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

Plaintiffs challenge an FDA rule that requires cigarette packaging and advertising to bear health warnings that have both graphical and textual components. Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020). Plaintiffs raise the following claims: (1) the warnings go beyond purely factual, uncontroversial matters of the sort that the First Amendment allows the government to compel in private speech; (2) the FDA lacked statutory authority to change the Tobacco Control Act's nine warnings into the rule's eleven warnings, to change the wording of the Act's warnings, or to take either step when it did; (3) the FDA's choice of wording and graphics for the rule is arbitrary, capricious, or an abuse of discretion within the meaning of the Administrative Procedure Act (APA); and (4) the FDA's notice-and-comment process fell short of the APA's procedural requirements. Doc. 1.

The court entered summary judgment for plaintiffs on their First Amendment challenge to the rule. Doc. 106. But the Fifth Circuit reversed that judgment and remanded for this court's consideration of the APA claims (which include the statutory-authority claims). 96 F.4th 863, 868 (5th Cir. 2024). On remand, the court has received plaintiffs' motion for interim relief on the remanded claims and defendants' motion for summary judgment on them. Docs. 122, 126.

Analysis

Plaintiffs argue that, absent prompt interim relief, the rule's looming effective date will cause plaintiffs to incur costs that cannot be reimbursed (due to sovereign immunity) if plaintiffs ultimately prevail in a final judgment. The court credits plaintiffs' evidence of those imminent, irreparable costs absent judicial relief. The court also finds that the burden to defendants of interim relief and the public interest do not significantly counterbalance those irreparable costs because the rule's only goal is achieving more information in the abstract, not achieving a real-world change in behavior (an interest that the rule disclaims). So the three equitable factors bearing on issuance of a preliminary injunction or 5 U.S.C. § 705 interim relief favor plaintiffs.

The question thus reduces to whether plaintiffs have a substantial likelihood of success on the merits of their pending claims. They do as to the claim of a lack of statutory authority. The court thus enters a preliminary injunction and postpones the rule's effective date pursuant to 5 U.S.C. § 705.

I. Statutory authority for the challenged rule

Plaintiffs argue that the FDA lacked authority under the Tobacco Control Act to compel the warnings in the rule. The defense of res judicata does not apply to this claim. The D.C. Circuit's 2012 decision addressed only the challengers' First Amendment claim. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). Moreover, the prior rule vacated there required only nine graphic warnings with the statutory text, not this rule's eleven warnings with mostly different text. *Id.* at 1208.

A. Statutory background

The relevant statutory authority rests in 15 U.S.C. § 1333. After the Tobacco Control Act's amendments, it reads in full:

§ 1333. Labeling

(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 [21 U.S.C. 301 et seq.]. 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) [1] 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) [1] 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 [21 U.S.C. 301 et seq.], if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

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[1] So in original. There are two subsecs. designated (d).

(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 [21 U.S.C. 301 et seq.].

(4) Retailers

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

15 U.S.C. § 1333 (2018). The first subsection (d) is cited as (d)[1], with the second cited as (d)[2].

To review, the Tobacco Control Act itself defines many specifics about the new cigarette warnings. The Act's "label requirements" for cigarette packaging include:

- Stating one of nine, listed warnings. *Id.* § 1333(a)(1).
- Displaying such a "label statement" in the top half of the front and back of the package. *Id.* § 1333(a)(2).
- Capitalizing the word "WARNING." *Id.*
- Placing the label statement in 17-point font unless an exception is met. *Id.*
- Displaying the text of the label statement as black on a white background or vice versa. *Id.*

The "advertising requirements" of subsection (b) are similar to subsection (a)'s requirements for packages. Advertising must display "one of the labels specified in subsection (a)," using specified typography, label sizes, and text colors. *Id.* § 1333(b)(1)–(2).

The FDA is then given regulatory authority as follows:

- Under § 1333(b)(2), the agency *may* (but need not) "revise the required type sizes" for advertising warnings.
- Under § 1333(b)(4), the agency *may* (but need not) adjust:
    - "the format and type sizes" (but not the text) of the label statements required "by this section," i.e., as to both packaging and advertising;
    - "the text, format, and type sizes of any required tar, nicotine yield, or other constituent" disclosures (which may be required under § 1333(e)(1));
    - "the text, format, and type sizes" for any disclosures required under the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 et seq.
- Under § 1333(b)(4), the agency *shall* issue regulations for adjusting the format and type sizes of any warnings

required for advertising, to ensure that the total text required will fit within an advertisement's 20-percent area.

- Under § 1333(c), the agency *shall* review each manufacturer's plan for rotating among "[t]he label statements specified in subsection (a)(1)" and *shall* approve the plan if, among other things, it assures that "all of the labels required under this section" will be displayed across different products and locations at the same time.
    - In other words, all nine warnings must, at the same time, be on display somewhere by a manufacturer or one of its importers, distributors, or retailers.
- Under § 1333(d)[1], the agency *shall* issue regulations that require color graphics "to accompany the label statements specified in subsection (a)(1)."
- Under § 1333(d)[1], the agency *may* (but need not) "adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2)" if a certain finding is made about clarity and legibility.
    - Recall that, whereas subsection (a)(1) specifies the text of the warnings, subsections (a)(2) and (b)(2) specify the type size of the text, what foreground and background color the text must appear in, and the size and location of the entire label statement. Subsection (a)(2) is thus titled "Placement; typography; etc." Subsection (b)(2) is similarly titled "Typography, etc."
- Under § 1333(d)[2], the agency *may* (but need not) "adjust the format, type size, color graphics, and text of any of the label requirements" and *may* (but need not) "establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]."
    - Either authority may be exercised, by rulemaking, only upon finding that "such a change would

promote greater public understanding of the risks associated with the use of tobacco products."

- The cited Food, Drug, and Cosmetic Act itself authorizes the agency to require packaging or advertising disclosures regarding tar, nicotine, and other constituents of tobacco products or smoke. *E.g.*, 21 U.S.C. § 387*o*. That Act does not define the text of any such required disclosures.

- Under § 1333(e)(1), the agency *shall* determine whether the warnings must also include tar and nicotine yields of a tobacco product.
- Under § 1333(e)(3), the agency *may* (but need not) require disclosure of the level of any constituent of a tobacco product or its smoke, if it would benefit public health or otherwise increase consumer awareness of the health consequences of the use of tobacco products.

Two of § 1333's new subsections took effect immediately. Sections 202(b) and 206 of the Tobacco Control Act enacted 15 U.S.C § 1333(d)[2] and (e) without a delayed effective date. Pub. L. No. 111-31, 123 Stat. 1776, 1842–50.

But the rest of the amendments to § 1333 were not effective immediately. Those amendments were made in § 201(a) of the Tobacco Control Act. And Congress directed that those amendments "shall take effect 15 months after the issuance of the regulations required by subsection (a)" of § 201. *Id.* § 201(b), 123 Stat. at 1845. Read literally, that provision creates a circularity. There are no regulations required by § 201(a) until § 201(a) takes effect. But the parties agree that "required by" should be read as meaning something like "required by § 201(a) were it in effect." *See* Doc. 30 at 4 n.1 (joint motion). The court agrees and adopts that reading to avoid absurdity.

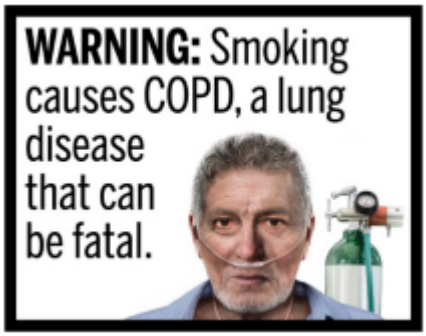
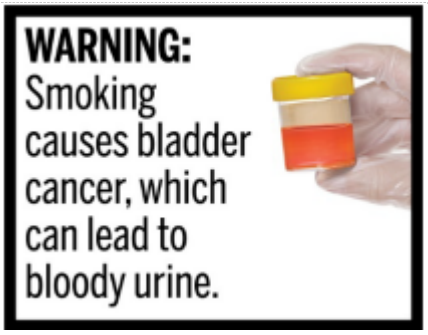
The parties also agree to another implied qualification: the 15-month countdown clock to the effectiveness of § 201(a)'s statutory amendments runs only if the contemplated regulations not just *are issued* but also *keep their effectiveness* throughout the

countdown period. Thus, the parties agree that the Act's new warning requirements are "tied to *the effective date* of the graphic-warnings Rule," which a court may postpone. *Id.* (citations omitted; emphasis added). On that view, judicial postponement of the effective date of the rule for a certain period also postpones for the same period 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, namely, 21 U.S.C. §§ 387c(a)(2), 387t(a). *See id.* The court previously accepted the parties' joint understanding of the effective date of the statutory provisions, acting on that understanding in postponing the effective date of the challenged rule. Doc. 33; *see* Doc. 106. Because plaintiffs' statutory-authority challenge has merit, the court now again postpones the effective date of the rule.

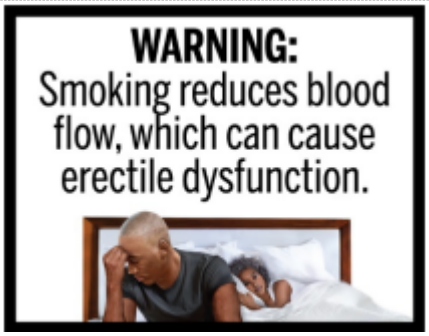
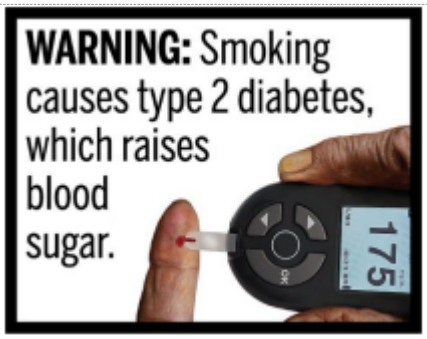
B. The rule's warnings versus the Act's warnings

Whereas the Tobacco Control Act requires one of nine warnings on cigarette packaging and advertising, the FDA's final rule requires one of eleven warnings. Plaintiffs contest the FDA's authority to require a different number of warnings than nine. Plaintiffs also contest the FDA's authority under § 1333(d)[2] to substantively depart from the Act's warnings. Lastly, even if the FDA's § 1333(d)[2] authority extends to both of those steps, plaintiffs argue that it cannot be exercised until after the effective date of initial regulations issued under § 1333(d)[1].

The FDA admits that, of the rule's warnings, only two use the exact text of the Act's warnings. And the FDA acknowledges that, of the rule's remaining warnings, only five mention a specific health risk from the Act's warnings. That leaves four of the rule's eleven warnings without any recognizable cognate in the Act's warnings. That state of affairs is shown in the chart below:

Tobacco Control Act:	**Final Rule:**
WARNING: Cigarettes are addictive.	(none)
WARNING: Tobacco smoke can harm your children. **exact wording in final rule*	
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.	(none)
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers. **exact wording in final rule*	
WARNING: Quitting smoking now greatly reduces serious risks to your health.	(none)

(none)	
(none)	
(none)	
(none)	

Before moving on to analyze the remanded APA claims, the court pauses to note one claim that it does not understand to be posed here: the constitutionality of the Act's compelled warnings, as opposed to the rule's warnings. Plaintiffs do challenge the constitutionality of both. Doc. 1 at 47–48. And if the FDA lacked statutory authority to substantively depart from the Act's warnings, the constitutionality of the Act's warnings would seem presented. But the court of appeals remanded only for consideration of "the APA challenge," which of course focuses on agency action as opposed to congressional action. 96 F.4th at 888. So the Act's constitutionality appears to be outside the scope of remand.

In the alternative, in case that claim is within the scope of remand, the court addresses it now in the interest of promoting efficient appellate review. Even then, the claim would fail under the Fifth Circuit's view of *Zauderer* review. To be sure, the D.C. Circuit vacated the prior rule as outside of *Zauderer*'s protection in part because it compelled "admonitions" to behave in a desired way. 696 F.3d at 1211. The D.C. Circuit singled out the "1-800-QUIT-NOW" warning as an impermissible attempt to "browbeat consumers into quitting." *Id.* at 1216–17. Analogously, the Act's compelled statement that "Quitting smoking now greatly reduces serious risks to your health" could flunk review under that principle by referencing quitting, not just disclosing the health risks. Indeed, that could explain why the agency omitted that statement in the final rule here.

But this court is bound by the Fifth Circuit, not the D.C. Circuit. And the Fifth Circuit, in contrast, does not identify a *Zauderer* problem simply because compelled statements advocate for the government's view of the "optimal . . . response" to a given product's harms. 96 F.4th at 886. Under that circuit precedent, this court would deny relief on the constitutional challenge to the Act even if it were within the scope of remand.

C. Statutory authority to increase the number of warnings

The final rule compels the use of one of eleven statements on every cigarette package. The Act itself makes it unlawful only for

packages to stray from one of nine statements. The first question is whether the agency has authority to increase the number of compelled warnings from nine to eleven. As the court reads the Act, Congress did not give the agency that authority.

At the outset, the court notes that its analysis proceeds without any deference to the agency's view. The APA "makes clear that agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024). It "remains the responsibility of the court to decide whether the law means what the agency says." *Id.* (quotation marks omitted).

Even after *Chevron*'s overruling, "the longstanding practice of the government—like any other interpretive aid—can inform a court's determination of what the law is." *Id.* at 386 (quotation marks omitted). Of course, the FDA's initial rulemaking in 2011 can hardly be described as longstanding. But even that rulemaking stayed within the limit now argued by plaintiffs. It selected only nine images, each matching to one of the Act's nine compelled statements. Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,648–57 (June 22, 2011). So the agency's claim of authority to compel more warnings is not aided by its prior practice, longstanding or otherwise.

Turning to the merits, the numerosity issue can be isolated conceptually by imagining that the final rule simply repeats the Act's nine required statements verbatim (rather than changing their wording) and then adds two new ones. That alone would exceed the agency's statutory authority.

The Act declares that it "shall be unlawful" to distribute cigarette packaging that does not carry "one of the following labels" and then lists nine, specific statements. 15 U.S.C. § 1333(a)(1). If the agency had authority to add two more statements to the Act's list of nine rotating statements, then 18% (2/11) of the statements required by rule would be unlawful under § 1333(a)(1). Likewise with § 1333(b)(1)'s declaration that it is unlawful to advertise cigarettes without "one of the labels specified in subsection (a)." No

provision of the Act mentions a power to lift or modify subsection (a)(1)'s and (b)(1)'s prohibition on omitting one of nine warnings.

The agency says that a power to compel additional statements is implied in subsection (d)[2]. But the language upon which the agency relies allows it, with the appropriate finding and procedure, to "adjust *the* format, type size, color graphics and text of *any of the* label requirements." 15 U.S.C. § 1333(d)[2] (emphases added). Even accepting for argument's sake the agency's view of what it means to "adjust . . . the text" of a label requirement (i.e., completely rewrite it), this power is limited to acting *on* one or more things in a statutory list of nine.

The word "the" before "text" is a definite article referring to the singular text of a label requirement. It does not convey an authority to add alternative texts to "the label requirement" at issue.

Neither does the phrase "any of the" before "label requirements." The word "any" means "one or some indiscriminately of whatever kind." *United States v. Gonzalez*, 520 U.S. 1, 5 (1997) (quoting Webster's Third New International Dictionary 97 (1976)). The word "of" indicates "the component material, parts, or elements or the contents." *Of*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/of. And the word "the" before "label requirements" is again a definite article, referring to the nine specific statements in subsection (a)(1). Putting those together, the agency has authority to adjust "the" singular text of any one or more of the items in the statute's list of nine required statements. Even if "adjusting the text" means changing words—not just the visual presentation of the words—the agency has not been given authority to *add* to the number of warnings by creating new ones.

At bottom, the agency questions why Congress would not have granted that power. The fact that Congress "happened" to choose nine warnings is not dispositive, the agency says, especially since eleven warnings are not too much more burdensome than nine. But what Congress "happens" to do is the law. Courts are not free

to second-guess policy decisions expressed in the plain text of the congressional enactments.

Nor is the absurdity canon implicated here. The agency does not dispute that manufacturers face a material, additional cost in incorporating and printing each additional required warning. Designers must perform more work. More printing cylinders must be engraved. A rotation plan must include more steps. Congress thus faced a policy choice about the desired cost to impose on manufacturers. And it struck that balance with a rule of nine, allowing the agency only to adjust the text of any of those nine labels.

With that matter of interpretation settled in plaintiffs' favor, the question becomes the proper remedy for the rule's lack of authority to require eleven warnings. The rule has a broad severability clause, as does the Act itself. 85 Fed. Reg. at 15,695–97 (quoting the Act's clause).

The problem in applying that clause here, however, is that the agency has not yet made, through APA procedure, the choice of what nine graphic warnings should be required. If the rule had announced a choice that two specific warnings should be severed and vacated if the agency lacked authority to require more than nine, then such a clause would control here. But the rule makes no such choice.

Alternatively, if the rule announced that the agency would need to reconsider all eleven graphics anew to arrive at a final set of nine, if that is the limit of its authority, the court would respect that policy choice. But the rule does not say that either.

As all parties agreed at oral argument, if this challenge to statutory authority succeeds, that choice belongs to the agency. The court cannot itself make that policy call. *See SEC v. Chenery*, 318 U.S. 80, 87–88 (1943) (courts cannot uphold an agency's action simply because it *might* have made certain required decisions). So the severability clauses do not allow any aspect of the rule to survive this meritorious claim of lack of statutory authority.

As such, and because the equitable factors support interim relief as noted above, the court postpones the effective date of the rule until the court enters final judgment. This relief is entered as a preliminary injunction as to plaintiffs pursuant to the court's inherent equitable power. And this relief is entered as to all whom the rule would otherwise govern pursuant to 5 U.S.C. § 705. If the court's final judgment departs from this analysis and ultimately favors defendants, the final judgment will specify the remaining time until the effectiveness of the rule and the associated Tobacco Control Act provisions.

Defendants argue that any § 705 relief should be limited to plaintiffs. But the Fifth Circuit has settled the question in this circuit, holding that the APA's text and longstanding administrative-law principles do not require a court "to limit any relief to the named parties." *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024), *cert. granted*, No. 24-413 (U.S. Jan. 10, 2025). The Fifth Circuit further holds that "the scope of preliminary relief under Section 705 *aligns with* the scope of ultimate relief under Section 706, which is not party-restricted." *Id.* (emphasis added); *see Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 951 (5th Cir. 2024) (holding that the statutory remedy of "setting aside agency action under § 706 has 'nationwide effect,' is 'not party-restricted,' and 'affects persons in all judicial districts equally'") (citations omitted), *cert. granted*, No. 24-316 (U.S. Jan. 10, 2025). Because § 706 relief is universal and not party-restricted, the court's § 705 relief must have the same scope under *Career Colleges*.

In the alternative, if the court had discretion but not an obligation to make § 705 relief universal, the court would exercise that discretion here. The public interest could be harmed by a world in which some cigarettes bear the new warnings but plaintiffs' cigarettes do not, suggesting that they do not in fact bear the same health risks. Nor does the rule even claim that the new warnings will cause a real-world reduction in smoking behavior.

D. Statutory authority to rewrite the warnings

Plaintiffs also dispute whether § 1333(d)[2] includes authority to rewrite the Act's warnings by editing any words at all or, at the least, by changing the substantive content of the warnings. The court finds that plaintiffs have some, substantial likelihood of success on this claim, justifying interim relief given that the equities strongly tilt in plaintiffs' favor, but that defendants also have a substantial likelihood of ultimate success after further analysis.

For the purposes of analyzing this argument, the court proceeds as if the agency first issued valid regulations under subsection (d)[1] specifying graphics for the Act's nine statements and now invokes subsection (d)[2] to completely rewrite those label statements, finding that doing so would promote greater public understanding of health risks. That analytical assumption isolates this specific argument by filtering out plaintiffs' first statutory-authority argument (the numerosity issue) and their third statutory-authority argument (the timing issue).

On this challenge, the statutory text is more supportive of the FDA's claimed authority. Subsection (d)[2] speaks of adjusting the "text" of any of the label requirements. And "text" has the natural meaning of the "words and form" of a printed work. *Text*, Merriam-Webster's Online Dictionary, https://www.merriam-webster.com/dictionary/text; *see* 85 Fed. Reg. at 15,642 (noting some commenters' concession that "text" "refers to both 'words and form,' not merely the latter"). Moreover, subsection (d)[2] itself uses "change" to describe what it means to "adjust" the text, undercutting the idea that "adjust" means something less than any change.

Yet the statute gives some indication that it uses the phrase "adjust the . . . text" in a more specialized sense. Subsection (d)[1] gives the agency authority, in issuing its initial regulations, to "adjust the type size, text and format" of the label statements as specified in subsections (a)(2) and (b)(2). Yet the two cited subsections specify only the form and placement of the text, not the words of it. The agency conceded as much in the rulemaking. 85

Fed. Reg. at 15,642 (in discussing subsection (d)[1]'s reference to subsections (a)(2) and (b)(2), stating: "the adjustments authorized by [subsection (d)[1]] focus on placement, typography, clarity, conspicuousness, and legibility—changes that go to the visual presentation of cigarette warnings").

So at least subsection (d)[1] uses the phrase "adjust the . . . text" to refer to adjusting the visual presentation of the text alone, not to changing the words of the text. That is some support for plaintiffs' argument that subsection (d)[2] uses the same phrase to mean adjusting the visual presentation of the text, not changing its words.

Nor would plaintiffs' meaning make meaningless subsection (d)[2]'s requirement that its authority requires a finding that an adjustment would promote greater public understanding of health risks. Greater public understanding could flow from changing the visual presentation of text, as subsection (d)[1] confirms. It would thus be coherent for Congress to have written the Act such that the subsection (d)[1] and (d)[2] authority to "adjust the . . . text" of a given warning refers to the same, limited power to change its visual presentation, but exercised at different times: initially under (d)[1] versus later under (d)[2].

At the same time, plaintiffs have not identified a plausible reason why Congress would have used the phrase "adjust the text" in that limited way in subsection (d)[2] while requiring that the adjustment promote greater public understanding of health risks. If the point of a (d)[2] adjustment is merely to further clean up visual presentation after a (d)[1] initial decision on visual presentation, the (d)[2] trigger would be expected to just repeat the (d)[1] trigger: a finding of greater clarity, conspicuousness, and legibility.

For those reasons, plaintiffs have some substantial likelihood of success on this claim, although questions of interpretation remain. Given the strong tilt of equitable factors in plaintiffs' favor, as discussed above, interim relief on this claim is also warranted.

E. Statutory authority to rewrite warnings initially

Finally, plaintiffs argue that the agency does not have the authority under subsection (d)[2] to adjust the text of the Act's statements (whatever that means) without first implementing the Act's warnings in a rulemaking under subsection (d)[1]. But if the agency's reading of the breadth of its subsection (d)[2] authority to "adjust the . . . text" of warnings is correct, then the court sees nothing in the Act requiring that authority to be exercised only after the effective date of a subsection (d)[1] rulemaking promulgating color graphics to accompany the Act's original warnings.

Subsection (d)[2] was enacted by § 202(b) of the Act and took effect immediately, so there is no concern with the (d)[2] authority itself having a delayed effective date. And no text in the Tobacco Control Act requires a subsection (d)[2] rulemaking to take effect any amount of time after a subsection (d)[1] rulemaking. The court sees no reason why the two rulemakings could not proceed on a parallel track, with a single proposed and final rule specifying that the subsection (d)[2] adjustment took effect one nanosecond after the subsection (d)[1] rulemaking took effect (15 months after its issuance without postponement). So this claim seems to do no work. *See* 5 U.S.C. § 706 (rule of prejudicial error).

The same is true for color graphics. Although graphics are not specified in the Act, the court sees no reason why the subsection (d)[2] power to adjust any set of graphics issued under subsection (d)[1] could not take effect only a nanosecond after the effective date of the subsection (d)[1] regulations. For that reason, the court does not find a substantial likelihood of plaintiffs' success on their third claim of lack of statutory authority.

II. Arbitrary, capricious, or abuse of discretion claim

Plaintiffs allege that the rule must be set aside as arbitrary, capricious, or an abuse of discretion within the meaning of 5 U.S.C. § 706. Although plaintiffs may develop that argument in further briefing, the court does not currently conclude that, under binding precedent, the agency's use of data or choice of images meets that standard for vacatur. Agency action does not violate that APA

standard if it is "reasonable and reasonably explained," or if the agency acts "within a zone of reasonableness and . . . has reasonably considered the relevant issues and reasonably explained the decision." *BNSF Ry. Co. v. Fed. R.R. Admin.*, 62 F.4th 905, 910 (5th Cir. 2023) (citing *FCC v. Prometheus Radio Proj.*, 592 U.S. 414, 423 (2021)).

The APA "imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies," so imperfect empirical or statistical data is not fatal to an agency's rulemaking. *Prometheus*, 592 U.S. at 427–28. But an agency must defend a rule on the bases it chooses, and a rule is arbitrary and capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

BNSF Ry. Co., 62 F.4th at 910 (quoting *Motor Veh. Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

1. Plaintiffs first advance several reasons why the rule fails to rationally make the Act's required finding that the rewritten warnings "promote greater public understanding of the risks associated with the use of tobacco products." They first contend that the effect on actual smoking rates must at least be considered as part of the issue, even if that is not the ultimate finding required by statute.

But, on appeal here, the Fifth Circuit accepted that a purely informational interest in increasing public understanding of the risks of smoking, without regard to any effect on smoking rates, is a valid and legitimate state interest for purposes of deferential *Zauderer* review. 96 F.4th at 883. First Amendment compliance is at least as important as APA compliance. So the court does not understand how reliance on that abstract interest, without more,

could be a valid and legitimate basis for state action under the First Amendment yet be arbitrary and capricious under the APA's deferential standard.

The agency's failure to conduct any cost–benefit analysis other than as required by executive order is likely excused for the same reason. If a valid state interest underlying the rule's compelled disclosures is the abstract, informational interest in promoting public understanding without any change in real-world behavior, as the Fifth Circuit held, it is hard to see how that interest can be assigned a dollar amount in a cost–benefit analysis.

2. Plaintiffs argue that the warnings are misleading and confusing. The court previously considered each of these eleven warnings and concluded that "each of the graphic warnings" had a capacity for multiple reasonable interpretations whose truth was not established by the record. Doc. 106 at 31.

The court stands by its view, which considered both the text and graphics of each warning. But the court is bound by the Fifth Circuit's contrary view that "when each image is paired with a fact-based, textual warning, any reasonable viewer interprets the image in light of the words" in a way that removes any impermissible ambiguity or misrepresentation. 96 F.4th at 880–81. The Fifth Circuit also saw no problem with the compelled warnings depicting side effects or manifestations of conditions that are rare or uncommon. *Id.* ("[W]e uncover no caselaw requiring the government to choose only the most common side-effect or consequence of the disease or injury discussed in a warning."). Given that ruling, this court does not perceive that plaintiffs have a substantial likelihood of success in convincing the Fifth Circuit that the images flunk APA rationality review.

3. On several matters concerning the agency's studies underlying the rulemaking, plaintiffs raise criticisms that the Fifth Circuit did expressly carve out and decline to address. *Id.* at 885. First, plaintiffs question whether the metrics used in the second quantitative study adequately demonstrate greater public understanding of health risks. They also note that the rule's warnings

score poorly on the "believability" metric for the first quantitative study, so much so that the FDA dropped the metric for the second quantitative study.

The rule determines that two metrics, "new information" and "self-reported learning," are "predictive for promoting understanding of the risks associated with cigarette smoking." 85 Fed. Reg. at 15,649. In doing so, the FDA relied on guidance from "communication and social science research" in selecting these two metrics as proxies for greater understanding. *Id.* at 15,664. And peer reviewers endorsed that reliance. *See, e.g.*, Admin R. 54097 (Doc. 71-25 at 193) ("[G]iven the outcomes listed in the original legislation, the outcomes chosen are appropriate."); Admin. R. 54105 (Doc. 71-25 at 201) ("The rationale for the new knowledge, learning and health beliefs is clear, but I would have liked to have seen some more rationale for including thinking about the risks, believability, and factuality.").

Regardless of whether use of those two metrics is analytically and statistically perfect in this court's opinion, the court must in good faith defer to the agency's choices rather than second-guess them. The agency's use of two metrics that provide early indicators of greater public understanding appears to place the rule outside the realm of purely arbitrary or capricious agency action. The agency notes an inverse relationship between levels of novelty and levels of perceived factualness or believability. It appears within the "zone of reasonableness" for the agency to conclude that its two primary metrics are predictive of *future* understanding caused by the warning labels.

4. Plaintiffs contend that the sample of survey respondents is not nationally representative. The rule itself acknowledges this, stating that the study was "not conducted with a nationally representative sample" and that the findings cannot be extrapolated to the generalized U.S. population. 85 Fed. Reg. at 15,660. The rule then states that its effect is still "valid and reliable." *Id.* at 15,663. It seems likely that a study can still "promote greater public understanding" (untethered to any concrete change in behavior)

even if that "understanding" is not equally distributed nationally. Further, one peer reviewer's acknowledgements that the study's participants were still "diverse" and "appropriate to address the research questions" reduce those concerns. At least one peer reviewer determined that these shortcomings made the studies "deeply flawed." But again, the FDA is not required to "have perfect empirical or statistical data" to implement Congress's command. *Prometheus*, 592 U.S. at 427.

5. Perhaps the strongest of plaintiffs' criticisms is that the second quantitative study compared the rule's warnings with the original Surgeon General's warnings as the control condition. If that were the only study and if the rule rested on studies alone, as opposed to normative judgments, the choice of control other than the Tobacco Control Act's warnings could well be arbitrary and capricious. But the first quantitative study did include comparisons between the Act's warnings and the rule's warnings. That study may have its own flaws in plaintiffs' view, but it did correctly include the Act's warnings as a control. Nor does it appear that the rule rested on studies alone.

6. Plaintiffs then argue that the rule is arbitrary and capricious because it ignored less-burdensome alternatives to the rule's provocative graphic warnings. If that complaint is about the visceral graphics chosen as compared to other graphics, it seems weakened significantly by the circuit's endorsement of the graphics together with the text as "incidental to [viewers'] retention of information about the health risks." 96 F.4th at 880–81.

If the complaint is about a failure to test smaller warnings, it seems more suited for a challenge under the First Amendment, which binds Congress as well as the agency. In contrast, the APA considers only the rationality of agency action. And the Act gives the agency specific directions on the required size and placement of the warnings. Likewise with the agency's failure to test a public-information campaign. Although potentially a persuasive First Amendment criticism, such a campaign was outside the agency's mandate under the Act.

III. Notice-and-comment claim

Plaintiffs next argue that the FDA failed to provide meaningful notice and a meaningful opportunity to comment. Each argument is addressed separately.

1. Plaintiffs argue that the FDA did not release the data underlying the quantitative and qualitative studies that it relied upon and that it did not release the peer-review reports relating to two quantitative studies. The APA requires that agencies publish a "general notice of proposed rule making" that includes "a description of the subjects and issues involved" in the proposed rule. 5 U.S.C. § 553(b)(3).

Courts cannot require more than the APA provides for. *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978). That notice must contain "sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019). The touchstone of this inquiry is whether persons are "fairly appris[ed] . . . of the subjects and issues the agency [is] considering." *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 448 (5th Cir. 2021).

The proposed rule listed fifteen warnings, ten of which end up in the final rule. 84 Fed. Reg. at 42,767–68. The eleventh warning (nonsmoker lung disease), which was not in the proposed rule, is unchanged from its original statement in the Act. The public, therefore, was given at least a general "description of the subjects . . . involved" in the final rule. 5 U.S.C. § 553(b)(3). The proposed rule surrounded its proposed warnings with context about the gaps in public understanding that could be improved with noticeable, color-graphic labels, thus giving a description of the issues involved. 84 Fed. Reg. at 42,762–63. And the proposed rule addressed each textual warning and analyzed the statistics surrounding each warning. *Id.* at 42,772–77.

Plaintiffs argue that, even with access to the reports underlying the agency's conclusions, they need access to the data underlying the reports. The legal merits of that argument come down

to a possible circuit split between the D.C. Circuit and the Fifth Circuit on the "every bit of information" principle.

The D.C. Circuit holds that "[i]ntegral to the notice requirement is the agency's duty 'to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. . . . An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.'" *Solite Corp. v. EPA*, 952 F.2d 473, 485 (D.C. Cir. 1991) (citation omitted); *see also United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 251 (2d Cir. 1977) ("failure to disclose to interested persons the scientific data upon which the FDA relied was procedurally erroneous"). That would seem to require disclosure of the study data here, unless it somehow does not qualify as "technical."

On the other hand, the Fifth Circuit has held that the public "need not have an opportunity to comment on every bit of information influencing an agency's decision." *Tex. Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 325–27 (5th Cir. 2001) (quoting *Texas v. Lyng*, 868 F.2d 795, 800 (5th Cir. 1989)). That supports the view that notice-and-comment procedure does not grant an interested party an informational right akin to discovery in litigation. *Cf. Exxon Mobil Corp. v. Mnuchin*, No. 3:17-cv-01930, 2018 WL 4103724, at *2 (N.D. Tex. Aug. 29, 2018) (noting the standard for the administrative record is "all documents and materials directly or indirectly considered by [the] agency") (alteration in original). Under that more forgiving side of the "every bit of information" split, plaintiffs have not persuaded this court of their substantial likelihood of success on this claim.

2. In contrast to their claim about release of underlying report data, plaintiffs also complain about the time within which they had to comment on certain qualitative reports: 15 days. Although a 60-day comment period has been recommended, the APA "does not specify a minimum time for submission of comments in an informal rulemaking." *Petry v. Block*, 737 F.2d 1193, 1201 (D.C.

Cir. 1984). Some opportunity to participate is all that the APA requires. *Phillips Petrol. Co. v. EPA*, 803 F.2d 545, 559 (10th Cir. 1986). The supplemental data released in the qualitative-study reports comprised only four new documents with hundreds, not thousands, of pages of scientific material. And plaintiff R.J. Reynolds, through RAI Services Company, managed to respond in the reopened comment period with a public comment.

Even then, the qualitative studies were described in detail in the proposed rule. 84 Fed. Reg. at 42,765–72. The final rule then notes the limits of the qualitative studies—they were based on small sample sizes and do not yield data that can be generalized, lending those studies what the agency calls a limited role in its iterative process. 85 Fed. Reg. at 15,666. Given that at least one plaintiff filed a comment and that the studies' limits were noticed by the agency, the court is unable to find a substantial likelihood of success in showing prejudicial error.

Conclusion

For the reasons given above, plaintiffs' motion for interim relief on their APA claims (Doc. 122) is granted. The effective date of the challenged rule, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020), is postponed for plaintiffs and all others whom it governs until the entry of final judgment in this case. Until that final judgment, defendants are preliminarily enjoined from enforcing against plaintiffs the cited rule and the associated statutory provisions cited above, 15 U.S.C. § 1333(a)(1), (b)(1); 21 U.S.C. §§ 387c(a)(2), 387t(a).

So ordered by the court on January 13, 2025.

J. CAMPBELL BARKER
United States District Judge