No. 25-13863

In the United States Court of Appeals for the Eleventh Circuit

PHILIP MORRIS USA INC., ET AL.,
Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF GEORGIA, NO. 2:24-CV-00143-LGW-BWC HON. LISA GODBEY WOOD

BRIEF FOR PLAINTIFFS-APPELLEES PHILIP MORRIS USA INC., ET AL.

CHRISTOPHER R. JORDAN
RANDALL A. JORDAN
HUNTER, MACLEAN, EXLEY & DUNN, PC
455 Sea Island Road
St. Simons Island, GA 31522
(912) 262-5996

LISA S. BLATT
Counsel of Record
STEPHEN D. ANDREWS
CHARLES L. MCCLOUD
CLAIRE R. CAHILL
ANDREW G. BORRASSO
HALLIE SAUNDERS
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000
lblatt@wc.com

Counsel for Philip Morris USA Inc., et al.

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs-Appellees request oral argument. This appeal raises important questions under the Administrative Procedure Act and Tobacco Control Act. Oral argument will significantly aid this Court's decisional process.

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INTRODUCTION

This is a textbook case of agency rulemaking run amok. For years, cigarette manufacturers have warned consumers about the health risks of smoking by printing text-only Surgeon General's warnings on cigarette packages and advertisements. Those warnings have succeeded: Today, cigarette smoking is at an all-time low among both adults and adolescents. *See* HHS, *Eliminating Tobacco-Related Disease and Death: Addressing Disparities*, Report of the Surgeon General 64-65 (2024).

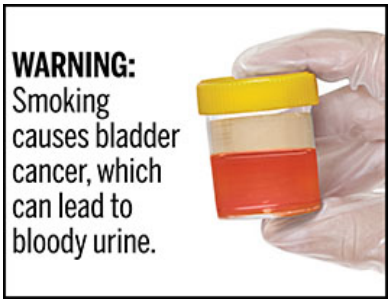
Seventeen years ago, Congress decided to overhaul cigarette warnings as part of broader efforts to empower the Food and Drug Administration (FDA) to regulate tobacco products. The Tobacco Control Act (TCA), Pub. L. 111-31, 123 Stat. 1776 (2009), required FDA to create graphic warnings about nine statutorily specified risks. Congress gave FDA limited authority to "adjust the format, type size, color graphics, and text" of those nine prescribed warnings, but only if doing so would improve "public understanding" of the risks of cigarettes. 15 U.S.C. § 1333(d)[2].

FDA's initial version of the rule required by the TCA was invalidated by the D.C. Circuit on First Amendment grounds. Several years later, FDA issued the current Rule. It would require cigarette manufacturers to display

eleven FDA-developed graphic health warnings across 50% of every cigarette package and across 20% of every advertisement, in constant rotation:

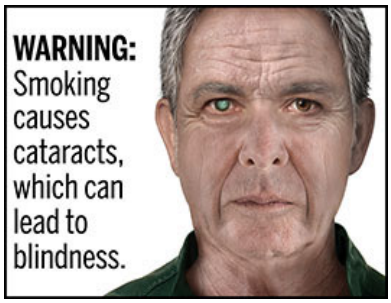
Harm to Children Warning

Fetal Harm Warning



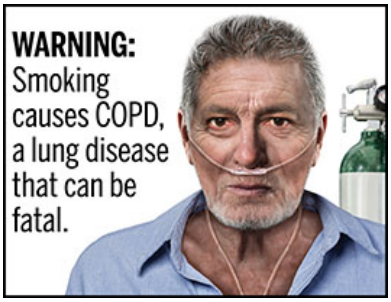
Bladder Cancer Warning

Amputation Warning

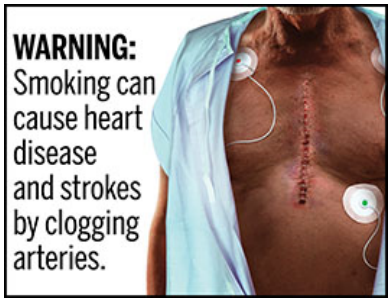


Blindness Warning

Head & Neck Cancer Warning



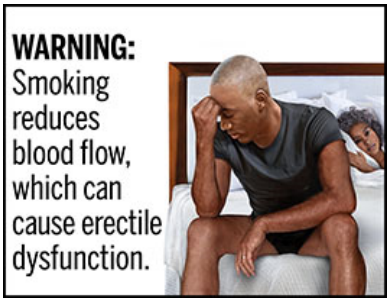
Smoker Lung Disease Warning



Heart Disease & Strokes Warning

Nonsmoker Lung Disease Warning

Diabetes Warning



Erectile Dysfunction Warning

The Rule is unlawful from start to finish. To begin with, FDA's rulemaking runs afoul of the bedrock requirements of the Administrative Procedure Act (APA). FDA failed to disclose the crucial studies and data on which it relied to choose the text-and-image pairings for the new graphic warnings (at least until litigation forced the agency's hand), depriving interested parties of a meaningful opportunity to participate in the rulemaking. The district court recognized as much and vacated FDA's Rule based on this notice-and-comment violation. FDA's insistence on appeal that it disclosed all the information it relied upon during rulemaking, as this Court's precedent requires, beggars belief. This Court should affirm the district court's judgment on this basis.

Alternatively, this Court should affirm the district court's judgment because FDA's Rule unlawfully contravenes multiple statutory directives about how the graphic warnings must be implemented. Congress prescribed nine—and only nine—warnings, each with specific text, 15 U.S.C. § 1333(a)(1). Yet FDA adopted *eleven* warnings, most of which were completely rewritten. Congress only empowered the agency to "adjust" the text of the statutory warnings, and even then, only if "such a change would promote greater public understanding of the risks associated with the use of tobacco products."

§ 1333(d)[2]. Yet FDA's Rule jettisons most of the congressionally prescribed warnings entirely, without finding that FDA's new warnings improve public understanding compared to Congress' originals. Indeed, FDA never even performed a head-to-head comparison between its new warnings and three of Congress' originals that it discarded.

In addition, the Court should affirm the district court's decision to remedy FDA's errors by vacating the Rule. As this Court has repeatedly held, vacatur is the ordinary remedy for an APA violation. The Supreme Court's universal-injunction decision in *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), does not change that rule. And in any event, vacatur is the only remedy that provides complete relief to Plaintiffs.

One last note: Although the district court did not reach the issue, Plaintiffs demonstrated below that the Rule infringes manufacturers' First Amendment right to speak messages of their own choosing and violates strict limits on the government's ability to compel speech. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018). If the Court does not affirm, it should remand for consideration of Plaintiffs' First Amendment challenge.

STATEMENT OF THE ISSUES

1. Whether the district court correctly granted summary judgment because FDA deprived Plaintiffs of a meaningful opportunity to participate in the rulemaking by failing to make available the raw data it relied upon before issuing the Rule, in violation of the APA.

2. Whether the district court's order should be affirmed on alternative grounds because FDA's Rule violates the TCA.

3. Whether the district court correctly vacated the Rule.

STATEMENT OF THE CASE

A. Statutory Background

Federal law has long mandated warnings about the health risks of smoking on tobacco packaging. *E.g.*, 15 U.S.C. §§ 1333, 1335; Dkt.1:pp.10-13, ¶¶ 33, 42. Cigarette manufacturers, in particular, are required to warn consumers about the health risks of smoking by printing text-only Surgeon General's warnings on cigarette packages and advertisements.

In 2009, Congress overhauled cigarette warnings as part of broader efforts to empower FDA to regulate tobacco products. The TCA requires FDA to develop graphic warnings depicting health-related risks associated with cigarette smoking. The statute spells out the text of those warnings,

prohibiting manufacturers from selling or advertising "any cigarette" unless its "package" and "advertising bear[] … one of the following" nine statements:

- 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)(1), (b)(1). The TCA also directed FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the[se] label statements" by June 22, 2011. § 1333(d)[1].[1]

These warnings must comprise "the top 50 percent of the front and rear panels of the package," § 1333(a)(2), and "at least 20 percent of the area of [any] advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement," § 1333(b)(2). Manufacturers

[1] Plaintiffs cite the duplicate subsections (d) the same way FDA does (FDA Br. 4 n.2).

must "randomly display[]" and "rotate[] quarterly in alternating sequence" the nine specified "label statements" and accompanying graphics. § 1333(c)(1)-(2).

The TCA gives FDA limited authority to "adjust" those warnings. FDA can make cosmetic changes "adjust[ing] the type size, text and format of the label statements" when it "issue[s] regulations that require color graphics" so that the "graphics and the accompanying label statements" together are "clear, conspicuous, legible and appear within the specified area." § 1333(d)[1]. FDA can also, through another rulemaking, "adjust the format, type size, color graphics, and text of any of the label requirements," but only if FDA "finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." § 1333(d)[2].

B. Factual Background

1. FDA's Invalid 2011 Graphic-Warnings Rule

In 2011, FDA implemented the TCA by mandating nine graphic warnings that paired the TCA's nine prescribed textual warnings with images of (among other things) disembodied organs, autopsies, and a distressed baby in an incubator. FDA's stated aim was to make consumers "depressed, discouraged, and afraid" to buy tobacco products. *See* Required Warnings for

Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,638 (June 22, 2011) (cleaned up).

The D.C. Circuit invalidated the 2011 Rule for violating the First Amendment. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1222 (D.C. Cir. 2012). The court explained FDA's graphic warnings were not "purely factual and uncontroversial information" as required under *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985), but were "primarily intended to evoke an emotional response," *R.J. Reynolds*, 696 F.3d at 1216.

2. FDA's Ensuing Rulemaking Process

FDA went back to the drawing board. FDA initially estimated that the rulemaking would take through 2021 because the warnings would be unprecedented and raise significant constitutional concerns. Decl. of Mitchell Zeller ¶¶ 10-11, 37, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. May 26, 2017), ECF No. 33-2. But a district court ordered FDA to issue a final rule by March 15, 2020—almost two years sooner than FDA thought was possible. *Am. Acad. of Pediatrics*, 2019 WL 1047149, at *3 (D. Mass. Mar. 5, 2019).

FDA's rushed rulemaking produced precisely the sort of defect-laden process the agency presumably feared when it asked for more time. FDA started by selecting seemingly arbitrary, extra-statutory health risks to focus on. FDA then developed warnings about those risks via (1) qualitative studies that FDA itself deemed unreliable and (2) quantitative studies in which FDA's warnings fared poorly on many key metrics. And FDA justified its Rule by ignoring the bad data and focusing only on two metrics from its quantitative studies that happened to most support its warnings.

1. FDA's Unexplained Choice of Health Risks. The TCA identifies nine warning topics: addiction, harm to children, fatal lung disease, cancer, strokes and heart disease, fetal harm, death, fatal lung disease in nonsmokers, and the benefits of quitting. 15 U.S.C. § 1333(a)(1). Early on, FDA decided to single out four new risks—amputation, blindness, diabetes, and erectile dysfunction. FDA also altered the TCA warning statements (like "[c]igarettes cause cancer"), deciding to test specific adjustments (such as specifically mentioning "bladder cancer"), but not other options (like mentioning other types of cancer).

Why and how FDA decided to require more and different warnings than what Congress specified remains a mystery *to this day*. The agency has *never*

explained these choices, which undergird everything else it did. FDA said only that it "review[ed] the scientific literature on the health risks associated with cigarette smoking," 85 Fed. Reg. 15,638, 15,658 (Mar. 18, 2020), and decided to "focus[] on less-known health consequences of smoking," *id.* at 15,640.

2. FDA's Qualitative Studies. FDA performed four qualitative studies testing participants' reactions to its thirteen categories of health consequences. Despite spending three years on these studies and relying on them to shape the development of the Rule, FDA later disavowed them as "not … nationally representative" and "not yield[ing] data that can be generalized." *Id.* at 15,666.

3. FDA's Quantitative Studies. FDA also performed two quantitative studies to test warnings covering FDA's thirteen pre-selected conditions.

April 2018 Quantitative Study: This text-only study was intended to test participants' reactions to fifteen FDA-drafted textual warnings and the TCA's nine warning statements to determine which "promote[d] greater public understanding" of smoking-related health risks. 84 Fed. Reg. 42,754, 42,767 (Aug. 16, 2019). But FDA never had participants assess head-to-head comparisons of any of its new proposed statements about amputation, blindness, diabetes, or erectile dysfunction against the three TCA warnings

FDA ultimately discarded, concerning addiction, death, and quitting. *Id.* at 42,769 n.8. *Compare* Dkt.56-10:p.210(FDA39337), *with* Dkt.56-10:pp.212-13(FDA39339-40).[2] FDA used this study to select fifteen textual statements—ten FDA-drafted statements and five TCA ones—for its final quantitative study. 84 Fed. Reg. at 42,769.

Although FDA had participants rate the textual warning statements across ten metrics, FDA decided that two would be dispositive: whether participants considered the warnings "new information" and whether participants perceived themselves as having learned something new from the warnings (or "self-reported learning"). *See id.*; 85 Fed. Reg. at 15,658; Dkt.56-10:p.708(FDA50772).[3] FDA selected for further development all ten of the fifteen FDA-drafted warnings based on its two curated metrics. 84 Fed. Reg. at 42,768.

FDA used nine FDA-drafted warning statements in its Final Rule; eight (covering amputation, bladder cancer, blindness from cataracts, diabetes,

[2] In citing supporting portions of the administrative record, this brief provides citations to the district court docket, using the pagination in the ECF header for these documents (*e.g.*, Dkt.56-10:p.210), and (parenthetically) to the number stamped in the footer (*e.g.*, (FDA39337)).

[3] This portion of Dkt.56-10 is in volume 2 of the supplemental appendix.

erectile dysfunction, fetal growth, head and neck cancer, and heart disease and strokes) showed *no* statistically significant improvements in informativeness over Congress' mandated warnings. Dkt.56-10:pp.216-18(FDA39343-45) & tbl.24. Participants rated six of the FDA-drafted warnings that FDA used in its Final Rule (covering amputation, bladder cancer, blindness from cataracts, diabetes, erectile dysfunction, and head and neck cancer) as both significantly *less* factual and *less* believable than the TCA's required warnings. *See* Dkt.56-10:p216-20(FDA39343-47) & tbls.24-25; Dkt.1:pp.44-45 ¶ 115.

May 2019 Quantitative Study: This was the only quantitative study evaluating the combined text and images comprising FDA's graphic warnings. Participants compared the four current Surgeon General's statements to sixteen graphic warnings.[4] Participants viewed the warnings multiple times and rated them on criteria like whether they contained "new information," caused participants to "learn[] something," and seemed "understandable" or "factual[]." 85 Fed. Reg. at 15,658-59; Dkt.56-10:pp.306-07(FDA39687-88).

[4] FDA created the sixteen warnings by (1) taking the text-image pairings in FDA's April 2018 qualitative study and (2) selecting the pairings associated with the fifteen textual statements FDA deemed most performant in the April 2018 quantitative study. *See* 84 Fed. Reg. at 42,769-72.

FDA then winnowed the sixteen warnings to the thirteen in the Proposed Rule.

Again, FDA ultimately judged warnings based only on "new information" and self-reported learning, ignoring its other metrics. *See* 85 Fed. Reg. at 15,658-59. Again, peer reviewers—people chosen for their trusted expertise—critiqued this "arbitrary" way of measuring consumer understanding. Dkt.56-11:p.21(FDA54059); *see* Dkt.56-11:p.25(FDA54063), Dkt.56-11:pp.32-35(FDA54070-73). And again, many warnings FDA mandated in the Final Rule performed terribly on the disregarded metrics. Dkt.56-10:pp.216-20(FDA39343-47) & tbls.24-25.

3. FDA's Proposed Rule

On August 16, 2019, FDA published its Proposed Rule. 84 Fed. Reg. 42,754. FDA proposed thirteen images, coupled with twelve textual warning statements. (The same text would accompany two images for chronic obstructive pulmonary disease (COPD).) *Id.* at 42,773-77.

The publication withheld significant information about FDA's warning development process. FDA cited its qualitative and quantitative studies, but it posted only "study reports" for its quantitative studies, not the underlying data or the peer reviews of the quantitative studies; FDA proposed the Rule

before peer review concluded. 85 Fed. Reg. at 15,658. And FDA did not release any underlying data or reports from its qualitative studies when it published the Proposed Rule.

On November 12, 2019, FDA reopened the comment period for 15 days after posting (on the same day) 600 pages of study reports for FDA's qualitative studies. *See* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period, 84 Fed. Reg. 60,966 (Nov. 12, 2019). Though these reports long pre-dated the Proposed Rule, FDA justified "not originally includ[ing]" them, claiming not to have "rel[ied] on these studies as part of the rulemaking." *Id.* at 60,967. But elsewhere, FDA admitted that it "used [these studies] to inform further research" by "test[ing] and refin[ing] image concepts and obtain[ing] feedback on which textual statements should be selected for further study." *Id.*; *see* 85 Fed. Reg. at 15,667. In fact, FDA had relied on the qualitative studies to rule out two of Congress' mandated warnings. *Supra* p.10.

C. FDA's Final Rulep

FDA issued its Final Rule on March 18, 2020. 85 Fed. Reg. 15,638 (to be codified at 21 C.F.R. pt. 1141). The Rule compels manufacturers to rotate the

graphic warnings depicted earlier (*supra* p.2) on packaging and advertisements. *Id.* at 15,638-39; Dkt.56-10:pp.6-164(FDA39133-291).

The Final Rule reveals other information missing from FDA's earlier releases, including a November 19, 2019 peer review report in which six experts in the fields of communications, behavioral science, and public health assessed FDA's quantitative studies. 85 Fed. Reg. at 15,661. The Rule says the peer reviewers deemed FDA's studies "strong" and "very well done." *Id.* In fact, peer reviewers identified serious issues with FDA's studies, ranging from the "significant weakness" of sampling methodology to "arbitrary" and "odd" focus on select study outcomes and FDA's failure to assess the "crucially important" issue of warning credibility. Dkt.56-11:p.21(FDA54059), Dkt.56-11:pp.34-35(FDA54072-73), Dkt.56-11:p.51(FDA54089).

FDA still did not disclose other data that FDA relied on, including the quantitative-study data. Instead, two days before publishing the Final Rule, FDA wrote a March 16, 2020 "Memo to File" acknowledging that "[a]ccess to the raw data could provide the ability to confirm that the findings reported in the study reports matched the pre-specified statistical analysis plan for each quantitative study." Dkt.56-2:p.482(FDA23863.2). But FDA speculated that "[a]ccess to the raw data would also allow third party attempts to analyze the

data in different and potentially selective, biased, or misleading ways other than what FDA pre-specified." *Id.* FDA thus denied anyone else a chance to identify red flags in FDA's data.

FDA only later released the raw study data as part of the administrative record in litigation. Analysis of the data reveals new findings that seriously impeach FDA's reasoning and conclusions. For instance, the data underlying FDA's May 2019 quantitative study shows that there was no statistically significant difference between the text-only Surgeon General's warning about carbon monoxide versus many of FDA's final graphic warnings on critical measures. *See* Dkt.23-11:pp.9-10, ¶ 24 (Vansickel Decl.). Not only that, the current carbon-monoxide warning even registered statistically significant *improvements* in "new information" as compared to FDA's graphic warnings for harm to children, nonsmoker lung disease, fetal harm, and COPD. *See id.*

D. Fifth Circuit Litigation Involving FDA's Final Rule

In April 2020, a group of plaintiffs—including cigarette manufacturer R.J. Reynolds—challenged FDA's Rule in the U.S. District Court for the Eastern District of Texas on both First Amendment and APA grounds. In December 2022, the district court vacated FDA's Rule on First Amendment grounds, leaving plaintiffs' separate APA claims unaddressed. *R.J. Reynolds*

Tobacco Co. v. FDA, 2022 WL 17489170, at *21 (E.D. Tex. Dec. 7, 2022). In March 2024, the Fifth Circuit reversed the district court's First Amendment holding, remanding for "the district court to consider the merits of the APA challenge." 96 F.4th 863, 888 (5th Cir. 2024).

On remand, the district court held that FDA lacked authority under the TCA to compel the warnings in the Rule. 762 F. Supp. 3d 529, 534-48 (E.D. Tex. 2025). Specifically, the court held the TCA did not empower FDA to "increase the number of compelled warnings from nine to eleven," *id.* at 544-45, and that relief was also warranted on plaintiffs' claim that section 1333(d)[2] did not authorize FDA to rewrite the TCA's warnings, *id.* at 546-47. The court entered a preliminary injunction as to plaintiffs and postponed the Rule's effective date "for plaintiffs and all others whom it governs until the entry of final judgment in this case." *Id.* at 552.

On March 14, 2025, FDA appealed the decision. *See* No. 25-40137 (5th Cir. 2025). The Fifth Circuit heard oral argument on February 3, 2026.

E. Procedural History

Plaintiffs sued FDA in the Southern District of Georgia claiming the Rule unconstitutionally compelled speech and that FDA's rulemaking violated

the APA and TCA. The court granted summary judgment to Plaintiffs and vacated the Rule.

1. The district court held that FDA's rulemaking process was procedurally defective and violated the APA because FDA "failed to turn over data and technical studies on which it relied," thereby depriving Plaintiffs of a meaningful opportunity to participate in the rulemaking. Dkt.68:p.35. The court explained that Eleventh Circuit (and other) precedent requires disclosing *data*, not just studies summarizing that data. Dkt.68:p.36. And it concluded that Plaintiffs had shown prejudice from being deprived of the data because "the rulemaking *process* might have been different" had FDA properly disclosed the data underlying its decision. Dkt.68:pp.43-48.

After they received the data through other litigation, Plaintiffs "identified that the data supports different conclusions than those reached by the agency." Dkt.68:p.42. Specifically, Plaintiffs' subsequent analyses found that the existing carbon monoxide warning ("Cigarette Smoke Contains Carbon Monoxide") had "a statistically significant *higher* value for the 'new information' measure than four of the FDA's revised warnings," and no statistically significant difference on the "self-reported learning" measure. Dkt.68:pp.46-47. The district court held that FDA's explanation "contradicts

one of the primary bases upon which the FDA relied to support the rulemaking," Dkt.68:p.47, and so FDA's failure to disclose the raw data underlying its quantitative studies "prejudiced Plaintiffs and thus violated APA § 706(2)(D)," Dkt.68:p.48. Because the court invalidated the Rule under the APA, the district court did not reach Plaintiffs' First Amendment argument.[5]

2. The district court rejected Plaintiffs' other statutory arguments. *First*, it held that the TCA authorizes FDA to change the number of required warnings from nine to eleven, because 15 U.S.C. § 1334(a) permits requiring "additional or different statements" issued "by a regulation." Dkt.68:p.18.

Second, the court held that FDA's finding that its warning promoted "greater public understanding" of associated risks, 15 U.S.C. § 1333(d)(2), was not arbitrary and capricious. Dkt.68:p.20. The court concluded that FDA's two variables, "new information" and "self-reported learning" are necessary parts of promoting public understanding, so FDA's reliance on those variables to measure understanding satisfied the TCA. Dkt.68:p.23.

[5] As noted elsewhere, if the Court does not affirm, it should remand for consideration of Plaintiffs' constitutional claim.

Third, the district court held that FDA "reasonabl[y]" complied with the TCA's requirement that FDA's new warnings provide the public with *greater* understanding of health risks, even though FDA never compared its new warnings to the statutory warnings it discarded. Dkt.68:pp.26-28.

3. The district court vacated the Final Rule based on FDA's prejudicial notice-and-comment error. The court held that FDA's error "prejudiced Plaintiffs' ability to have full notice and meaningfully participate in the comment process," and that such an error "almost always requires vacatur." Dkt.68:p.49 (citation omitted). Citing the Fifth Circuit *R.J. Reynolds* litigation, the court noted that the district court there had already postponed the Rule's enforcement against all affected parties, *see* 762 F. Supp. 3d at 552, so vacatur would not "significantly disrupt the entities affected by the Rule," Dkt.68:p.50.

SUMMARY OF ARGUMENT

I. This Court should affirm the district court's holding that FDA's failure to disclose the raw data underlying its studies violates the APA.

A. This Court has held that "[w]hen a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it." *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561, 1565 (11th Cir. 1985). The district court faithfully applied that precedent, holding that an

agency must disclose "the data the agency used to develop its proposed rule" to allow for meaningful comment. Dkt.68:pp.38-39 (cleaned up).

FDA's internal qualitative and quantitative studies were the only studies that assessed participants' reactions to the graphic warnings FDA selected. It was thus incumbent on FDA to disclose not just the studies but also their underlying data, so that commenters could check FDA's work and challenge the assumptions underlying FDA's Proposed Rule. Yet FDA failed to disclose *any* of that raw data, despite requests. Instead, the agency provided only its own curated study reports. But those reports merely summarized the results of FDA quantitative studies based on *FDA*'s assessment of the relevant information.

B. FDA's failure to disclose its studies' data seriously prejudiced Plaintiffs. After obtaining access to the raw data during litigation, Plaintiffs identified specific, relevant examples where the data supported different conclusions than those reached by FDA. And FDA's own justification of its decision to withhold the data conceded that "[a]ccess to the raw data could provide the ability to confirm that the findings … matched the pre-specified statistical analysis." Dkt.56-2:p.482(FDA23863.2). Yet FDA refused to give commenters that chance, citing the risk they might take a "different" or "potentially … misleading" approach to analyzing the data "than what FDA

pre-specified." *Id.* What FDA called an unwanted "different" approach is the kind of genuine interchange that notice-and-comment rulemaking demands.

By hiding these findings during the rulemaking, FDA prevented commenters from raising these critical points during the notice-and-comment period. The district court correctly concluded that this was error.

II. This Court may also affirm because FDA's rulemaking violated the TCA's limits.

A. The TCA's plain language mandates that cigarette packages and advertising bear one of *nine* warnings about specific health risks. FDA's Rule unlawfully adopted *eleven* warnings, which rewrote, added to, and discarded Congress' selected warnings.

FDA's Rule incorrectly relied on 15 U.S.C. § 1333(d)[2] to change the number of warnings required and to completely rewrite their content. That provision only allows FDA to "adjust" the "text" of the warnings. In ordinary usage, that means FDA can slightly alter the *wording* of Congress' warnings. Congress neither authorized FDA to "establish" the text of the warnings (which would permit wholesale rewrites) nor to adjust the "number" of warnings (which would permit FDA to add or delete warnings).

The district court meanwhile held that 15 U.S.C. § 1334(a) authorized FDA to revise the number of warnings Congress prescribed. That was error. *First*, section 1334(a) is a *preemption* provision, and it contains no affirmative

grant of authority to FDA to change the number of warnings. Rather, the preemption provision bars *other entities* from requiring cigarette label statements that are not authorized by FDA. *Second*, FDA never relied on section 1334(a) as a grant of authority for its Rule. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). And finally, section 1334(a) does not even support FDA's argument that section 1334(a)'s language suggests Congress anticipated that FDA would be allowed to change the number of warnings under section 1333(d)[2].

B. Even if FDA were authorized to change the number of warnings or rewrite their content, it could do so only if it found that each adjusted warning "would promote greater public understanding of the risks associated with the use of tobacco products." § 1333(d)[2]. FDA never satisfied that standard. *First*, it measured public understanding incorrectly, choosing its new warnings only based on how well they performed regarding isolated components of "understanding"—specifically, whether the warnings would provide the public with "new information" and help them learn something. As FDA's own peer reviewers noted, those metrics failed to assess genuine understanding, which requires comprehension.

Second, FDA did not consider whether its new proposed warnings *improved* public understanding *compared to* the TCA warnings that FDA

discarded. To do so, FDA would have needed to compare FDA's new warnings to the original TCA warnings that FDA discarded and then show that FDA's warnings provided greater understanding of health risks. Instead, FDA's studies pitted its warnings against random TCA warnings. FDA thus failed to address a "relevant factor" Congress required FDA to consider.

III. Vacatur is the correct remedy twice over.

A. The district court correctly applied this Court's two-prong test for vacatur from *Insurance Marketing Coalition Ltd. v. FCC*, 127 F.4th 303, 317 (11th Cir. 2025). It evaluated both the seriousness of the Rule's deficiencies (severe) and the disruptive consequences of an interim change (none) to come to the "ordinary" conclusion that vacatur was appropriate. FDA does not challenge the court's application of that standard to this case. Nor could it. FDA's errors were serious and vacatur preserves the status quo; it does not upset it.

B. FDA's efforts to inject equitable principles into the analysis are wrong and would support affirmance anyway. FDA says traditional principles should limit relief to the parties based on novel readings of the TCA and the APA. But the TCA's severability clause does not limit the Court's ability to

issue vacatur under the APA. And no principle of equity writes vacatur out of the APA.

In any event, FDA concedes prevailing plaintiffs are entitled to a remedy that provides complete relief. Here, the only remedy that provides complete relief to Plaintiffs is vacatur. That is because the Rule would be enforceable against manufacturers, distributors, and retailers—all of whom exist in a nationwide marketplace and supply chain with Plaintiffs. Party-specific relief would leave the parties unable to sell products free of FDA's unlawful warnings within that nationwide market.

ARGUMENT

I. FDA'S FAILURE TO DISCLOSE KEY INFORMATION PREVENTED MEANINGFUL COMMENT

"The purpose of notice under the APA is to disclose the thinking of the agency *and the data relied on*" so that the public may offer "meaningful comments on the proposed rule." *Lloyd*, 762 F.2d at 1565 (emphasis added); *see also Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236-40 (D.C. Cir. 2008). FDA's internal qualitative and quantitative studies were the only studies that assessed participants' reactions to the graphic warnings FDA selected. It was thus incumbent on FDA to disclose the studies and their underlying data during the notice-and-comment period, so that commenters

could check FDA's work and challenge the assumptions underlying FDA's Proposed Rule. Yet FDA failed to disclose *any* of the raw data underlying the studies that the agency relied on in its rulemaking, despite requests. Dkt.56-8:p.56(FDA36897) & nn.16-17; *see also* 84 Fed. Reg. at 42,771 (quantitative studies without disclosed data); 85 Fed. Reg. 15,659 (same); Dkt.56-10:pp.165-297(FDA39292-424); Dkt.56-10:pp.298-516(FDA39679-897) (study reports containing no raw data). As the district court correctly held with respect to the quantitative study, FDA's serious procedural error in failing to disclose data invalidates the Rule. Dkt.68:pp.47-48.[6]

A. FDA Failed to Disclose the Required Data

1. The APA requires agencies to provide notice of a proposed rule that includes "the terms or substance of the proposed rule" and provides interested persons "an opportunity to participate in the rule making." 5 U.S.C. § 553(b)(3), (c). Courts, including this one, have consistently held that "among the information that must be revealed for public evaluation are the technical studies and data upon which the agency relies in its rulemaking." *Am. Radio*,

[6] The district court held that FDA's failure to disclose the *qualitative* study transcripts was harmless. Dkt.68:p.46. As explained below, withholding that data was also prejudicial. *Infra* pp.32-37. But the Court need not reach that issue if it agrees with the district court as to the quantitative study data.

524 F.3d at 236 (cleaned up); *accord Lloyd*, 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."). The district court faithfully applied that precedent, holding that an agency must disclose "the data the agency used to develop its proposed rule" to allow for meaningful comment. Dkt.68:pp.38-39 (quoting *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 315 (D.D.C. 2016) (cleaned up)); *contra* FDA Br. 17 (arguing court "dramatically expanded" this Court's precedent).

FDA failed to comply with this requirement. FDA singled out two quantitative studies as the critical evidence supporting its Proposed Rule. The first study tested participants' reactions to the FDA-drafted textual warning statements to determine which warnings would "promote greater public understanding" of smoking-related health risks, as compared with the TCA's nine warning statements. 84 Fed. Reg. at 42,767. FDA used the results of this study to create the sixteen graphic warnings it evaluated in its second study. In that second study, participants evaluated text-image pairings on criteria like whether they contained "new information," caused participants to "learn[] something," and seemed "understandable" or "factual[]." 85 Fed. Reg. at 15,658-59; Dkt.56-10:p.306. FDA relied heavily on the studies' finding that

FDA's eleven new warnings scored well on the "new information" and "self-reported learning" efficacy measures when it selected the warnings in the Proposed Rule. 85 Fed. Reg. at 15,659; *see also supra* pp.10-14 (describing studies).

Despite the APA's requirement that when a "proposed rule is based on scientific data, the agency should identify the data," *Lloyd*, 762 F.2d at 1565, FDA declined to release the data underlying these quantitative studies. Instead, the agency provided only its own curated study reports. These study reports do not "disclose[] enough of the evidentiary basis" of the Rule to permit Plaintiffs to "contest the basis on which an agency reached the result that it did." *FBME*, 209 F. Supp. 3d at 315 (emphasis omitted). The study reports "summarized the results" of its quantitative studies in tables that, in *FDA's* estimation, "best captured the range of responses" from the studies, and provided "the results of additional statistical analyses." FDA Br. 19-20. FDA further withheld harshly critical peer reviews of these studies until issuing the Final Rule. *See supra* p.15.

FDA similarly withheld key information about FDA's four qualitative studies assessing consumer perceptions of various text and image options for FDA's graphic warnings. Like the quantitative studies, FDA released only

study reports, not the actual data underlying them. And FDA has *never* disclosed the notes of the interviews that formed the basis for the study reports that it eventually released. *See, e.g.*, Dkt.56-1:p.440(FDA23288). In short, as the district court correctly concluded, FDA here attempted 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." Dkt.68:p.40. The APA precludes that stratagem.

2. FDA (at 22) argues that it had no obligation to disclose the study data because its Rule relied on the reports, not the underlying data. That defies logic. That is no different than saying that when this Court cites the Supreme Court, the Court relies only on precedent completely divorced from the constitutional or statutory provisions that precedent interprets and any attendant reasoning. Agencies cannot circumvent the notice-and-comment requirement so easily through semantics. The relevant inquiry is whether "the most critical factual material used by the agency [was] subjected to informed comment." *Am. Radio*, 524 F.3d at 236 (cleaned up). FDA (at 22) attempts to distinguish *American Radio* by arguing that it disclosed all of the "study reports" on which the rulemaking relied. As explained above, those study reports were inadequate. And in any event, *American Radio* expressly

required raw data along with the study reports: "[A]mong the information that must be revealed for public evaluation are the 'technical studies *and data*' upon which the agency relies." 524 F.3d at 236 (emphasis added); *accord id.* (the agency must "identify and make available *technical studies and data* that it has employed" (emphasis in original)).

FDA (at 18) further argues that it provided "ample information to allow the public to understand the methodology used and the results obtained." But the requirement is not just that the public understand; it must also be able to "*participate* in the rulemaking process" via "*meaningful* comments." *Lloyd*, 762 F.2d at 1565 (citation omitted) (emphasis added). That requires access to data both to confirm FDA's results and perform additional analyses. "[O]missions in data … may make it impossible to reproduce an agency's results or assess its reliance upon them," thereby inhibiting commenters' opportunity to participate in the rulemaking. *Am. Radio*, 524 F.3d at 238 (cleaned up).

Lastly, FDA (at 22) argues that "no logical stopping point" exists if FDA's "indirectly relying on the raw data through its reliance on study reports discussing the raw data" required disclosure because "[e]very agency study or document may be derived from other materials." That is not a frightening

slippery slope so much as the process working: If studies are "derived" from other source data, that data must be produced. This disclosure requirement does not impose insurmountable burdens. Agencies have disclosed the same materials in other rulemakings.[7] Indeed, FDA requires manufacturers to submit all data underlying every study when it reviews safety and health claims about tobacco and other products. *See, e.g.*, 21 U.S.C. § 387k(d).

If anything, there is no logical end to *FDA's argument* that agencies need only to disclose a summary report. The data disclosure requirement—and section 553's assurance of a meaningful opportunity to participate in the rulemaking process—is hollow if agencies can draft *summaries* of any problematic data and thereby foreclose review and public comment.

[7] *E.g.*, *Prometheus Radio Project v. FCC*, 652 F.3d 431, 447 (3d Cir. 2011) (FCC released 10 studies with associated "large underlying data sets"); CMS, *FY 2020 Final Rule Data File*, https://www.cms.gov/files/zip/fy-2020-final-rule-hcris-data-file.zip (CMS disclosure of a huge amount of data underlying a proposed rule); *see also* FDA, *Public Access to Results of FDA-Funded Scientific Research* (Feb. 13, 2018), https://www.fda.gov/science-research/about-science-research-fda/public-access-results-fda-funded-scientific-research ("underlying data allow[s] for the critical review, replication, and verification of findings that are central to the scientific method" and "promotes robust and open communication").

B. FDA's Withholding Prevented Plaintiffs from Meaningfully Participating in the Rulemaking

FDA's failure to disclose its studies' data seriously prejudiced Plaintiffs. Prejudice arises "when the rulemaking process might have been different." Dkt.68:pp.42-43. "[A]n 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. FDA*, 47 F.4th 1191, 1205 (11th Cir. 2022) (citation omitted) (emphasis added). To show prejudice, a plaintiff simply "must indicate with reasonable specificity the aspect of the rule to which it objects and how it might have responded if given the opportunity." *Miami-Dade County v. EPA*, 529 F.3d 1049, 1061 (11th Cir. 2008) (cleaned up).

FDA (at 23) argues that Plaintiffs failed to identify any data or potential comment that "would have affected either FDA's rulemaking process or the substance of FDA's final rule." But Plaintiffs have done just that. After obtaining access to the raw data during litigation, Plaintiffs identified specific, relevant examples where the data supported different conclusions than those reached by FDA. The district court correctly agreed with respect to the quantitative studies.

1. Exchanges about the raw data underlying the quantitative studies would have been critical. For the first quantitative study, FDA reported *no* data for two of the TCA warnings (about quitting and death) that FDA discarded, leaving open questions about what data justified those choices. And for the second quantitative study, FDA did not report individual data for the four Surgeon General's warnings it tested. Instead—in an approach that drew peer reviewer critiques, Dkt.56-11:p.26(FDA54064)—FDA lumped all of the Surgeon General's warnings together, averaging their scores on the study measures and comparing that average score against each of its new graphic warnings.

Worse, those averages deceptively masked findings that undermine central premises of FDA's rulemaking. For example, FDA's later-disclosed raw data in subsequent litigation reveals that the Surgeon General's warning for carbon monoxide either outperformed or did not significantly differ from *four* of FDA's final graphic warnings (harm to children, nonsmoker lung disease, fetal harm, and COPD) on FDA's favored "new information" and "self-reported learning" measures. *See* Dkt.23-11:pp.9-10, ¶24 (Vansickel Decl.). By hiding these findings during the rulemaking, FDA prevented

commenters from raising these critical points during the notice-and-comment period.

FDA (at 24-25) argues that it did not "purport to premise its decisions on analysis of this kind," and that the "purpose of the study" was to ascertain which warnings should be selected, not "to assess [the] utility of the Surgeon General's warnings." But the statute requires exactly that assessment if FDA was purporting to "adjust … the text" of the warnings, 15 U.S.C. § 1333(d)[2], and at any rate, FDA cannot deny that Plaintiffs could have used this data to provide relevant comments. Indeed, FDA's "Memo to File" justifying its decision to withhold the data, which FDA finalized immediately before issuing the Rule, noted: "Access to the raw data could provide the ability to confirm that the findings … matched the pre-specified statistical analysis." Dkt.56-2:p.482(FDA23863.2). Yet FDA refused to give commenters that chance, citing the risk they might take a "different" or supposedly "misleading" approach to analyzing the data "than what FDA pre-specified." *Id.* What FDA called an unwanted "different" approach is the kind of "genuine interchange" that notice-and-comment rulemaking demands. *Am. Radio*, 524 F.3d at 236-37.

2. As to the qualitative studies, FDA's withholding made it impossible to verify whether its reports accurately identified "patterns across responses" in interviews, 85 Fed. Reg. at 15,666-67, and whether FDA omitted reactions that cast doubt on FDA's choices of text and images. Now, voluminous raw data from the transcripts FDA disclosed in litigation suggests that FDA indeed downplayed important reactions to FDA's proposed text and images, including reactions showing just how unbelievable FDA's warnings are. One participant put it bluntly: "It's a scare tactic. It's misleading." Dkt.56-3:p.303(FDA24162); *see also* Plaintiffs' Summary Judgment Br. Dkt.23-2:p.52 & n.4 (collecting numerous examples). Withholding this information prevented commenters from identifying misleading conclusions in FDA's study reports—clearly "something useful to say" had commenters been "given the opportunity to comment." *See Am. Radio*, 524 F.3d at 237-38. Indeed, FDA's decision to "suppress[] meaningful comment by failure to disclose the basic data relied upon is akin to rejecting comment altogether." *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977) (concluding that "scientific data should have been disclosed" because that data was "the stuff of scientific debate").

To be sure, FDA's Final Rule ultimately disclaimed reliance on the qualitative studies due to their serious methodological flaws. *See* 85 Fed. Reg. at 15,666-67. But FDA still used these studies to winnow its options for text and graphics—deeming them "formative" in one instance. *Id.* at 15,664. That means FDA's failure to disclose the relied-upon data violated notice-and-comment requirements.

3. FDA (at 25-26) calls Plaintiffs' analyses of statistical significance *based on the data FDA withheld* "[i]solated statistics" that "could not plausibly have caused FDA to restructure its approach and consider retaining the Surgeon General's warnings." But FDA cannot claim Plaintiffs' analyses were irrelevant. FDA issued the Rule to implement the TCA's cigarette warning requirements that would replace the longstanding Surgeon General's warnings. And, as the district court correctly explained, "one of the primary bases upon which the FDA relied to support the rulemaking" was 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.68:p.47 (quoting 84 Fed. Reg. at 42,760). Plaintiffs' analyses based on the raw data directly address this point.

Moreover, the APA's notice-and-comment requirement does not permit FDA to preemptively disregard comments it might receive. Rulemaking is designed to enable interested parties to identify aspects of the problem the agency was not already considering, including other applications of and conclusions from the raw data that FDA had not yet considered. As the district court explained, "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." Dkt.68:pp.47-48. FDA (at 25) deems that conclusion "speculation," but Plaintiffs need not prove the result would necessarily have been different to obtain relief. *See Bidi Vapor*, 47 F.4th at 1205. Indeed, "if 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." *United States v. Reynolds*, 710 F.3d 498, 517 (3d Cir. 2013) (quotation omitted). This Court should not countenance such gamesmanship.

II. FDA'S RULE VIOLATES THE APA FOR ADDITIONAL REASONS

This Court can affirm the decision below on the grounds that FDA's rulemaking suffered from other fatal flaws. *See Cuddeback v. Fla. Bd. of Educ.*, 381 F.3d 1230, 1236 (11th Cir. 2004) (allowing affirmance on any basis

the record supports "regardless of the grounds addressed, adopted, or rejected by the district court" (citation omitted)). *First*, FDA exceeded its statutory authority by requiring eleven rewritten warnings instead of the nine Congress required.[8] And *second*, FDA violated the TCA by failing to make statutorily required findings to adjust any of Congress' prescribed text. Each error independently warrants affirming the district court's decision to vacate the entire Rule.

A. FDA Lacked Authority to Issue Eleven Warnings, Including Completely Rewritten Warnings

Congress prescribed nine specific cigarette warnings and nine only. FDA's limited authority to "adjust the … text" of those nine warnings does

[8] The district court rejected FDA's argument below that Plaintiffs waived their statutory arguments by failing to raise them before the agency during rulemaking. Dkt.68:p.13. That was not an abuse of discretion. *Smith v. R.J. Reynolds Tobacco Co.*, 880 F.3d 1272, 1280 (11th Cir. 2018). No statutory provision or Eleventh Circuit precedent requires exhaustion of statutory arguments in rulemaking. And even the courts that do enforce such a requirement find exhaustion when the issue "was raised by *any* commenter"—the "party petitioning for judicial review need not have done so itself." *Bd. of Cnty. Comm'rs of Weld Cnty. v. EPA*, 72 F.4th 284, 294 (D.C. Cir. 2023) (emphasis added) (citation omitted). Here, other commenters objected that the TCA mandates nine warnings, and FDA engaged with these arguments in the Rule. 85 Fed. Reg. at 15,641-42. Plaintiffs were not obligated to re-raise the same objection. FDA's alternative argument that Plaintiffs somehow affirmatively waived their statutory argument by raising workability issues with FDA's Rule is unsupported by any administrative law authority.

not grant FDA carte blanche to add, delete, or completely rewrite warnings, as it did for most of the *eleven* warnings included in its Final Rule.

1. The TCA limits FDA to promulgating nine graphic warnings about certain types of health risks. Specifically, the TCA requires cigarette packages to bear "one of *the following labels*" and then lists nine warnings with the exact wording that Congress selected, such as "WARNING: Cigarettes are addictive," and "WARNING: Cigarettes cause cancer." 15 U.S.C. § 1333(a)(1) (emphasis added). Advertising for cigarettes too must bear "one of the labels specified in [section 1333(a)(1)]," *i.e.*, one of the nine specified warning labels. § 1333(b)(1). And other provisions repeatedly refer to "*[t]he label statements* specified in [section 1333(a)(1)]" or "all of *the labels required* under this section," again citing the list of nine. § 1333(c)(1)-(3), (d)[1] (emphasis added).

This list is "exclusive," even if Congress did not spell out word-for-word that these were the only nine labels permitted. *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 661 (2007). The language it used sufficiently conveyed that message. When Congress prohibits something unless "one of the following" nine conditions is met, Congress affords exactly nine ways of complying. For example, 6 U.S.C. § 672 allows "one of the following" actors to

designate a "critical infrastructure protection program," then lists the President and the Secretary of Homeland Security. That means only those two actors can make designations; Congress did not allow the Secretaries of Treasury or Education to designate critical programs just by omitting the word "two." *See also* 16 U.S.C. § 1533(b)(3)(B) (Secretary of the Interior shall "make one of the following findings"); 31 U.S.C. § 5112(w)(2)(B) ($1 coins must bear "one of the following" features).

Section 1333(a)(1) is no different. Congress certainly could have authorized FDA to create whatever warnings it deemed necessary to highlight health risks related to smoking. But here, Congress took the pen and itself drafted nine specific warnings, thereby limiting FDA's authority to issue additional or substantially rewritten warnings. Courts have a "duty to respect not only what Congress wrote but, as importantly, what it didn't write." *Va. Uranium, Inc v. Warren*, 587 U.S. 761, 765 (2019) (plurality op.).

FDA's Final Rule unlawfully required cigarette labels to carry one of *eleven* warnings, few of which resembled the nine Congress specified in section 1333(a)(1). Only two of Congress' warnings survived FDA's rulemaking, while FDA added four new warnings, deleted three, significantly rewrote three, and split one warning into two materially rewritten warnings. Because an agency

"literally has no power to act"—much less eliminate or rewrite statutorily required warnings—unless "Congress authorizes it to do so by statute," *FEC v. Cruz*, 596 U.S. 289, 301 (2022) (citation omitted), FDA needed to identify some affirmative statutory authorization for it to deviate from the number and substance of the warnings that Congress selected.

2. The sole provision FDA cited in its Final Rule that supposedly authorized its new and rewritten warnings is section 1333(d)[2]. *See* 85 Fed. Reg. at 15,639, 15,641-43. That provision grants FDA limited authority to "adjust the format, type size, color graphics, and text of any of the label requirements" if FDA finds such an adjustment would "promote greater public understanding of the risks" of smoking. 15 U.S.C. § 1333(d)[2]. That provision cannot bear the weight FDA placed on it.

To start, FDA misunderstood the meaning of the word "adjust." To "adjust" means "to alter slightly." *Adjust*, Collins English Dictionary (7th ed. 2005); *see Adjust*, The New Oxford American Dictionary (2d ed. 2005) ("alter or move (something) slightly in order to achieve the desired fit, appearance, or result"); *Adjust*, Cambridge Dictionary of American English (2d ed. 2008) ("to change something slightly to make it fit, work better, or be more suitable"). These definitions comport with ordinary usage. If, for instance, a judge allows

her clerk to "adjust the format, type size … and text of" a draft opinion if the clerk believes that doing so "would promote greater public understanding" of the opinion, the judge obviously is not authorizing her clerk to adopt a new legal rationale or change the disposition of the case. So too here. Congress settled on specific warnings and allowed only slight alterations in wording.

Had Congress wanted to authorize FDA to supersede statutorily prescribed risks and warnings, it would have used a different verb or just authorized FDA to write the text itself. Indeed, Congress elsewhere allowed FDA to "establish the … text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act [FDCA]," 15 U.S.C. § 4402(d) (smokeless tobacco)—but did not give FDA similar power to "establish the … text" of the relevant cigarette warnings. The "presumption is that [a] different term denotes a different idea." *Sw. Airlines Co. v. Saxon*, 596 U.S. 450, 457-58 (2022) (citation omitted).

FDA's Final Rule explained that the TCA granted FDA discretion to make "substantive changes" to Congress' warnings because section 1333(d)[2] "explicitly requires rulemaking under 5 U.S.C. § 553 for the adjustments it authorizes," while section 1333(d)[1]—which authorizes typographical adjustments to improve the warnings' visual clarity—supposedly "does not."

85 Fed. Reg. at 15,642. That, again, is inaccurate: FDA's "adjust[ments]" under section 1333(d)[1] require rulemaking, too.

Section 1333(d)[1] contains Congress' initial directive to FDA to "issue regulations" within 24 months of the TCA's enactment "that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in [section 1333(a)(1)]." While issuing those new graphic warnings regulations, FDA could "adjust the type size, text and format of the label statements" in section 1333(a)(1) "so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." 15 U.S.C. § 1333(d)[1]. In other words, FDA could make typographical "adjust[ments]" while issuing the graphic warning regulations. And those regulations, of course, must be developed through rulemaking, just like the "adjust[ments]" in section 1333(d)[2]. *See* 5 U.S.C. § 553.

The fact that Congress also required rulemaking for section 1333(d)[2] indicates only that Congress wanted to authorize "adjust[ments]" to the "format, type size, color graphics, and text" of the warnings even after the graphic warning regulations were issued through rulemaking. Congress was

not granting FDA sweeping powers to amend the number or rewrite the content of Congress' warnings.

In any event, even if "adjust" were as broad as FDA claimed, that would not authorize FDA to change the *number* of warnings. Congress allowed FDA only to "adjust" certain features of the labels—the "format, type size, color graphics, and text." Conspicuously, not mentioned is *the number of warnings*. *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (recognizing that when Congress lists related items but not others, the "items not mentioned [are] excluded by deliberate choice, not inadvertence").

In adopting its Rule, FDA claimed it may change the number of warnings because section 1333(d)[2] authorizes it to "adjust the 'text of any of the label *requirements*.'" 85 Fed. Reg. at 15,642 (emphasis in original). "[L]abel requirements," FDA reasoned, includes "numeric requirement[s]." *Id.* But FDA emphasized the wrong word in the statute. Section 1333(d)[2] does not authorize "adjustment to any of the label requirements," as FDA claims. *Id.* It authorizes FDA to "adjust the … *text* of any of the label requirements." 15 U.S.C. § 1333(d)[2] (emphasis added). And "text" does not mean number. Indeed, as FDA's Rule itself explained, the "plain meaning of 'text'" is "words and form." 85 Fed. Reg. at 15,642; *see R.J. Reynolds Tobacco*

Co. v. FDA, 762 F. Supp. 3d 529, 547 (E.D. Tex. 2025). Had Congress permitted FDA to change the total number of warnings, Congress would have authorized FDA to "adjust the *number* of label requirements," not merely the "text" of "any" given label.[9]

Finally, FDA's theory lacks limits. Under FDA's view, FDA could have required graphic warnings for a hundred conditions if it determined that doing so would improve public understanding. But it defies credulity that Congress painstakingly spelled out nine specific warnings and listed permissible types of adjustments, while obliquely empowering FDA to rewrite them, discard them, or add as many more as FDA wanted.

3. The district court, for its part, held that FDA's "affirmative statutory authorization" for changing the number of warnings came from the TCA's preemption provision, 15 U.S.C. § 1334(a). Dkt.68:p.18. That provision states:

> Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, … pursuant to the [TCA], or as required under [21 U.S.C. §§ 387c(a)(2),

[9] FDA also asserted authority to "reasonably construe[] the statute to allow [FDA] to adjust the number of warnings" because (in FDA's view) "the statutory language does not speak directly to [the] issue" because it did not use the words "9 labels." 85 Fed. Reg. at 15,642. But courts no longer defer to agencies' interpretations of purportedly ambiguous legal text. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024).

> 387t(a)], 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). For multiple reasons, the district court erred in relying on this provision.

First, the district court fundamentally misunderstood the purpose of section 1334(a). Section 1334(a) is a preemption provision that prevents entities *other than FDA* (such as state or local governments) from requiring particular statements on cigarette packages. In other words, it is a negative prohibition on statements that are not authorized by FDA, not an affirmative grant of authority to FDA to change the number of warnings required under section 1333(a)(1).

Second, and relatedly, section 1334(a) is *not* the legal provision FDA cited as its authority to add new warnings. 85 Fed. Reg. at 15,639 (citing 15 U.S.C. § 1333 as the Final Rule's "Legal Authority"); *id.* at 15,642 (explaining how section 1333(d)[2] authorized the change in the number of warnings). FDA cited the preemption provision only as an "indicat[ion]" that "Congress did not consider nine warnings to be a fixed statutory requirement," not as an express grant of authorization to change the number of warnings. *Id.* at 15,642. The district court's rationale for holding that FDA "did not violate the

TCA by increasing the number of warning statements," Dkt.68:p.20, therefore violated the Supreme Court's rule that courts must review agency action "solely by the grounds invoked by the agency" at rulemaking, *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *see also Mozilla Corp. v. FCC*, 940 F.3d 1, 82 (D.C. Cir. 2019) (declining to consider different legal basis for agency action than what agency listed under the heading "Legal Authority").

Third, even if the district court read section 1334(a) as FDA does—as support for FDA's interpretation of section 1333(d)[2]—it still would not support FDA's decision to change the number of warnings required under section 1333(a)(1). Section 1334(a) simply explains that there are limited categories of statements that must appear on any individual cigarette package: a graphic health warning (15 U.S.C. § 1333), brand and product information (21 U.S.C. § 387c(a)(2)), a "sale only allowed in the United States" label (21 U.S.C. § 387t(a)), and "additional or different statements" that the Secretary has discretion to require. For example, FDA has discretionary authority to require additional labels on cigarette packages disclosing characteristics of different lines of cigarette products (like tar, nicotine, or smoke constituent). 15 U.S.C. § 1333(e)(1), (3). FDA also may require cigarette packages to carry other disclosures required under the FDCA. § 1333(d)[2].

The preemption provision's reference to "additional or different statements" means that each cigarette package may be required to carry additional *types* of warnings or disclosures. For example, cigarette packages may be required to display the section 1333(a) warnings *and additionally* bear a label disclosing the cigarette brand's tar and nicotine yields under section 1333(e). The preemption provision does not indicate FDA may add to the warnings or disclosures within a given label category, such as by adding more health risks to the section 1333(a) warning statements or adding an "Advertising only allowed in the United States" statement to the label required under 21 U.S.C. § 387t(a).

Section 1334(a) therefore neither alters the meaning of section 1333 nor grants FDA the authority to change the number of warnings.

B. FDA's Rule Failed to Gauge Public Understanding, as the TCA Requires

Even if FDA's reading of section 1333(d)[2] were correct, FDA's authority to "adjust" the text of the TCA's statutory warnings is triggered only when the agency finds that each of its proposed adjusted warnings "would promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2]. Here, FDA replaced seven of the TCA's statements with nine new and reworked warnings based on its

conclusion that the new warnings met that standard. In reaching that conclusion, however, FDA made two critical mistakes: (1) it measured public understanding incorrectly, and (2) it did not compare public understanding of the new proposed warnings to public understanding of Congress' warnings.

1. In its Rule, FDA claimed that its warnings would promote greater public understanding of the health risks of tobacco usage based on the warnings' "statistically significant higher levels" of providing "new information" and "self-reported learning" compared to the statutory TCA warnings and the Surgeon General's warnings. 85 Fed. Reg. at 15,658. The "new information" metric measured whether the warnings provided "new information to participants" while "self-reported learning" measured whether participants "learned something" from the warnings. *Id.* at 15,658-59. But FDA failed to explain how those two isolated metrics sufficiently captured what Congress actually required FDA to assess: whether the new warnings would improve understanding.

By definition, the ordinary meaning of "understanding" refers to more than receiving new information and claiming (without validation) to have learned it. An essential component of "understanding" is "comprehension." *See Understanding*, The New Oxford American Dictionary (2d ed. 2005);

Understanding, Merriam-Webster's Collegiate Dictionary (11th ed. 2008) ("a mental grasp; comprehension"). In other words, "understanding" requires the ability to grasp the acquired new information, ascribe meaning to it, and internalize it. *See Comprehend*, The New Oxford American Dictionary (2d ed. 2005) ("grasp mentally"); *Comprehend*, Merriam-Webster's Collegiate Dictionary (11th ed. 2008) ("to grasp the nature, significance, or meaning of").

But FDA's "new information" and "self-reported learning" metrics did not sufficiently assess whether its warnings better helped the public to comprehend the risks of tobacco than the TCA's warnings. While "new information" and "learning" may be preconditions to understanding, "understanding" (as FDA acknowledges) is a "multifaceted process." 85 Fed. Reg. at 15,655. Promoting "awareness" of health risks is an "important *first* step in promoting public understanding of health risks," *id.* at 15,659 (emphasis added), but not the only step.

FDA's own peer reviewers criticized FDA's focus on "new information" and "self-reported learning" as "arbitrary," "odd," "underdetermined," and "not convincing." *See* Dkt.68:p.49 ¶¶ 128-29. One peer reviewer illustrated the disconnect between actual understanding and FDA's chosen measures of understanding: "If I created an exam for students in my class and I asked

them 'is this information new to you and I asked them to report whether they learned something from the information' would I then conclude that they understood it? I think the answer is obviously no." Dkt.56-11:p.83(FDA54121). Peer reviewers condemned FDA's choice as disconnected from "the ordinary concept of understanding," *i.e.*, "comprehension and linkage with established knowledge." *Id.*

The district court held that because "new information" and "learning" are "element[s]" of "understanding," they sufficiently "account for individual's 'understanding of a topic.'" Dkt.68:pp.22-23. That is no more right than saying that there is a contract as long as there is an offer and consideration. Essential elements of "understanding" are still missing. FDA's Rule itself acknowledged that measures like "attention" and "recall" can "increase[] the likelihood of understanding." 85 Fed. Reg. at 15,659. Yet FDA selected only two metrics from its studies—"new information" and "self-reported learning"—as the make-or-break measures for the warnings. *Id.* at 15,658.

FDA's justification for narrowly relying on those metrics is unpersuasive. Rather than make a statutory interpretation argument, FDA simply asserted: "Consumer perceptions that a warning provides new information and can contribute to self-reported learning are necessary

precursors to message comprehension and learning." *Id.* at 15,659. But FDA's testing of only some precursors to understanding guaranteed that its assessments would not assess the actual statutory threshold: whether the warnings would improve understanding. Again, the peer reviewers recognized this problem. They explained that conveying "new" information to consumers is pointless and counterproductive if consumers do not understand the information, reject the information as non-factual or not credible, or fail to process the new information in a way that influences their beliefs about the risks of smoking—problems that peer reviewers thought FDA's warnings raised. *See* Dkt.56-11:p.21(FDA54059), Dkt.56-11:p.35(FDA54073), Dkt.56-11:p.43(FDA54081). By focusing solely on the "new information" and "self-reported learning" measures, FDA blinded itself to the statutory question (and its own metric) by ignoring other "crucially important" considerations. Dkt.56-11:p.35(FDA54073).

2. FDA independently violated the TCA by never engaging in a head-to-head comparison between each of its new warnings and the three TCA warnings that FDA discarded entirely. *Compare* Dkt.56-10:p.203(FDA39330), *with* Dkt.56-10:pp.212-13(FDA39339-40). FDA replaced three TCA warnings—"Cigarettes are addictive," "Smoking can kill you," and "Quitting

now greatly reduces serious risks to your health"—with four new warnings: "Smoking causes type 2 diabetes, which raises blood sugar," "Smoking reduces blood flow, which can cause erectile dysfunction," "Smoking causes cataracts, which can lead to blindness," and "Smoking reduces blood flow to the limbs, which can lead to amputation."

Contrary to the district court's holding, Dkt.68:p.27, the text of section 1333(d)[2] required FDA to determine that each new textual warning would better promote public understanding of health risks than the particular TCA warning it replaced. For FDA to "adjust" the text of "any of the" TCA warning statements, FDA must also show 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). The phrase "such a change" unambiguously refers to replacing the "text" of "any" TCA warning statement with new text. And the word "greater" unambiguously indicates that FDA needs to compare the old text to the new. So FDA can jettison a particular statutory TCA warning statement only if FDA finds the new text better informs the public, as compared to the statutory text. For example, to replace "Smoking can kill you" with the erectile-dysfunction warning, FDA

had to compare the two and show that the erectile-dysfunction warning better promotes consumer understanding.

FDA never did that. Instead, in its April 2018 quantitative study, FDA "randomly selected" a TCA warning to compare to the four new warnings, for instance comparing the TCA warning that "Smoking during pregnancy can harm your baby" to both the new blindness and erectile dysfunction textual warnings. Dkt.56-10:pp.212-13(FDA39339-40). But finding that the blindness and erectile-dysfunction warnings promoted consumer understanding compared to the TCA pregnancy warning (which FDA did not discard) says nothing about whether FDA's new warnings might improve consumer understanding compared to any of the TCA warnings that FDA actually eliminated.

FDA's failure to show that any "adjustment" improved upon the warning that Congress wrote means, in APA terms, that FDA failed to address a "relevant factor" Congress required FDA to consider. *Bidi Vapor*, 47 F.4th at 1204. The D.C. Circuit in fact recently criticized FDA for making a similar error in *Cigar Association of America v. FDA*, 964 F.3d 56 (D.C. Cir. 2020). There, FDA adopted regulations under the TCA requiring warnings for cigar and pipe tobacco packages. *Id.* at 59-60. But FDA never made the

statutorily required finding that triggered its rulemaking authority—that the new warnings would likely affect the number of smokers. *Id.* at 60. The D.C. Circuit rejected FDA's argument that Congress gave it "leeway to determine what measures would be appropriate" to protect public health. *Id.* at 62 (citation omitted). Instead, it held that when Congress prescribes certain factors to be considered, FDA "cannot regulate" without making that finding. *Id.* So too here.

The district court improperly upheld FDA's actions because it thought itself bound to defer to FDA's chosen methodology. Dkt.68:pp.27-29. The court agreed that section 1333(d)[2] requires "some type of comparison between the existing warnings and new warnings," but deferred to the agency's "reasonable" interpretation of the statute to allow FDA to compare a randomly selected TCA warning to FDA's new warnings. Dkt.68:pp.27-28. The agency, though, gets no deference in determining whether it has made the findings the TCA requires. *Ins. Mktg. Coal. Ltd. v. FCC*, 127 F.4th 303, 311 (11th Cir. 2025) ("[T]he scope of an agency's statutory authority and whether an agency has acted within that authority are legal questions we decide independently."). The plain text of section 1333(d)[2] requires FDA to engage

in a head-to-head comparison between the warnings' new text and discarded text, and FDA's failure to do so was error. *See Cigar Assoc.*, 964 F.3d at 62.

III. VACATUR IS AUTHORIZED AND APPROPRIATE

A. The District Court Correctly Applied Vacatur Law

In fashioning a remedy, the district court applied this Court's two-prong test from *Insurance Marketing Coalition Ltd. v. FCC*, and evaluated the "seriousness of the order's deficiencies" as well as "the disruptive consequences of an interim change." Dkt.68:p.49 (quoting 127 F.4th at 317). Weighing those factors, the court came to the correct and "ordinary" conclusion that vacatur was appropriate. Dkt.68:p.50.

FDA does not challenge the *Insurance Marketing* standard or its application here.[10] This Court should therefore affirm, particularly given that this Court defers to the exercise of the district court's "sound discretion" in its choice of remedy in APA cases. *See Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1291 (11th Cir. 2015) (district courts are "best-suited to make the[] fine-grained and fact-intensive determinations" weighing the remedial equities).

[10] At most, FDA (at 29) notes that the "availability of [vacatur] was not challenged" in *Insurance Marketing*.

Regardless, the district court's straightforward analysis on both prongs was sound and shows that vacatur is appropriate here, whether this Court affirms on the same ground found by the district court or on the alternative grounds raised by Plaintiffs.

First, FDA's errors were serious. Vacatur is appropriate when "the agency lacked the authority to issue the rule, the agency omitted a critical procedural safeguard, or the agency failed to address an issue that was central to its decision to issue the rule." *Am. Secs. Ass'n v. SEC*, 147 F.4th 1264, 1279 (11th Cir. 2025) (citation omitted). FDA exceeding the TCA's authority (*supra* pp.37-56) plainly requires vacatur. As do FDA's notice-and-comment errors because, as the district court correctly recognized, "[d]efficient notice is a 'fundamental flaw' that almost always requires vacatur." Dkt.68:pp.49-50 (quoting *Allina Health Serv. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). On either ground, then, vacatur was the appropriate remedy.

Second, FDA does not argue vacatur has been disruptive. Nor could it. The Rule has never been in effect, and there has been no showing that vacatur "would significantly disrupt the entities affected by the Rule." Dkt.68:p.50.

Because FDA has neither challenged the Eleventh Circuit's standard nor shown that the district court erred in applying that standard to this case, FDA has not shown the district court abused its discretion in ordering vacatur.

B. FDA Is Wrong About the TCA, APA, and the Right Remedy

In any case, FDA's affirmative arguments challenging vacatur all fail. FDA (at 26) argues that instead of vacating the Rule, the court should have only held that the Rule is not enforceable against Plaintiffs. But neither the TCA nor the APA demand party-specific relief here. And contrary to FDA's assertions, only vacatur provides complete relief to Plaintiffs.

1. FDA (at 26) suggests that the TCA requires party-specific relief because "the TCA's express language recogniz[es] the importance of tailoring relief to the parties." FDA cites only the Act's severability provision. But the TCA's severability provision does not alter the remedial analysis under the APA.[11] That clause addresses only situations where "the *application* of any … provision to any person or circumstance" is unlawful. 21 U.S.C. § 387 note (emphasis added). In those circumstances, "the *application* of such provisions

[11] Notably, FDA never goes so far as to argue that the TCA alters the APA's remedial scheme. It (at 26) explains only that the TCA "recogniz[es] the importance" of and expresses a desire for "warnings to take effect to the greatest extent possible."

to any other person or circumstance shall not be affected." *Id.* (emphasis added).

That language has no purchase here. FDA's facial errors—exceeding its authority and providing deficient notice—mean there are no lawful applications of the Rule. Indeed, FDA (at 29) admits as much when it argues elsewhere that pre-APA suits for prohibitory injunctions are apt analogies in part because of the "absence of a special review statute." No matter what one makes of that argument's merits, those cases can fit here only if the TCA is not a special review statute—*i.e.*, if the TCA does not displace APA's remedial scheme.

2. As for the APA, FDA (at 27-31) argues that "longstanding equitable principles preclud[ing] relief to nonparties" govern the Court's exercise of remedial discretion under the APA. That argument fails for a host of reasons.

FDA's primary authority against nonparty relief—*Trump v. CASA, Inc.*, 606 U.S. 831 (2025)—is inapt. In *CASA*, the Supreme Court held that, under the Judiciary Act of 1789, lower courts may usually order only party-specific injunctive relief. *Id.* at 837. FDA (at 27) argues that *CASA*'s holding about universal injunctions under the Judiciary Act should be imported into

the APA as an exposition of "longstanding equitable principles." Not so. The reason is simple: The practices of "the High Court of Chancery in England at the time of the adoption of … the original Judiciary Act," 606 U.S. at 841-42, do not resolve what the APA meant in 1946 by directing courts to "set aside" agency action.

When "Congress enacted the APA in 1946, the phrase 'set aside' meant 'cancel, annul, or revoke.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 829 (2024) (Kavanaugh, J., concurring) (citation omitted) (surveying applicable legal definitions). Indeed, even FDA's leading authority supporting its APA argument, Justice Gorsuch's concurrence in *United States v. Texas*, refused to "equate vacatur of agency action with [the] universal injunctions"—the issue in *CASA*. 599 U.S. 670, 701-02 (2023) (Gorsuch, J., concurring). And the *CASA* majority explicitly held that "[n]othing we say today resolves the distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action." 606 U.S. at 847 n.10. In short: *CASA* did not address the meaning of the APA's directive to "set aside" unlawful agency actions, so it did not render a sea change eschewing nonparty relief under the APA.

That same realization renders the rest of FDA's APA arguments irrelevant. FDA's lengthy exposition of the "traditions of equity practice" is beside the point. FDA Br. 27-28 (citation omitted).

And FDA's arguments about the structure of the APA do not move the needle either. FDA Br. 28-30 (citing 5 U.S.C. §§ 703, 706(2))). FDA (at 28-29) argues that section 703 (entitled "Form and venue") somehow governs the Court's APA remedial powers or demotes vacatur out of its "ordinary" place. Yet "no court has ever held that Section 703 implicitly delimits the kinds of remedies available in an APA suit." *Corner Post*, 603 U.S. at 838-39 (Kavanaugh, J., concurring) (citation omitted).

Regardless, FDA's arguments (at 29-30) simply double down on the false premise that APA remedies should be limited to "pre-existing remedies" and thus "function in the same way" as eighteenth-century equitable practice. That is all wrong: the APA's "set aside" language was clear at the time of its passage, *supra* p.60, and "vacatur was not a new remedy" when the APA was enacted, *Corner Post*, 603 U.S. at 840 (Kavanaugh, J., concurring). "On the contrary, several pre-APA statutes authorized courts to 'set aside' specific kinds of agency actions." *Id.* And the Supreme Court "correctly understood those statutes to authorize vacatur." *Id.* Nothing in *CASA* or the APA calls

into question this Court's unchallenged precedent establishing vacatur as the "ordinary remedy" for violations of the APA. *See Am. Secs.*, 147 F.4th at 1274.

FDA's radical argument is also precluded by "decades" of "countless" Supreme Court decisions confirming that courts should issue vacatur "rather than merely providing injunctive relief … enjoin[ing] enforcement of the rules against the specific plaintiffs." *Corner Post*, 603 U.S. at 830-31 (Kavanaugh, J., concurring); *see also id.* at 830-31 (collecting cases affirming vacatur of agency rules). Neither *CASA* nor the APA counsel in favor of overturning "the longstanding consensus—a consensus based on text, history, precedent, and common sense—that vacatur is an appropriate remedy when a federal court holds that an agency rule is unlawful." *Id.* at 842-43.[12]

3. FDA admits that this Court has held "vacatur … is the ordinary … remedy" in APA cases. FDA Br. 26 (citation omitted). Yet FDA (at 27) argues that "equitable principles" render vacatur "inappropriate here." But traditional equitable principles support affirmance.

[12] Not even Justice Gorsuch's concurrence in *United States v. Texas* argues that decades of Supreme Court precedent should be cast aside. For instance, he admits to merely raising "questions" and that "the matter is [not] open and shut." 599 U.S. at 701-02. Those hypotheses may be interesting, but they are not the law.

FDA's brief notably offers few case-specific equitable arguments. Indeed, FDA (at 27-28, 32) argues only that "parallel litigation … in the Fifth Circuit" renders "relief to nonparties" inapt because such relief would "pretermit the Fifth Circuit litigation." Not so. That multiple parties in multiple Circuits have brought facial challenges to the Rule shows that the Rule is seriously flawed. But vacatur from this Court does not "pretermit" anything in the Fifth Circuit. Each court retains discretion to adjudicate the suits before it and issue the appropriate remedy to the parties before it. FDA's complaint (at 32) that it may prevail in the Fifth Circuit yet be unable to enforce the Rule against those parties because of this Court's vacatur is of no moment—FDA has no valid interest in enforcing an unlawful rule. That the appropriate remedy here may benefit the parties before the Fifth Circuit is a consequence of the Rule's serious, facial flaws and nothing more.

FDA further presumes that an injunction limited to the parties would "provide complete relief *to the plaintiffs*." FDA Br. 31 (quoting *CASA*, 606 U.S. at 852). But that is wrong. The only remedy that will "provide complete relief" from this unlawful Rule to these Plaintiffs, situated in a national supply chain, is vacatur. And that is true for all Plaintiffs because the Rule's

requirements apply to manufacturers, distributors, and retailers under 15 U.S.C. § 1333(a)(1).

Start with Philip Morris, a "leading manufacturer of cigarettes in the United States" (Dkt.1:p.7 ¶ 16), who coordinates with many other businesses—like co-Plaintiffs (Dkt.1:pp.7-8 ¶¶ 17-19)—to deliver its products to consumers nationwide (Dkt.1:pp.55-56 ¶ 146). For Philip Morris to sell its products across the country, its partner distributors and convenience stores (parties and nonparties alike) cannot be bound by the unlawful Rule. If FDA could enforce the Rule against nonparties, Philip Morris would be limited to a single Georgia distributor selling to party convenience stores and co-Plaintiff GACS's members. To put it mildly, its access to the nationwide marketplace would be severely curtailed. That is not complete relief.

Similarly, Plaintiffs Dhaliwal and Stewart Candy sell "cigarettes manufactured by Plaintiff [Philip Morris], in addition to many other cigarette manufacturers" (Dkt.1:pp.7-8 ¶¶ 17-18), so party-specific relief would leave other manufacturers' products marred with the unlawful Rule's warning labels. Plaintiffs would be subject to the unlawful warnings via other manufacturers' products. And the same fate would befall GACS's members (Dkt.1:pp.8, 55-56, ¶¶ 19, 146).

In sum, even if FDA were correct that the "ordinary" remedy under the APA should be limited to the parties, the only remedy that provides complete relief to the plaintiffs here *is* vacatur. *See Am. Secs.*, 147 F.4th at 1279 (reasoning that vacatur was appropriate when its absence would leave regulated entities "without a remedy").

IV. IF THE COURT DOES NOT AFFIRM, IT SHOULD REMAND FOR CONSIDERATION OF PLAINTIFFS' FIRST AMENDMENT CHALLENGE

Although the district court did not need to reach the issue, Plaintiffs explained at length below that the Rule grotesquely infringes manufacturers' First Amendment right to speak messages of their own choosing and violates strict limits against the government's ability to compel speech. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018). FDA would force Plaintiffs to disparage their own products by displaying provocative images that affirmatively mislead consumers about relative risks of different health effects.

Were the Rule allowed to go into effect, it would open the floodgates to government-compelled messaging in any context. Today's graphic cigarette warnings foretell tomorrow's grocery store aisles dominated by disgusting junk food warnings or parking lots full of cars with government-mandated

anti-fossil fuel broadsides painted on their hoods. The district court was well within its right to decline to address these issues considering its APA holding. But if this Court does not affirm, it should remand with directions that the district court consider these significant First Amendment concerns in the first instance.

CONCLUSION

For the foregoing reasons, the Court should affirm.

Respectfully submitted

/s/ *Lisa S. Blatt*

LISA S. BLATT
Counsel of Record
STEPHEN D. ANDREWS
CHARLES L. MCCLOUD
CLAIRE R. CAHILL
ANDREW G. BORRASSO
HALLIE SAUNDERS
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000
lblatt@wc.com

Counsel for Philip Morris USA Inc., et al.

CHRISTOPHER R. JORDAN
RANDALL A. JORDAN
HUNTER, MACLEAN, EXLEY & DUNN, PC
455 Sea Island Road
St. Simons Island, GA 31522
(912) 262-5996

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CERTIFICATE OF COMPLIANCE
WITH TYPEFACE AND WORD-COUNT LIMITATIONS

I, Lisa S. Blatt, counsel for Plaintiffs-Appellees Philip Morris USA Inc., et al., and a member of the Bar of this Court, certify, pursuant to Federal Rule of Appellate Procedure 32, that the attached Brief for Plaintiffs-Appellees Philip Morris USA Inc., et al., is proportionately spaced, has a typeface of 14 points or more, and contains 12,942 words.

/s/ *Lisa S. Blatt*
LISA S. BLATT

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