In the United States District Court for the Southern District of Georgia Brunswick Division

PHILIP MORRIS USA INC., DHALIWAL & ASSOCIATES, INC., STEWART CANDY COMPANY d/b/a Stewart Distribution, and GEORGIA ASSOCIATION OF CONVENIENCE STORES, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROBERT M. CALIFF, in his official capacity as Commissioner of the United States Food and Drug Administration, and XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,[1]

Defendants.

2:24-CV-143

ORDER

Before the Court are Defendants' and Plaintiffs' cross-motions for summary judgment. Dkt. Nos. 23-2, 39. The motions have been fully briefed, dkt. nos. 23-2, 39, 53, 55, and a hearing on

[1] The Clerk is **DIRECTED** to substitute as the proper defendants Commissioner Martin A. Makary, M.D., M.P.H., for Robert M. Califf and Secretary Robert F. Kennedy, Jr., for Xavier Becerra.

the motions was held on April 11, 2025. Dkt. No. 63. The motion is therefore ripe for review. For the reasons set forth below, Plaintiffs' motion is **GRANTED**, and Defendants' motion is **DENIED**.

BACKGROUND

This case arises out of the parties' dispute over an FDA Final Rule that requires certain warning labels and graphics for cigarette packaging.

I. Statutory and Regulatory Background

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA"). Pub. L. 111-31, 123 Stat. 1776 (2009) (codified at 15 U.S.C. § 1333). Pertinent to the case at hand is § 1333(a)(1), which makes it unlawful to manufacture, package, sell, distribute, or import for sale or distribution any cigarettes that fail to include one of the following labels on the packaging:

- **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.

15 U.S.C. § 1333(a). Section 1333 also directs the U.S. Food and Drug Administration ("FDA") to "issue regulations that require color graphics depicting the negative health consequences of

smoking to accompany the label statements specified in subsection (a)(1)." Id. § 1333(d)(1).[2] The statute directs the FDA to do this "[n]ot later than 24 months after June 22, 2009." Id. Congress identified the placement of these warnings—the statements must "comprise the top 50 percent of the front and rear panels of the package" and "at least 20 percent of the area of [an] advertisement" in a conspicuous and prominent format. Id. §§ 1333(a)(2), (b)(2). Furthermore, the statute authorizes that through a rulemaking, the Secretary "may adjust the format, type size, color graphics, and text of any of the 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." Id. § 1333(d)(2).

In 2011, the FDA promulgated the Final Rule which contained nine images (one for each of the warning statements in the TCA). Required Warnings for Cigarette Packages & Advertisements, 76 Fed. Reg. 36628-01 (June 22, 2011); R.J. Reynolds Tobacco Co. v. Food & Drug Admin. (R.J. Reynolds I), 696 F.3d 1205, 1209 (D.C. Cir. 2012).[3] Each graphic included the phone number for the National

[2] Section 1333 has two subsections labeled as (d). The first, titled "Graphic Label Statements," codifies § 201(a) of the TCA. The second, titled "Change in Required Statements," codifies § 201(b) of the TCA. Both parties refer to these subsections as 1333(d)(1) and 1333(d)(2), respectively, so the Court does, too.

[3] Because the Court cites to the 2012 R.J Reynolds proceedings in the D.C. Circuit as well as the ongoing R.J. Reynolds proceedings

Cancer Institute's smoking quitline—1-800-QUIT-NOW. R.J. Reynolds I, 696 F.3d at 1209. The stated purpose of the Final Rule was "reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use." Id. Ultimately, the D.C. Circuit vacated the graphic requirements and remanded the Rule to the FDA on the basis that it violated the First Amendment. Id. at 1222.

In March 2020, the FDA promulgated the new Rule consisting of eleven graphics to accompany eleven text warnings on cigarette packaging and advertisements. See 21 C.F.R. § 1141 (2025).

III. Overview of Pertinent FDA Studies

The methodology that the FDA used in creating the new graphics and warning statements is significant to multiple claims discussed below. Thus, the Court provides a brief overview of the studies relevant to these claims.

First, the FDA reviewed scientific literature "on the health risks associated with cigarette smoking, evaluating the public's general awareness and knowledge of those health risks, and assessing the Agency's own consumer research on potential revised warning statements." Dkt. No. 23-6 at 22 (85 Fed. Reg. 15658); see also Dkt. No. 23-5 at 13 (84 Fed. Reg. 42765). Next, the FDA

in the Eastern District of Texas, the Court refers to each as R.J. Reynolds I and R.J. Reynolds II, respectively.

developed revised statements and corresponding graphic images depicting negative health consequences of smoking. Dkt. No. 23-5 at 13 (84 Fed. Reg. 42765). The FDA conducted a series of sixteen focus groups to arrive at fifteen revised label statements to consider, in addition to the nine TCA statements. Id. at 15 (84 Fed. Reg. 42767).

From there, the FDA conducted its first quantitative study (Quantitative Study One) "to assess which, if any, of 15 revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to the 9 TCA statements." Dkt. Nos. 23-5 at 15 (84 Fed. Reg. 42767); 23-6 at 22 (85 Fed. Reg. 15658); Dkt. No. 56-10 at 172–73 (AR 39299–39300) (detailing study procedure in study report); id. at 178–83 (AR 39305–39310) (same). In part one, phase one, of Quantitative Study One, "participants in the control condition viewed all nine TCA text warning statements presented in a random order" while "[p]articipants in each of the 16 experimental conditions viewed 8 of the TCA statements, plus 1 of the revised statements in a random order." Dkt. No. 56-10 at 178 (AR 39305). In part two, phase one, participants were asked questions to assess their beliefs about "the negative health consequences of smoking contained in the warning statement." Id. at 180 (AR 39307). In phase two, "participants viewed a set of warning statements in a single exposure and then indicated their beliefs about the negative health

consequences of smoking contained in the warning statements by selecting relevant health consequences from a list."[4] Id.

Quantitative Study One found that ten of the fifteen FDA-created statements "demonstrated statistically significant higher levels of both 'new information' and 'self-reported learning' [the variables on which the FDA chose to focus] when compared to a TCA warning statement." Dkt. No. 23-5 at 17 (84 Fed. Reg. 42769). These ten statements, along with five TCA warnings, were then used in the second quantitative study that measured ten variables, including the previously selected variables of "new information" and "self-reported learning" (Quantitative Study Two). Dkt. No. 23-6 at 22 (85 Fed. Reg. 15658).

In Quantitative Study Two, participants were divided into six subgroups: adolescent smokers, adolescents susceptible to smoking, young adult smokers, young adult nonsmokers, older adult smokers, and older adult nonsmokers. Dkt. No. 56-10 at 311 (AR 39692). Participants within each subgroup were then randomly assigned to view one of sixteen treatment conditions[5] or the control condition

[4] In Phase Two, participants were divided into two groups: (1) a treatment group consisting of any participants from the sixteen experimental conditions in part one, phase one, and (2) a control group consisting of participants who were in the control condition in part one, phase one. Dkt. No. 56-10 at 180 (AR 39307).

[5] Quantitative Study Two included sixteen treatment conditions, even though only fifteen statements were tested. "Conditions 10 and 11 used the same statement ('Smoking causes COPD, a lung disease that can be fatal.') but with different images (diseased lungs or man with oxygen); because the images differed, conditions

(existing Surgeon General's warnings). Id. at 311–12 (AR 39692–39693); see also id. at 312–17 (AR 39693–39699) (detailing study procedure for Quantitative Study 2). This study resulted in thirteen warning statements that outperformed the Surgeon General's existing statements. Id. at 357 (AR 39737). The FDA included these thirteen warnings in the Proposed Rule but only eleven warnings were included in the Final Rule. Dkt. No. 23-5 (84 Fed. Reg. 42772) (identifying the thirteen statements in the Proposed Rule); 21 C.F.R. § 1141 (2025) (listing the eleven statements in the Final Rule).

LEGAL AUTHORITY

Under Federal Rule of Civil Procedure 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." However, "[w]hen a party seeks review of agency action under the [Administrative Procedures Act ("APA")], the district judge sits as an appellate tribunal." Lane v. United States, 338 F. Supp. 3d 1324, 1331 (S.D. Ga. 2018) (internal quotation marks and citation omitted). "Accordingly, the standard set forth in Rule 56 does not apply because of the limited role of a court in reviewing the administrative record." Id. "Summary judgment is the mechanism for deciding whether as a matter

10 and 11 were treated as distinct warnings." Dkt. No. 56-10 at 312 (AR 39693).

of law the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review." Id.

The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Under Section 706, "[t]he reviewing court shall—(1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions" the reviewing court finds to be "(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] (D) without observance of procedure required by law." 5 U.S.C. § 706. This standard "requires that agency action be reasonable and reasonably explained." FCC v. Prometheus Radio Project, 592 U.S. 414, 423 (2021) (collecting cases). Importantly, under this provision, judicial review is deferential, "and a court may not substitute its own policy judgment for that of the agency." Id.

The agency's decision is arbitrary and capricious if the agency relies on factors that "are not what Congress would intend," the agency "entirely failed to consider an important aspect of the problem," the agency "offered an explanation counter to the

evidence before the agency," or "the agency action is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Florida v. Dep't of Health & Hum. Servs., 19 F.4th 1271, 1290 (11th Cir. 2021) (citation and quotations omitted); Defs. of Wildlife v. U.S. Dep't of Navy, 733 F.3d 1106, 1115 (11th Cir. 2013) (same); Fund for Animals, Inc. v. Rice, 85 F.3d 535, 541 (11th Cir. 1996) ("To determine whether an agency decision was arbitrary and capricious, the reviewing court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." (internal quotation marks omitted)). "The arbitrary and capricious standard is 'exceedingly deferential.'" Defs. of Wildlife, 733 F.3d at 1115 (citation omitted). As a result, "a party seeking to have a court declare an agency action to be arbitrary and capricious carries a heavy burden indeed." Legal Env't Assistance Found. v. EPA, 276 F.3d 1253, 1265 (11th Cir. 2001) (internal quotation marks and citation omitted), abrogated on other grounds by Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024).

Importantly, the Court cannot substitute its judgment for the agency's if the agency's conclusions are rational. Id. (citing Miccosukee Tribe of Indians of Fla. v. United States, 566 F.3d 1257, 1264 (11th Cir. 2009)); see also Sierra Club v. Flowers, 526 F.3d 1353, 1360 (11th Cir. 2008) ("The court's role is to ensure

that the agency came to a rational conclusion." (citation omitted)); Pres. Endangered Areas of Cobb's History, Inc. v. U.S. Army Corps of Eng'rs (PEACH), 87 F.3d 1242, 1246 (11th Cir. 1996) ("The role of the court is not to conduct its own investigation and substitute its own judgment for the administrative agency's decision." (citation omitted)). Further, because "[t]he APA requires meaningful review," the Supreme Court has "stressed the importance of not simply rubber-stamping agency factfinding." Dickinson v. Zurko, 527 U.S. 150, 162 (1999) (citing Universal Camera Corp. v. NLRB, 340 U.S. 474, 490 (1951)). Judicial review under the APA does not relieve the agency of its obligation to develop an evidentiary basis for its findings. See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). To the contrary, the APA reinforces this obligation. See SEC v. Chenery Corp., 318 U.S. 80, 94 (1943). However, the Supreme Court also explained that Section 706 of the APA "does mandate that judicial review of agency policymaking and factfinding be deferential." Loper Bright Enters., 603 U.S. at 392 (citing 5 U.S.C. §§ 706(2)(A), 706(2)(E)).[6]

[6] Defendants contend that a portion of their motion is not a motion for summary judgment but a partial motion to dismiss for lack of subject matter jurisdiction. Dkt. No. 39 at 58-59 n.17; see also Dkt. No. 23-2 at 22 (Plaintiffs arguing that the FDA's enforcement timeline contravenes the APA); Dkt. No. 39 at 57 (Defendants arguing in response that the scope of the FDA's enforcement timeline is committed to agency discretion and thus beyond the Court's subject matter jurisdiction). This issue is now moot in

DISCUSSION

Plaintiffs argue that the FDA's rulemaking process violated the TCA and the APA. Dkt. No. 23-2 at 23–24. Specifically, Plaintiffs contend that the FDA exceeded its authority under the TCA by (1) issuing eleven warnings instead of only the nine included in the statute and (2) failing to make the required findings about public understanding to alter the text Congress prescribed. Id. at 24, 28. Moreover, Plaintiffs allege several ways that the FDA violated the APA rulemaking process, namely (1) the agency failed to show a rational connection between the facts found and the health risks featured in its Rule, id. at 31, (2) the agency arbitrarily assessed whether the health warnings it selected promoted "greater public understanding of the negative health consequences of smoking," id. at 33 (quotation and citation omitted), and (3) the agency failed to disclose key information thereby precluding Plaintiffs' opportunity to meaningfully engage in notice and comment, id. at 39.

In response, Defendants argue that the TCA authorizes the FDA to require eleven warnings as long as the agency does so via rulemaking and finds that the warning promotes greater public

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light of R.J. Reynolds Tobacco Co. v. Food & Drug Admin. (R.J. Reynolds II), 762 F. Supp. 3d 529, 552 (E.D. Tex. 2025) (postponing the Rule's effective date "for plaintiffs and all others whom [the Rule] governs until the entry of final judgment in this case"); Dkt. No. 53 at 19. Therefore, the Court need not address the standard for motions to dismiss.

understanding of the dangers of smoking. Dkt. No. 39 at 49. Defendants also contend that the FDA made the necessary findings to justify the new warnings and that a "head-to-head comparison" of the old and new warnings is not required by the TCA. Id. at 55 (quotation omitted). Furthermore, Defendants maintain that the Rule is consistent with the APA and, in fact, that the "FDA exceeded those standards." Id. at 12. In particular, Defendants argue that the FDA relied on "rigorously designed studies" to provide a "thorough, well-reasoned" explanation for the Rule, id., the agency's metrics for measuring "consumer understanding" were rational, id. at 15, 24, and the FDA ensured the public had a meaningful opportunity to comment on the proposed rule, id. at 24.

I. Number of Warnings

As a preliminary matter, Defendants contend that Plaintiffs have waived the eleven-warnings argument, or are precluded by judicial estoppel from raising it, because during the notice and comment stage, Plaintiff Philip Morris asked the FDA to consider only twelve or nine warnings instead of the proposed thirteen warnings. Dkt. No. 39 at 50; see also Dkt. No. 56-5 at 8 (AR 28475) ("First, as an initial matter, FDA should reduce the number of required graphic warnings from 13 to either 12 or 9."). Importantly, the chief reasoning behind Philip Morris's comment that the number of warnings should be decreased was manufacturing struggles—not that the FDA's revised warnings violate the TCA.

Dkt. No. 56-5 at 19 (AR 28486) ("This modification is necessary due to extremely difficult and potentially insurmountable technical challenges with printing and distributing 13 warnings equally and randomly on cigarette packages."); id. at 20–24 (AR 28487–28491) (discussing the basis for decreasing warnings further and noting that "manufacturers cannot satisfy the 'random and equal' requirement for 13 different warnings without drastic and uncertain changes to packaging production"). Plaintiffs argue that even if Philip Morris waived this argument, the remaining Plaintiffs did not. Dkt. No. 63.

D.C. Circuit precedent states that a "failure to raise a particular question of statutory construction before an agency constitutes waiver of the argument in court," even if the parties "had made other 'technical, policy, or legal' arguments before the agency." Lake Carriers' Ass'n v. EPA, 652 F.3d 1, 7 (D.C. Cir. 2011) (citations and quotations omitted). Under that standard, it may be true that Philip Morris waived its ability to now argue that the number of warnings violates the TCA. Though precedent from other circuits is persuasive, neither the Court nor the parties have identified binding Eleventh Circuit caselaw to show with certainty that the same rule applies to all Plaintiffs here. Accordingly, the Court declines to hold that Plaintiffs have waived their argument on this matter. Having resolved the question of waiver, the Court now turns to address whether the FDA exceeded

its statutory authority in promulgating a Final Rule with eleven warning statements.

As discussed supra, section 1333(a)(1) lists nine warning "labels" and provides that "[i]t 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*[.]" 15 U.S.C. § 1333(a)(1) (emphasis added). A related provision, section 1333(d)(2), states that the Secretary, via rulemaking, "may *adjust* the format, type size, color graphics, and text of any of the 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." Id. § 1333(d)(2) (emphasis added).

Plaintiffs argue that Defendants lacked authority under the TCA to change the number of required warnings for cigarette packages from nine to eleven. If true, the agency exceeded its statutory authority under the TCA.[7] See 5 U.S.C. § 706(2)(C); Legal

[7] To be clear, the Court is not engaging in *ultra vires* review. Here, the cause of action and the relief sought (setting aside agency action) is consistent with APA review. See Dkt. No. 1 at 60 (citing 5 U.S.C. § 706(2)(C) (The reviewing court shall set aside agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.")). Nor have Plaintiffs clearly put forth an *ultra vires* cause of action. See DCH Regional Med. Ctr. v. Azar, 925 F.3d 503, 509 (D.C. Cir. 2019) (stating that the requirements for *ultra vires* review set forth in Leedom v. Kyne, 358 U.S. 184 (1958) are "'(i) the statutory preclusion of

Env't Assistance Found., Inc. v. U.S. EPA, 118 F.3d 1467, 1473 (11th Cir. 1997) ("'The power of an administrative agency to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" (alterations adopted) (quoting Dixon v. United States, 381 U.S. 68, 74 (1965))). According to Plaintiffs, section 1333(a)(1) "unambiguously" precludes the FDA from adopting more than nine warning labels in the Final Rule because the only label options included in the statute are "one of the following" nine warnings listed. Dkt. No. 23-2 at 24. Put differently, Plaintiffs contend that the list of labels in § 1333(a)(1) is exclusive because "[w]hen Congress prohibits something unless 'one of the following' nine conditions is met, Congress affords exactly nine ways of complying." Id. In Plaintiffs' view, the FDA is unable to identify "affirmative statutory authorization for it to deviate from the number of warnings that Congress selected." Dkt. No. 53 at 3–4. Additionally, although Plaintiffs recognize that section 1333(d)(2) authorizes the Secretary to "adjust" the text of the labels, Plaintiffs argue that this means "to alter slightly," not

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review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" (quoting Nyunt v. Chairman, Broad. Bd. of Governors, 589 F.3d 445, 449 (D.C. Cir. 2009))).

to wholly rewrite or create new warnings as was done here. Dkt. No. 23-2 at 25 (quoting Adjust, Collins English Dictionary (7th ed. 2005)).

Defendants disagree with Plaintiffs' interpretation of the statute. Instead, they urge the Court to consider that section 1333(d)(2) authorizes the Secretary to "*adjust* the format, type size, color graphics, and *text* of *any of the label requirements*." Dkt. No. 39 at 50 (quoting 15 U.S.C. § 1333(d)(2) (emphasis added)). According to Defendants, "adjust" means to "change [something] so that it is more effective or appropriate." Id. (quoting Adjust, Collins English Dictionary, https://archive.ph/E1Wwm). Thus, Defendants argue that the FDA acted within the scope of the TCA because the statute allows the Secretary to change the text of the label requirements to be more effective or appropriate, and that is what the FDA did. Furthermore, Defendants contend that TCA § 202(a), codified as 15 U.S.C. § 1334, explicitly authorizes the agency to add label statements on cigarette packages by way of rulemaking. Dkt. No. 39 at 51. Specifically, that provision states that "[e]xcept to the extent the Secretary *requires additional or different statements on any cigarette package by a regulation*, . . . no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334(a) (emphasis added).

According to Plaintiffs, Defendants treat section 1333 as a "blank check," contending the *quantity* of warnings is a "label requirement" that the agency could adjust. Dkt. No. 23-3 at 26. Plaintiffs counter that, in order to conclude that label requirements can be changed without any intervention by Congress, one must assume that "label requirement" and "label statement" have drastically different meanings. Id. at 27. In essence, Plaintiffs' position is that because section 1333(d)(2) is titled "Changes in Required Statements"—not "Changes in Required Labels"—Congress intended only the *content* of the warnings—not the *number* of warnings—to change. Id. (citing Yates v. United States, 574 U.S. 528, 540 (2015) (plurality opinion) (stating that titles and headings can "resol[ve] doubt about the meaning of a statute")). In response, Defendants contend that section 1333(d)(2) allows the Secretary to "adjust the . . . text of any of the label requirements" and section 1333(a) is titled "Label Requirements." Dkt. No. 39 at 54. According to Defendants, adding two new warnings amounts to "adjust[ing] . . . the text of any of the label requirements." Id. Moreover, Defendants argue that their interpretation does not create a "blank check" because the agency must abide by (1) rulemaking procedures and (2) making the necessary findings that new warnings promote better understanding about the risks of smoking (i.e., fulfill the goal of the Rule). Dkt. No. 39 at 54.

Essentially, the question of how many warnings can be included in the Final Rule is a matter of statutory interpretation. To answer questions of statutory interpretation in the post-Chevron world, courts "must exercise their independent judgment" to determine whether an agency's interpretation of the statutes it administers comports with the agency's statutory authority. Loper Bright, 603 U.S. at 412.

The Court finds that there is "affirmative statutory authorization" supporting the agency's ability to change the number of warning labels provided. Dkt. No. 53 at 3–4. Specifically, changing the number of warnings is authorized by section 1334 which provides that the Secretary can "require *additional or different statements* on any cigarette package *by a regulation*." 15 U.S.C. § 1334(a) (emphasis added). Section 1334 reflects the precise situation at hand—through formal rulemaking, the FDA promulgated "additional or different statements" to be included on cigarette packages. Id.

Plaintiffs suggest that Defendants' statutory interpretation "presupposes a world of difference between 'label statements,'" the heading of sections 1333(d)(2) and 1334(a),[8] and "'label requirements,'" the heading of section 1333(a)(1). Dkt. No. 23-2 at 27. This is not so. "Label statements" are types of "label

[8] The precise heading of section 1334(a) is "*Additional* Statements." 15 U.S.C. § 1334(a) (emphasis added).

requirements."[9] This interpretation is supported by the fact that other parts of section 1333 discuss the "label statements" included in part (a)(1), even though part (a) is titled "label requirements." For instance, section 1333(a)(2), which also falls under the "label requirements" heading, addresses the placement on packaging and typography of the "label *statements* required by paragraph (1)." 15 U.S.C. § 1333(a)(2) (emphasis added). Similarly, section 1333(b)(2) sets forth advertising standards for the "label *statement[s]* required in subsection (a)." 15 U.S.C. § 1333(b)(2) (emphasis added). Thus, the varying uses of "label statements" and "label requirements" in sections 1333(a), 1333(d)(2), and 1334 further support the conclusion that the FDA has the authority to promulgate warning statements that are "additional or different" from those already provided by Congress. 15 U.S.C. § 1334(a).[10]

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[9] This is akin to the geometric truth that "all squares are rectangles, but not all rectangles are squares." In this context, label statements are label requirements, even if a label requirement encompasses other elements too. See, e.g., 15 U.S.C. § 1333(a)(2) (describing placement and typography of label statements under the "label requirements" section).

[10] Plaintiffs argue that "in ordinary language, a 'disclosure' is a 'statement,'" so "statements" as it is used in section 1334 might refer to "'disclosures' about tar or nicotine under § 1333(e)," and not "statements" in section 1333(a)(1). Dkt. No. 53 at 6. Yet Plaintiffs provide no explanation as to why "statements" as it is used in section 1334 has a different meaning than "statements" in section 1333. To conclude as much flies in the face of the canon of consistent usage. See Atl. Cleaners & Dyers v. United States, 286 U.S. 427, 433 (1932) ("Undoubtedly, there is a natural

At bottom, the plain language of the TCA provides that the FDA is not limited to the nine statements included in section 1333(a)(1), provided that the proper rulemaking procedures are followed and the agency makes adequate findings that its changes promote greater public understanding of tobacco use risks. Thus, the Court holds that Defendants did not violate the TCA by increasing the number of warning statements.

II. Required Findings to Select New Warnings

A. Greater Public Understanding

Section 1333(d)(2) authorizes "adjust[ments]" of the 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." 15 U.S.C. § 1333(d)(2) (emphasis added). Plaintiffs contend that the FDA's Final Rule did not properly gauge public understanding. Dkt. No. 23-3 at 28. According to Plaintiffs, the "ordinary meaning" of "understanding" is "comprehension of a concept," and Defendants did not employ this definition or "make any statutory interpretation argument." Id. at 29–30 (quoting The New Oxford American Dictionary (2d ed. 2005)).

Defendants respond by noting that the FDA "had no obligation" to engage in statutory interpretation to assess "whether the warnings in the Rule 'would promote greater public understanding

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presumption that identical words used in different parts of the same act are intended to have the same meaning.").

of the risks associated with the use of tobacco products'" because that is "a factual question of science and public policy." Dkt. No. 39 at 16 (quoting 15 U.S.C. § 1333(d)(2)). In other words, Defendants' position is that the Court need not determine what the definition of "understanding" is because whether a warning "promotes greater understanding" is a factual question on which the FDA is entitled to deference. Dkt. No. 55 at 8.

In order to determine whether the agency's findings that its warnings promote greater understanding of smoking risks are arbitrary and capricious, the Court must ascertain the meaning of "understanding." 15 U.S.C. § 1333(d)(2). When a term is undefined in a statute, courts "look to the plain and ordinary meaning of the statutory language as it was understood at the time the law was enacted." United States v. Dawson, 64 F.4th 1227, 1236 (11th Cir. 2023) (citation and quotations omitted). To do this, the Court can turn to "dictionaries in existence around the time of enactment." Id. (citations and quotations omitted).

Section 1333(d)(2) of the TCA was last amended in 2009. The applicable edition of Black's Law Dictionary defines "understanding" to mean "[t]he process of comprehending; the act of a person who understands something." Understanding, Black's Law Dictionary (9th ed. 2009). Plaintiffs submit that "understanding" means "comprehension" and thus reflects "the ability to grasp the acquired new information, ascribe meaning to it, and internalize

it." Dkt. No. 53 at 9 (first citing Understanding, The New Oxford American Dictionary (2d ed. 2005); Understanding, Merriam-Webster's Collegiate Dictionary (11th ed. 2008), then citing Comprehend, The New Oxford American Dictionary (2d ed. 2005); Comprehend, Merriam-Webster's Collegiate Dictionary (11th ed. 2008) (internal parentheticals omitted)). In instances such as this, where both popular and legal dictionaries "concur[]," it serves as "powerful evidence" of the word's "ordinary meanings." United States v. Pate, 84 F.4th 1196, 1201 (11th Cir. 2023). As such, the Court finds that "understanding" as it is used in the TCA means "comprehension" or "the process of comprehending."[11]

To measure "understanding," Defendants focused on two variables that the FDA perceived were "predictive of improved understanding:" 1) "new information"[12] and "self-reported learning."[13] Id.; see also Dkt. No. 23-6 at 22 (explaining the FDA's approach to testing the warnings). Plaintiffs argue that these variables fail to measure "public understanding" as defined in the TCA. Dkt. No. 53 at 10. Yet one of these variables—"new

[11] Courts owe no deference "to an agency interpretation of the law simply because a statute is ambiguous." Loper Bright, 603 U.S. at 413. In this case, Defendants did not ask the Court to adopt a specific interpretation, so there is no concern about deference to the FDA. Loper Bright, 603 U.S. at 413.

[12] This variable measured "[w]hether the warning was new information to participants." Dkt. No. 23-6 at 22.

[13] This variable measured "[w]hether participants learned something from the warning." Id.

information"—is an element of *Plaintiffs'* proffered definition of "understanding." Moreover, as Defendants explain in the Final Rule, and as Plaintiffs point out, "new information" and "self-reported learning" are "necessary precursors to message comprehension and learning" and are "[a]n important first step in promoting public understanding of health risks." Id. at 9 (quoting 85 Fed. Reg. at 15659). Put differently, both Defendants and Plaintiffs acknowledge that these variables account for individuals' "understanding" of a topic, at least in the early stages of comprehension. Accordingly, the Court concludes that the FDA's reliance on "new information" and "self-reported learning" to measure "understanding" is in accordance with the TCA.

Next, the Court considers whether the FDA's findings that the new warnings promoted greater public understanding of tobacco product risks was arbitrary and capricious. Nat'l Parks Conservation Ass'n v. U.S. Dep't of the Interior, 835 F.3d 1377, 1384 (11th Cir. 2016). Courts are "extremely deferential" to an agency's findings, id., so the agency's decision will only be deemed 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." Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43. The Court cannot "make up for such deficiencies" by "supply[ing] a reasoned basis for the agency's action that the agency itself has not given." Id. (citation and quotation omitted). However, the Court can "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." Id. (citation and quotation omitted).

Here, the record shows that the FDA's findings were not arbitrary and capricious. The Agency explained why it relied on "new information" and "self-reported learning" as the key variables and detailed its "in-depth review of the scientific literature" to determine that "warnings that provide new information and lead to learning promote understanding about the negative health consequences of smoking." Dkt. No. 23-6 at 26 (85 Fed. Reg. 15662); see also id. at 23 (85 Fed. Reg. 15659) (explaining that "understanding is multifaceted and composed of multiple processes," so "[c]onsumer perceptions that a warning provides new information and can contribute to self-reported learning are necessary precursors to message comprehension and learning"); id. at 17 (85 Fed. Reg. 42769) (explaining that, from the FDA's examination of "communication science research," the Agency "found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning").

Moreover, the findings from the FDA's studies support that the added warnings promote greater public understanding of the risks of tobacco products. The first quantitative study examined whether any of the fifteen revised warning statements would promote greater public understanding of smoking risks compared to the nine statements in the TCA. Dkt. No. 23-6 at 22–23 (85 Fed. Reg. 15658). The results of the first study informed which warning statements were tested in the second quantitative study—only the statements that out-performed the TCA warnings to a statistically significant degree on the two key variables, new information and self-reported learning, were included in the second study. Id. at 23. Warnings that did not out-perform the original TCA warnings were discarded. Id. Indeed, only thirteen warnings proceeded to the second study and, from that, eleven performed well enough to be included in the Final Rule. Id. Thus, the warnings included in the Final Rule were selected because the FDA's studies purportedly show that the warnings promoted greater public understanding of the risks of smoking in comparison to the original TCA warnings.[14] Id. ("All 11

[14] The warnings included in the Final Rule outperformed the TCA warnings on the measures of "new information" and "self-reported learning." However, the final warnings also outperformed the TCA warnings on "six other measures of understanding (i.e., thinking about health risks of smoking, attention to the warnings, perceived informativeness, perceived understandability, perceived helpfulness in understanding health effects, recall)," which further supports that "the study results demonstrate that the required warnings will promote greater public understanding of the

of the final required warnings demonstrated statistically significant improvements over the current Surgeon General's warnings.").

In sum, even if the Court or commenters on the Proposed Rule disagree with the FDA's decision to rely on the variables "new information" and "self-reported learning" as indicia of "understanding," that does not make the Agency's action arbitrary and capricious. "[T]he [C]ourt must in good faith defer to the agency's choices rather than second-guess them." R.J. Reynolds II, 762 F. Supp. 3d at 550. Thus, the Court finds that the FDA's reliance on "two metrics that provide early indicators of greater public understanding" pushes the Final Rule "outside the realm of purely arbitrary or capricious agency action." Id.

B. Head-to-Head Comparison of Warnings

Plaintiffs also argue that Defendants failed to properly show that the new warnings actually "promote[d] greater public understanding" of smoking risks as required in the TCA because Defendants did not conduct a "head-to-head comparison between each of its new warnings and the three TCA warnings that FDA discarded." Dkt. No. 23-2 at 30. Plaintiffs claim that failing to compare the warnings at a one-to-one level precludes the agency from examining if the FDA's "adjustment[s] improve[] upon the warning that

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negative health consequences of smoking." Dkt. No. 23-6 at 26 (85 Fed. Reg. 15662).

Congress wrote." Id. Defendants respond that not only is a head-to-head comparison not required by the TCA, but the FDA *did* compare the new warnings against the existing TCA warnings. Dkt. No. 39 at 23–24 (quoting AR 54176).

Plaintiffs argue that the phrases "such a change" and "greater" as they are used in 15 U.S.C. § 1333(d)(2) mandates head-to-head testing of the warnings. Dkt. Nos. 23-2 at 27; 63. In other words, head-to-head testing of the warnings is required to demonstrate that "such a change" in the warnings actually "promote[s] greater public understanding" of smoking risks. Dkt. Nos. 23-2 at 28–31, 53 at 11. Although this language may indicate that the FDA must engage in some type of comparison between the existing warnings and new warnings to justify replacements, nothing in the TCA states that the only way to satisfy this requirement is through a head-to-head comparison of warnings, and the Court declines to read this requirement into the statute. See Defs. of Wildlife v. Bureau of Ocean Energy Mgmt., 684 F.3d 1242, 1250 (11th Cir. 2012) ("It is not the duty of this court to determine the propriety of the methodology used by [the agency.]"); Am. Waterways Operators v. Wheeler, 507 F. Supp. 3d 47, 67 (D.D.C. 2020) ("Although the plaintiff[s] may disagree with the science or the methodology the agency elects to use, absent a statutory mandate that requires a particular methodology, the agency's

choice of methodology need only be 'reasonable' to be upheld." (citation and quotations omitted) (alterations adopted)).

Moreover, a review of Defendants' stated methodology reveals that the FDA's studies compared the original TCA warnings and revised statements and found that the "change[d]" statements "promote[d] greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)(2). The studies compared the original TCA warnings against the revised warning statements and only the warnings that outperformed the TCA warnings to a statistically significant degree were included in the Proposed and Final Rule. See Dkt. No. 23-5 at 16 (84 Fed. Reg. 42768) (describing the first quantitative study[15] where ten of the fifteen revised statements performed statistically significantly better on the measures of "new information" and "self-reported learning" and continued to the second study, but the five

[15] In phase one of the first quantitative study, "participants viewed nine warning statements, one at a time, presented in random order." Dkt. No. 23-5 at 16 (84 Fed. Reg. 42768). This consisted of either the original nine TCA statements, which were shown to the control group, or eight TCA statements and one of the fifteen revised statements, which were shown to those in the treatment group, i.e., participants in the experimental conditions. Id.; see also Dkt. No. 56-10 at 180 (AR 39307). In phase two of this study, the control condition participants viewed all the TCA statements at once, and the treatment condition participants viewed "one of several different combinations of nine revised warning statements." Dkt. No. 23-5 at 16 (84 Fed. Reg. 42768). All participants answered questions about their beliefs on the link between smoking and the health consequences presented in the warning. Id.

statements that did not were discarded); id. at 20 (84 Fed. Reg. 42772) (describing the second study[16] where the FDA cut the number of warning statements from fifteen to thirteen that were subject to public comment in the Proposed Rule). Accordingly, given the level of deference owed to the FDA's choice of methodology under section 706 review, and the Agency's findings that the "such changes" to the warnings "promote greater public understanding of the risks associated with the use of tobacco products," the Court concludes that Defendants' conduct was not arbitrary and capricious or in violation of the TCA.

III. Rational Connection Regarding the Selection of Warnings

Plaintiffs argue that the FDA did not adequately explain how it chose what health-related consequences to feature in the warnings. Dkt. No. 23-2 at 32. Specifically, Plaintiffs question why the FDA chose some of the "newly identified" conditions listed in the Surgeon General's 2014 report while ignoring others, especially if all or many of these conditions are lesser known to

[16] Participants in the control group viewed one of the existing TCA warnings and participants in the treatment group (those in the experimental conditions) viewed one of the new warnings. Dkt. No. 23-5 at 19 (84 Fed. Reg. 43771). The study took place in three different sessions over the course of two weeks. Id. During the first two sessions, participants viewed the warning statement and then answered questions about their beliefs on the consequences of smoking. Id. After the third session, at the end of the two-week period, participants answered these same questions and their recall about the warning they viewed was assessed. Id. at 20 (84 Fed. Reg. 42772).

the public. Id. at 33. Defendants respond that the fact there are other possible warnings about the risks of smoking that may be effective does not make the FDA's rule arbitrary and capricious. Dkt. No. 39 at 15.

The U.S. Supreme Court has explained that a court's scope of review under section 706 is "narrow." Dep't of Commerce v. New York, 588 U.S. 752, 773 (2019). Indeed, the court "determine[s] only whether the Secretary examined the relevant data and articulated a satisfactory explanation for his decision, including a rational connection between the facts found and the choice made." Id. (citation and quotation omitted); see also Islam v. Sec'y, Dep't of Homeland Security, 997 F.3d 1333, 1346 (11th Cir. 2021) (discussing APA section 706 review and stating "[u]nder that deferential standard, we assess whether the agency's decision demonstrates a rational connection between the facts found and the choice made" (citation and quotation omitted)); Autauga Cnty. Emergency Mgmt. Commc'n Dist. v. FCC, 17 F.4th 88, 98 (11th Cir. 2021) (same). Defendants have done so.

In both the Proposed Rule and the Final Rule, the FDA explained its process for developing the cigarette warnings such that the Court can conclude that there is a rational connection between the facts found by the Agency and the warnings it chose. Dkt. Nos. 23-5, 23-6. To start, the FDA explained that it "undertook a science-based, iterative research and development

process" to decide whether revising the TCA statements "would promote greater public understanding of the risks associated with smoking and then to develop and test paired concordant color graphics to accompany the textual warning statements." Dkt. No. 23-5 at 13 (84 Fed. Reg. 42765). The FDA reported that it reviewed risks associated with smoking and sought to focus on "less known, less understood" risks. Id. In some instances, this included addressing "well-known" risks but "providing '*more specific* information about the negative health effects of smoking.'" Dkt. No. 55 at 4 (alterations adopted) (quoting 84 Fed. Reg. 42766). From there, the FDA developed its initial revised warnings and color graphics. Id. Then, based on "careful review of the scientific literature on the health risks associated with cigarette smoking, evaluation of the public's general awareness and knowledge of those health risks, and assessment of the Agency's own consumer research on potential revised warning statements," the FDA concluded there was a sufficient basis to adjust some of the TCA statements. Id.

To identify the specific risks it would address, the FDA "considered the evidence presented in Surgeon General's Reports to identify all negative health consequences that are causally linked to cigarette smoking and exposure to secondhand smoke." Id. at 14. The FDA "determined that some of the health conditions newly identified in the 2014 Surgeon General's Report represented an

opportunity to educate the public about negative health consequences of cigarette smoking that are subject to particularly low awareness and understanding." Id. Next, the FDA reportedly developed revised statements and its "internal epidemiological experts" reviewed them to ensure, among other things, that they were accurate and the named conditions were not rare. Id. at 15. From there, the agency deployed a series of studies, sixteen focus groups, and two quantitative studies to assess the statements on a variety of factors;[17] this allowed the FDA to make data-driven decisions to winnow the total number of TCA and new statements from the initial twenty-four warnings to the thirteen included in the Proposed Rule and ultimately the eleven statements included in the Final Rule. Id. at 15–20.

[17] The variables tested were (1) new information ("whether the warning was new information to participants"), (2) self-reported learning ("whether participants learned something from the warning"), (3) thinking about risks ("whether the warning made participants think about the health risks of smoking"), (4) perceived informativeness ("whether the warning was perceived to be informative"), (5) perceived understandability ("whether the warning was perceived to be understandable"), (6) perceived factualness ("whether the warning was perceived to be a fact or opinion"), (7) health beliefs ("whether participants reported beliefs linking smoking and each of the health consequences presented in the warning"), (8) perceived helpfulness understanding health effects ("whether the warning was perceived to help participants understand the negative health effects of smoking") (9) attention ("whether the warning grabbed their attention"), and (10) recall ("whether the warning was recalled"). Variables nine and ten were tested only in the second quantitative study. Dkt. No. 23-5 at 20 (84 Fed. Reg. 42772).

In order to be included in the Final Rule, the statements had to show statistically significant improvements (compared to the control condition) for both the "new information" and "self-reported learning" variables.[18] Dkt. No. 23-5 at 19 (84 Fed. Reg. 42771). The FDA explained that this was because "scientific literature demonstrates that the outcomes 'new information' and 'self-reported learning' are predictive for the task of identifying which, if any, of the revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to a TCA statement." Id. at 17 (84 Fed. Reg. 42769). Furthermore, "[c]ommunication science research shows that an important first step in promoting public understanding of health risks is to raise public awareness of those risks, particularly if the risks are not commonly known." Id. This is especially true since "people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning." Id. Thus, measuring whether the warnings provided new information assisted the FDA in

[18] Even though these two variables were the factors on which the FDA relied to select the statements included in the Final Rule, all of the warning statements included in the Final Rule "also surpassed the Surgeon General's warnings on six other measures . . . all 11 final required warnings also led to more thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness understanding health effects; attracted more attention; and were better recalled." Dkt. No. 23-6 at 22 (85 Fed. Reg. 15658).

determining whether the warnings would help improve understanding. Id. The FDA also explained why it concluded that other variables, such as "thinking about health beliefs" and "health beliefs," were less informative variables and, as such, would not drive the Agency's decisions. Id.

In sum, Defendants provide in the Proposed Rule, and again in the Final Rule, a thorough discussion of how the FDA selected its starting place for assessing health conditions to include, how the statements were designed, and the facts on which the FDA relied to select the eleven statements included in the Final Rule. See id.; Dkt. No. 23-6. Thus, although there may be other warning statements that identify lesser-known consequences of smoking, the Final Rule was not arbitrary and capricious. When examining the record with the deferential standard required under section 706, the Court concludes that the FDA examined the pertinent data, provided an adequate explanation for its decisions, and made a rational connection between its reported findings and the statements included in the Final Rule.[19] Dep't of Commerce, 588 U.S. at 773.

[19] Plaintiffs cite District Hospital Partners, LP v. Burwell, 786 F.3d 46 (D.C. Cir. 2015), and News-Press v. Department of Homeland Security, 489 F.3d 1173 (11th Cir. 2007), as support for their position that the FDA's Final Rule is arbitrary because the Agency did not explain why it selected the health consequences it did. However, both cases present a different situation than the one at issue here. In District Hospital Partners, the agency identified 123 hospitals in the Notice of Proposed Rulemaking (NPRM), "a formal agency document that was published in the Federal Register." 786 F.3d at 58–59. Then, the Secretary identified only fifty

IV. Notice and Comment Process

Plaintiffs argue that the FDA's rulemaking process was procedurally defective because the Agency failed to turn over data and technical studies on which it relied. Dkt. No. 23-2 at 39. As such, Plaintiffs claim that they did not have a meaningful opportunity to be heard as part of the notice and comment process and that this failure was arbitrary and capricious. Id. at 39, 42. Defendants dispute that Plaintiffs lacked a meaningful opportunity to comment and argue that the APA does not require an agency to provide the public with the opportunity to comment on every piece of information impacting its decision. Dkt. No. 39 at 25. Further, Defendants argue that even if the nondisclosure of the raw data was an error in the notice and comment process, Plaintiffs did not show they were prejudiced by it. Id. at 27.

APA § 553(b) requires that a "general notice of proposed rulemaking . . . shall include either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). "[T]he purpose of notice under the APA is to disclose the thinking of the agency and the data

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hospitals in the Rule without explaining how they differed from the other seventy-three on the list. Id. Here, the FDA discussed the standards it employed to identify the health conditions it prioritized and how the final warnings were culled down from the initially proposed warning statements. News-Press is also inapposite here; that case involved FEMA's actions surrounding a Freedom of Information Act request—not a rulemaking. 489 F.3d 1173.

relied on." Lloyd Noland Hosp. & Clinic v. Heckler, 762 F.2d 1561, 1565 (11th Cir. 1985). Thus, "[w]hen a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it." Id. (citing United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 251 (2d Cir. 1977)); see also Am. Radio Relay League, Inc., v. FCC, 524 F.3d 227, 236 (D.C. Cir. 2008) ("[A]mong the information that must be revealed for public evaluation are the technical studies and data upon which the agency relies in its rulemaking." (citation and quotations omitted) (alterations adopted)); Endangered Species Comm. of Bldg. Indus. Ass'n of S. Cal. v. Babbitt, 852 F. Supp. 32, 36 (D.D.C. 1994), as amended on reconsideration (June 16, 1994) ("[W]here an agency relies upon data to come to a rulemaking decision, it generally has an obligation under the APA to provide such data for public inspection." (citations omitted)). A rule will not be set aside for failure to disclose data for public comment unless the plaintiffs can show "that they suffered prejudice from the agency's failure to provide an opportunity for public comment." Am. Radio Relay League, 524 F.3d at 237 (citation and quotation omitted).

Defendants contend that "a meaningful opportunity to comment does not require making available *all* potentially relevant underlying *data*." Dkt. No. 39 at 26 (emphasis in original). Defendants' response misapprehends the issue Plaintiffs raised; Plaintiffs do not argue that they needed the opportunity "to

comment on every bit of information influencing [the] agency's decision." Chamber of Com. v. SEC, 85 F.4th 760, 779 (5th Cir. 2023); Dkt. Nos. 53 at 17, 39 at 25. Instead, Plaintiffs take issue with Defendants' failure to disclose *any* of the *raw data* underlying the studies that the agency relied on in its rulemaking. See, e.g., Dkt. Nos. 23-5 at 19 (84 Fed. Reg. 42771) (detailing quantitative studies for which no data was disclosed); 23-6 at 23 (85 Fed. Reg. 15659) (same); see also Dkt. No. 56-10 at 165–297 (AR 39292–39424); id. at 298–516 (AR 39679–39897) (study reports containing no raw data). Defendants try to explain away Plaintiffs' concern by noting that the FDA disclosed "the qualitative and quantitative study *reports*," that, according to the FDA, "provided more than enough information about the studies for interested parties to analyze and comment on any supposed shortcomings."[20] Dkt. No. 39 at 26

[20] Defendants direct the Court to Chemical Manufacturers Ass'n v. EPA, 870 F.2d 177 (5th Cir. 1989), to suggest that the FDA satisfied its obligations by disclosing the reports for its quantitative and qualitative studies. Dkt. No. 39 at 26. The Court does not find Chemical Manufacturers persuasive on this matter. In Chemical Manufacturers, between issuing the proposed rule and the final rule, the agency adjusted one of the financial databases on which it relied for an economic-impact study; it shifted from using the "FIN/STAT" database to the "Dun & Bradstreet" database. Id. at 201. The change was made "in response to industry criticisms" voiced in the public comments. Id. at 202. In other words, the issue in that case was whether the agency's changes in response to comments made the initial notice insufficient. The Fifth Circuit held that it did not because the agency did not "replace its original data with completely new and different data, but, in response to industry criticisms, updated and expanded one of several data sources." Id. Further, "[t]he [agency's] use of the updated and expanded Dun & Bradstreet data base was a logical and

(emphasis in original); Dkt. No. 56-2 at 471 (AR 23863.1) (FDA stating "the raw data are not necessary for replicating the studies or evaluating the adequacy or scientific rigor of FDA's consumer research"); see also Dkt. No. 56-10 at 165–297 (AR 39292–39424); id. at 298–516 (AR 39679–39897) (study reports). To support this, Defendants point out that their peer reviewers did not "raise[] any concerns with the amount of data that had been provided, let alone request[] any of the raw data," so it follows that Plaintiffs did not need any more information to submit comments. Dkt. No. 23-2 at 26; Dkt. No. 56-2 at 481 (AR 23863.1) (concluding that because "the peer reviewers who reviewed the initial study reports of FDA's quantitative consumer research studies conducted their review without requesting or commenting on needing to review the studies' raw data" then other "commenters did not need the raw data . . . to meaningfully comment").

"To fulfill its obligation to provide adequate notice, an agency must 'make available to the public, in a form that allows

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reasonable development based on industry comments and as such did not require further notice and comment." Id.

Here, Plaintiffs assert that the FDA's failure to disclose its data meant that notice was insufficient from the start and Plaintiffs did not have a "meaningful opportunity to be heard" in the comment process. Dkt. No. 53 at 16 (citation and quotations omitted). This is a subtly different argument. Unlike in Chemical Manufacturers, where the agency made database changes in response to public comments about its credibility, Plaintiffs argue that they were unable to even submit comments about the integrity of the Defendants' data because they did not have access to the data underlying the studies.

for meaningful comment, the data the agency used to develop its proposed rule.'" FBME Bank Ltd. v. Lew, 209 F. Supp. 3d 299, 315 (D.D.C. 2016) (alterations adopted) (quoting Am. Med. Ass'n v. Reno, 57 F.3d 1129, 1133 (D.C. Cir. 1995)). This disclosure is required "in order to 'allow the parties to focus on the information relied on by the agency and to point out where that information is erroneous or where the agency may be drawing improper conclusions from it.'" Id. (alterations adopted) (quoting Nat'l Ass'n of Regulatory Util. Comm'rs v. FCC, 737 F.2d 1095, 1121 (D.C. Cir. 1984)). The key question is whether "the 'most critical factual material' used by the agency [was] subjected to informed comment." Am. Radio Relay League, 524 F.3d at 236 (quotation and citation omitted). Put differently, the Court must consider whether "*the agency has disclosed enough of the evidentiary basis and supporting documentation for its rule to allow parties to comment meaningfully and contest the basis on which an agency reached the result that it did*." FBME Bank, 209 F. Supp. 3d at 315 (citation omitted) (emphasis in original).

In American Radio Relay League, the D.C. Circuit concluded that the FCC erred by placing redacted studies in the rulemaking record. 524 F.3d at 239. The court noted that the FCC "c[ould] point to no authority allowing it to rely on the studies in a rulemaking but hide from the public parts of the studies that may contain contrary evidence, inconvenient qualifications, or

relevant explanations of the methodology employed." Id. In a similar vein, Defendants in this case attempt to rely on pieces of raw data in its studies for a rulemaking while also trying to keep that data out of the rulemaking record. Thus, the FDA's rule is based on "uncommented upon data and calculations." Id. at 237. "Allowing such 'omissions in data and methodology' may 'make it impossible to reproduce' [the] agency's results or assess its reliance upon them" thereby undercutting Plaintiffs' ability to meaningfully engage in the notice and comment process.[21] Id. at 238

[21] Defendants raise a strong argument that the FDA did not violate the APA by failing to disclose the data underlying its studies because the text of the APA does not require it to do so. Dkt. No. 39 at 25. This argument aligns with that of then-Judge Kavanaugh in his concurrence in American Radio Relay League. 524 F.3d at 245. In his opinion, then-Judge Kavanaugh critiques the Portland Cement doctrine, stating that it "stands on a shaky legal foundation" and "cannot be squared with the text of § 553 of the APA." Id. at 246; see also Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 393 (D.C. Cir. 1973) (standing for the proposition that agencies need to disclose the data on which they rely in rulemaking because "[i]t is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, [to a] critical degree, is known only to the agency"). Specifically, then-Judge Kavanaugh emphasized that the Portland Cement doctrine imposes more notice requirements on agencies than the text of APA § 553 mandates and therefore contravenes the U.S. Supreme Court's holding in Vermont Yankee. Am. Radio Relay League, 524 F.3d at 246. Though the Court recognizes the persuasiveness of this argument, it does not align with the binding Eleventh Circuit precedent that this Court *must* apply. See Lloyd Noland Hosp. & Clinic, 762 F.2d at 1565 ("When a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it."). Additionally, the majority in American Radio Relay explained that there is no inconsistency with construing APA section 553 to require that agencies disclose technical studies and data on which it relies. 524 F.3d at 240 ("[T]he court's precedent construing

(quoting City of Brookings Mun. Tel. Co. v. FCC, 822 F.2d 1153, 1168 (D.C. Cir. 1987)).

Defendants argue that even if the FDA's failure to disclose the raw data for its studies amounts to a notice and comment error, such error was harmless. Dkt. No. 39 at 27. Put differently, Defendants submit that Plaintiffs have not shown they were prejudiced by any notice and comment error. Id. Plaintiffs contend that that the error was not harmless because it could have impacted the FDA's procedure or substance of its decision. Dkt. No. 53 at 19 (citation omitted).

The Eleventh Circuit has stated that "[b]efore we may vacate an agency action for procedural failure during the notice-and-comment period, we must take due account . . . of the rule of prejudicial error." Miami-Dade Cnty. v. EPA, 529 F.3d 1049, 1061 (11th Cir. 2008) (alterations adopted) (quoting Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin., 494 F.3d 188, 202 (D.C. Cir. 2007) (quoting 5 U.S.C. § 706)). To show that an error was prejudicial, a plaintiff "must indicate with reasonable specificity the aspect of the rule to which it objects and how it might have responded if given the opportunity."

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section 553 to require agencies to release for comment the 'technical studies and data' or 'staff reports' on which they rely during a rulemaking is not inconsistent with the view that 'the Portland Cement doctrine should be limited to *studies on which the agency actually relies* to support its final rule.'" (internal citations omitted)).

Id. "At base, the petitioner must demonstrate that on remand, it can mount a credible challenge [to the Rule] . . . and was thus prejudiced by the absence of an opportunity to do so before the agency." Id. (quotations and citations omitted) (alterations adopted).

Plaintiffs argue that they were prejudiced by being deprived of the raw data on which the FDA relied during the rulemaking. Specifically, Plaintiffs contend that the denial inhibited their ability to identify and raise errors. Their argument is bolstered by the fact that after obtaining access to the raw data during litigation Plaintiffs identified that the data supports different conclusions than those reached by the agency. Dkt. No. 53 at 19; Dkt. No. 63. Defendants seek to minimize any prejudice by emphasizing that that Plaintiffs received a significant amount of information. At oral argument, Defendants noted "it is hard to overstate how much information was disclosed." Dkt. No. 63. In other words, Defendants' view is that Plaintiffs were not prejudiced because there were "hundreds of pages of study reports" that provided "more than enough detail" on which Plaintiffs could comment. Id.; Dkt. No. 39 at 27. Defendants contend that so much information was disclosed, so no prejudice could issue by nondisclosure of some information.

Ultimately, resolving this question hinges on whether prejudice arises 1) only when the *outcome* of the rulemaking might

have changed or 2) when the rulemaking *process* might have been different. The Court finds the latter; "an agency decision is harmless only when a mistake of the administrative body is one that *clearly* had no bearing on the *procedure used* or the substance of the decision reached." Bidi Vapor LLC v. U.S. Food & Drug Admin., 47 F.4th 1191, 1205 (11th Cir. 2022) (citation and quotations omitted) (emphasis added); see also United States v. Reynolds, 710 F.3d 498, 517 (3d Cir. 2013) ("[I]f the harmless error rule were to look solely to result, an agency could always claim that it would have adopted the same rule even if it had complied with the APA procedures. Accordingly, to avoid gutting the APA's procedural requirements, harmless error analysis in administrative rulemaking must focus on the process as well as the result." (alterations adopted) (citation and quotations omitted)).

Plaintiffs identify two examples of prejudice. First, Plaintiffs argue they were prejudiced by Defendants' failure to disclose the transcripts of its qualitative studies.[22] Dkt. No. 23-

[22] Plaintiffs also take issue with the fact that the FDA did not initially disclose even study reports for its qualitative studies. Dkt. No. 23-2 at 41. Instead, the Agency re-opened the comment period for fifteen days in November 2019 for interested parties to review over 600 pages of qualitative study reports. Id. The Court does not base its finding of prejudice on this delayed disclosure. Plaintiffs do not contend that they were unable to review the materials during that time or unable to issue a comment if desired. Furthermore, the APA does not specify a *minimum* time that interested parties must have to submit comments. See 5 U.S.C. § 553(c). "Some opportunity to participate is all that the APA requires." R.J. Reynolds II, 762 F. Supp. 3d at 552.

2 at 41. Defendants argue that nondisclosure of the transcripts did not prejudice Plaintiffs because "[t]he qualitative study reports disclosed the exact sorts of stray statements from focus group members that Plaintiffs unconvincingly cite as evidence of supposed confusion generated by the proposed warnings." Dkt. No. 39 at 28. Indeed, at oral argument, Defendants' counsel stated that "additional, cumulative quotes on top of the quotes they already had saying more or less the same thing . . . certainly wouldn't have changed the outcome of the rulemaking . . . [and] it wouldn't have even meaningfully altered the process for them to add a few additional citations to their string cite about why they think the warnings are misleading, or gruesome, or outrageous . . . ." Dkt. No. 63.

Defendants correctly point out that Plaintiffs had access to many of the quotes from focus group participants in the study reports. See, e.g., Dkt. No. 56-1 at 433–531 (AR 23281–23379) (focus group report). However, Plaintiffs point out that the qualitative study data was pertinent to their argument that the rule violates the First Amendment, and if they had access to the more than two thousand pages of information in the transcripts, then Plaintiffs could have been more "forceful" in presenting their First Amendment argument. Dkt. No. 63.

This is particularly relevant because Defendants advocate for the Court to apply the Zauderer standard to assess the First

Amendment implications of the warning statements. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985). Under Zauderer, a central issue is whether the warning statements are "purely factual and uncontroversial." Zauderer, 471 U.S. at 651 (invoking a lesser degree of First Amendment protection on commercial speech for "purely factual and uncontroversial" government-required disclosures that are "reasonably related to the State's interest in preventing deception of consumers"); see Nat'l Institute of Fam. & Life Advoc. v. Becerra, 585 U.S. 755, 768 (2018) (explaining that the U.S. Supreme Court "has afforded less protection" for speech that "require professionals to disclose factual, noncontroversial information in their commercial speech" (citations and quotations omitted)); id. (discussing that Zauderer governs "only commercial advertising and require[s] the disclosure of purely factual and uncontroversial information" (alterations adopted) (quotations and citation omitted)). Despite Defendants' assertion that additional citations to quotes would not have impacted the rulemaking process, Plaintiffs point out that the transcripts reveal many examples of how the "warnings trigger emotion, not comprehension" and the "chosen warnings were 'trying to make people feel afraid.'" Dkt. No. 23-2 at 52. Thus, at a minimum, access to the transcripts would have allowed Plaintiffs the opportunity to further flesh-out their First Amendment arguments during rulemaking and perhaps show that some,

or all, of the warnings are too controversial to comply with the First Amendment.

Although there are many possibilities for how Plaintiffs could have used this information during notice and comment, they offer no specifics to show how they could have "mounted a 'credible challenge'" to justify a finding of prejudice on this ground. Miami-Dade Cnty., 529 F.3d at 1061. In other words, despite now gaining access to the transcripts during the litigation process, Plaintiffs fail to demonstrate that there is sufficient information within those documents to actually support their claims that consumers found the warnings shocking, misleading, or scary. Dkt. No. 23-2 at 52; id. at 52 n.5. Without such a showing, Plaintiffs are unable to demonstrate that the FDA's disclosure of the qualitative studies transcripts would have impacted either the FDA's procedure or the substance of its decision.

Plaintiffs' second example of prejudice is that their inability to access the FDA's raw data prevented them from being able to "proffer[] new analyses" to "debunk[] FDA's claims of efficacy" for the revised warnings. Dkt. No. 53 at 19. In particular, after Plaintiffs received the raw data during the litigation process, they discerned that the existing Surgeon General's warning about carbon monoxide[23] had a statistically

[23] This warning reads "Cigarette Smoke Contains Carbon Monoxide." Dkt. No. 23-5 at 8 (84 Fed. Reg. 42760).

significant *higher* value for the "new information" measure than four of the FDA's revised warnings. Dkt. No. 23-11 at 9. Relatedly, "[w]ith respect to the 'self-reported learning' measure," Plaintiffs identified "that there was no statistically significant difference" between the FDA's final revised warnings and the Surgeon General's carbon monoxide warning. Id.

Defendants argue that this shows only that one of the Surgeon General's warnings were "less stale" than the others, and Plaintiffs' findings ultimately would not have impacted the rulemaking process because the FDA tested the revised warnings against an average of the four Surgeon General's warnings. Dkt. No. 63. This argument contradicts one of the primary bases upon which the FDA relied to support the rulemaking, which is that "a substantial body of research shows that the current 1984 Surgeon General's warnings do not effectively promote greater public understanding of the negative health consequences of smoking and that there are better approaches to cigarette health warnings." Dkt. No. 23-5 at 8 (84 Fed. Reg. 42760). Moreover, Plaintiffs argue this revelation suggests that the data averages on which Defendants rely "deceptively mask[] findings that undermine central premises of FDA's rulemaking." Dkt. No. 23-2 at 41.

To be sure, even if Plaintiffs had the opportunity to submit comments on these points, it may not have changed the FDA's ultimate decision. On the other hand, perhaps Plaintiffs' comments

would have motivated the FDA to adjust its rulemaking process, such as changing the methodology or considering keeping the carbon monoxide warning.[24] The Court need "not make a moral judgment—only a procedural one." Bidi Vapor LLC, 47 F.4th at 1206. Accordingly, because the Court is unable to conclude that the FDA's disclosure of the raw data during the notice and comment period "would clearly have no bearing on the *procedure* used," the Court must hold that Defendants' notice and comment error prejudiced Plaintiffs and thus violated APA § 706(2)(D). Id. at 1205 (emphasis in original) (alteration adopted) (citation and quotations omitted).

V. Relief[25]

"Vacatur is the ordinary APA remedy, but it is not the only one." Ins. Marketing Coalition Ltd. v. FCC, 127 F.4th 303, 317 (11th Cir. 2025) (alterations adopted) (internal quotation marks and citation omitted). Remand without vacatur may be appropriate "where it is not at all clear that the agency's error incurably

[24] The Court is in no way insinuating what it believes the FDA should have done. It merely notes the rulemaking process very well could have been impacted if the FDA had disclosed the raw data during the notice and comment period.

Relatedly, the Court restates that the FDA is entitled to deference on the methodology it chooses to use. See Defs. of Wildlife v. Bureau of Ocean Energy Mgmt., 684 F.3d 1242, 1250 (11th Cir. 2012) ("It is not the duty of this court to determine the propriety of the methodology used by [the agency.]"). The Court does not hold otherwise.

[25] Plaintiffs withdrew their request for a preliminary injunction and concede their disparate enforcement timeline argument is now moot. Dkt. No. 53. Accordingly, the Court need not address these arguments.

tainted the agency's decisionmaking process." Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs, 781 F.3d 1271, 1290 (11th Cir. 2015). "When considering whether to vacate and remand, or just remand, we consider 'the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed.'" Ins. Marketing Coalition Ltd., 127 F.4th at 317 (quoting Black Warrior Riverkeeper, Inc., 781 F.3d at 1290). Ultimately, the decision to vacate is within the Court's "broad equitable discretion." Id. (citation and quotations omitted). However, "remand without vacatur remains an exceptional remedy" but may be "appropriate when vacatur would disrupt settled transactions." Am. Great Lakes Ports Ass'n v. Schultz, 962 F.3d 510, 519 (D.C. Cir. 2020). Plaintiffs request that the Court vacate the entire Rule while Defendants ask the Court to remand without vacatur.[26] Dkt. Nos. 23-2 at 68, 39 at 64.

In this case, the Court finds that the FDA erred in the notice and comment stage of rulemaking and that error prejudiced Plaintiffs' ability to have full notice and meaningfully participate in the comment process. "Deficient notice is a 'fundamental flaw' that almost always requires vacatur." Allina

[26] Defendants ask the Court to sever any portion of the Rule it finds invalid. However, severability is a non-issue in this case because the Court finds that the rulemaking process, not a portion of the Rule, was flawed.

Health Servs. v. Sebelius, 746 F.3d 1102, 1110 (D.C. Cir. 2014) (citation omitted). This is particularly true when "there is no indication that vacatur would lead to disruptive consequences." Id. at 1111. Per the court's decision in R.J. Reynolds II, enforcement of the Rule at issue is postponed against all "whom it governs until entry of final judgment in th[at] case." 762 F. Supp. 3d at 552; Dkt. No. 35-1 at 31. Currently, the district court's order granting a preliminary injunction and postponing the Rule's effective date is in the briefing stage on appeal to the Fifth Circuit. In light of this, there is no clear timeline for when the Rule will be enforceable, and neither party has shown that Plaintiffs have already taken steps to comply such that vacatur would significantly disrupt the entities affected by the Rule.

The Court is cognizant of the time, resources, and effort that goes into rulemaking. Thus, its decision to vacate the FDA's rule for an error that ultimately might not lead to a different outcome is not made lightly. However, the APA mandates both substantive and procedural integrity, Bidi Vapor LLC, 47 F.4th at 1205, and one "purpose of notice under the APA is to disclose the thinking of the agency and the data relied on," Lloyd Noland Hosp. & Clinic, 762 F.2d at 1565. Accordingly, because Defendants failed to disclose the raw data for its studies on which the FDA relied during rulemaking, Plaintiffs were prejudiced during the rulemaking process, and the proper course is vacatur.

To conclude, "[t]his is not a case in which the 'egg has been scrambled,' and it is too late to reverse course," or at least, follow the proper rulemaking procedures. Allina Health Servs., 746 F.3d at 1110 (citation omitted). As such, the Final Rule is hereby **VACATED.**

CONCLUSION

The Final Rule is not arbitrary, capricious, or violative of the TCA. See 5 U.S.C. §§ 706(2)(A), (C). It was promulgated, however, "without observance of procedure required by law." Id. § 706(2)(D). The FDA's failure to disclose the raw data for its studies resulted in prejudicial error to Plaintiffs' ability to engage in the notice and comment process. For these reasons, Defendants' motion for summary judgment, dkt. no. 39, is **DENIED**, and Plaintiffs' motion for summary judgment, dkt. no. 23-2, is **GRANTED**. The Final Rule is **VACATED**, and the Clerk is **DIRECTED** to close this case.

SO ORDERED this 29th day of August, 2025.

HON. LISA GODBEY WOOD, JUDGE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA