwise be inclined to present."[115] But *Zauderer* viewed that requirement as materially different than a rule that wholly prevents 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]

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

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

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 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.

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[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.

[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).

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.

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

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

[131] *See* Lawrence Solum, Legal Theory Lexicon: Fact and Value, https://lsolum.typepad.com/legaltheory/2019/07/legal-theory-lexicon-fact-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.

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

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

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:

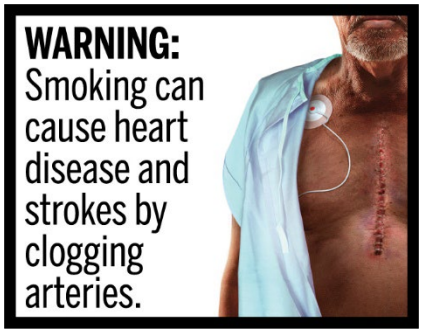
Its verbal aspect makes a falsifiable claim—that smoking causes head and neck cancer. But it is unclear how a court would go about determining whether its graphic aspect is "accurate" and "factual" in nature. The image may convey one thing to one person and a different thing to another. One person might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

[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").

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 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-

[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.

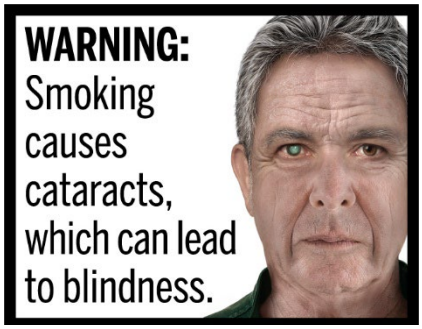
[139] Notably, in rejecting a facial challenge to the Tobacco Control Act's requirement of a graphic component to health warnings, the Sixth Circuit reasoned that the graphics could "merely be[] words" and offered the example of "handwriting"—not provocative, photorealistic images. *Discount Tobacco*, 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.

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

surgical treatment is 2.5 times more common or typical.[141] Neither does the FDA's cited source disprove that statistic.[142]

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 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

[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 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.

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

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

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.

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

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[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.

[147] 447 U.S. at 540.

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

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]

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 narrower alternative would achieve the government's interest.

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[149] 15 U.S.C. § 1331(1).

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

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

[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).

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]

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

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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 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-demonstrating-continued-success-agencys-youth-smoking-prevention-efforts-and.

[158] Doc. 37 at 60.

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 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.

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[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.

[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.*

D. Plaintiffs' other claims need not be resolved.

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

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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.

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

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

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 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

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[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).
[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.

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 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,

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[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).

[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.

rendering it devoid of legal effect in the same way that an appellate vacatur acts on a district-court judgment.[184]

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?

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

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[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 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.

"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 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

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

[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.").

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 "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] That is understood to allow a court to compel rulemaking that will bind nationwide, even on persons not

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[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).

[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).

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 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).

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 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*

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

[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).

Association v. 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

[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).