IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 6:20-cv-00176

DEFENDANTS' COMBINED CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND A PRELIMINARY INJUNCTION

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INTRODUCTION

It should be uncontroversial that the government can require manufacturers of dangerous products to warn the public about the very dangers they are responsible for creating. And for no other consumer product is that danger greater—nor the manufacturers' responsibility clearer—than cigarettes. Smoking remains the leading cause of preventable death in the United States. But that oft-repeated fact risks eclipsing the myriad ways in which cigarette smoking is harmful. It causes type 2 diabetes; it causes fatal lung disease even in non-smokers; and it results in consequences as varied as amputation, blindness, bloody urine, and erectile dysfunction.

Even though cigarette use remains a public-health scourge, the public remains strikingly under-informed about many of smoking's negative health consequences. In March, the Food and Drug Administration (FDA) completed a years-long effort to develop cigarette health warnings that will help correct that deficit in public knowledge. The result of that undertaking, announced in the final rule at issue here, was eleven new warnings (the "final warnings") that describe and depict some of the serious, but lesser-known, health consequences of smoking. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) ("the Rule" or "the Final rule"). The Rule implements provisions of the Tobacco Control Act (TCA) that reflect Congress's judgments about the appropriate content, size, and placement of cigarette health warnings. Consistent with those congressional judgments, the final warnings include color graphics and must be featured prominently on cigarette packages (occupying at least the top 50% of the front and back panels) and advertisements (occupying at least the top 20%).

The Rule is FDA's second effort to implement these statutory provisions. Its prior attempt was invalidated by the D.C. Circuit in 2012, in a case featuring many of the same cigarette manufacturers that are plaintiffs here. *See R.J. Reynolds Tobacco Co. v. FDA ("R.J. Reynolds I")*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The D.C. Circuit concluded that FDA's prior warnings did not just "convey information to consumers" but instead crossed the line into advocacy. *Id.* at 1217. The court found that several of the images in the warnings did "not offer any information about the health effects of smoking," and

it determined that FDA's "unabashed" aim was "to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *Id.* at 1216, 1217.

In response, FDA discarded the prior warnings, went back to the drawing board, and undertook an exhaustive effort to get it right the second time. The agency conducted a thorough review of the relevant literature, carefully consulted with agency experts and medical illustrators, and carried out some of the largest quantitative consumer-research studies *ever* conducted on cigarette warnings. At each step of this process, FDA had a singular focus: developing warnings that will help consumers better understand the negative health consequences of cigarette smoking. The record in this case reflects the agency's success. Of particular note, an FDA study with nearly 10,000 participants found that all eleven of the final warnings outperformed the current Surgeon General's warnings, to a statistically significant degree, on measures that predict improved understanding.

Despite the dramatic differences between this rulemaking and FDA's first attempt, Plaintiffs have recycled many of the criticisms from the prior litigation. But the industry's old playbook is a poor fit for FDA's new rule. Plaintiffs again decry FDA's alleged "attempt to compel Plaintiffs to disparage their own products, frighten and shame their own customers, and proclaim . . . [an] anti-smoking message[]." Pls.' Mot. for Summ. J. & Prelim Inj. ("Pls.' Br.") at 3, ECF No. 34. But the agency expressly disavowed any such efforts. And even if the agency had not spoken so clearly on the issue, the record speaks for itself. The agency repeatedly made methodological choices—about the iterative research process it would undertake and the outcomes it would measure—that can only be explained by the goal of *informing* consumers, not shaming them.

The final warnings themselves reinforce this point. The warnings consist of factual statements about the health consequences of smoking—statements of undisputed veracity—paired with photorealistic images that illustrate those harms. Although Plaintiffs quibble with some of the details of the final warnings, they do not meaningfully contest that the warnings are medically accurate. And although they characterize the warnings as exaggerated and misleading, they do not engage with *any* of the agency's analysis on this point, even though FDA addressed the same concerns—in painstaking detail—in the Rule itself. Accordingly, and particularly in light of the deference FDA should receive

for its record-based factual findings, this Court should uphold FDA's determination that the warnings are factual and nonmisleading.

From there, the conclusion that the Rule is constitutional is straightforward. The final warnings convey purely factual, uncontroversial information about the negative health consequences of smoking; they are (at a minimum) reasonably related to the government's interest in ensuring that the public understands those risks; and they are not unduly burdensome, particularly in light of the critical purpose they serve. Under the Supreme Court's test for commercial disclosures set forth in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), no more is required.

Plaintiffs, however, insist that some form of heightened scrutiny is necessary. But their arguments rest on a distorted view of the warnings. The final warnings do not mandate an "ideological message" or compel tobacco companies to take sides in a "public debate." Pls.' Br. 2 (citations omitted). Their role is simply to ensure that, when tobacco companies sell or advertise cigarettes, they also describe and depict the health consequences that their products undeniably cause. To the extent Plaintiffs consider *that* message controversial, it is an indictment of cigarettes, not of these cigarette health warnings. That some may find truthful depictions of the harms caused by cigarettes upsetting is perhaps unsurprising, but the level of First Amendment scrutiny does not somehow *increase* when warnings concern products that happen to cause more profound harms. And even if the Court were to agree with Plaintiffs that heightened scrutiny is appropriate, the Rule would withstand it. Promoting public understanding about the health risks of smoking is a substantial—indeed, compelling—government interest, and FDA's research confirms that the Rule directly furthers it. Moreover, given the agency's careful consideration of alternatives and Congress's considered judgment about the necessary size and content of cigarette health warnings, the Rule is appropriately tailored.

Because the Rule is constitutional, so too are the Tobacco Control Act provisions it implements. Indeed, although one would not know it from reading Plaintiffs' brief, a federal court of appeals has already rejected a facial constitutional challenge—also brought by Plaintiff R.J. Reynolds, among others—to those same provisions. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012). The Sixth Circuit's persuasive analysis applies with equal force here.

Plaintiffs' remaining arguments are equally meritless. For largely the same reasons the Rule satisfies the First Amendment, it is not arbitrary and capricious under the Administrative Procedure Act (APA). Moreover, FDA complied fully with the APA's notice-and-comment requirements. Plaintiffs claim they were entitled to all of FDA's raw study data during the comment period, and they complain of insufficient opportunity to comment on several qualitative study reports. But FDA had no obligation to solicit comments on raw data, particularly given that it disclosed more than sufficient information to facilitate feedback on the agency's studies, and FDA in fact provided a standalone comment period dedicated *solely* to its qualitative study reports. The APA does not require more.

FDA also complied with the TCA, and furthered the statute's purpose, when it modified the default text of the warnings listed in the statute after finding 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]. Congress explicitly authorized FDA to do so, in a provision aptly titled "Change in Required Statements."

Finally, Plaintiffs' requests for relief are overbroad. Plaintiffs ask this Court to ignore clear severability clauses in both the Rule and the TCA, to disregard Article III's limits and grant nationwide relief, and to enter a preliminary injunction even though that request will be fully briefed at the same time as their request for a final judgment on the merits. Accordingly, the Court should resolve the case on the merits, rather than on a preliminary basis, and if it rules for Plaintiffs, narrow the scope of any relief awarded.

But the merits of this case are clear. FDA developed warnings that will significantly improve the public's understanding of the negative health consequences of smoking; it did so based on a record that demonstrates why those warnings are needed and why they will be effective; and it complied with every applicable substantive and procedural requirement along the way.

The Court should enter summary judgment for Defendants.

RESPONSE TO PLAINTIFFS' STATEMENT OF THE ISSUES

Defendants agree with Plaintiffs' statement of the issues, except (1) Plaintiffs have imprecisely paraphrased the Tobacco Control Act, which speaks for itself, 15 U.S.C. § 1333; and (2) Plaintiffs omitted the following additional issues that may also be presented by this case: (a) whether Plaintiffs' request for a nationwide injunction or vacatur of the Rule is appropriate, (b) whether the Rule or the relevant provisions of the Tobacco Control Act are severable, and (c) whether Plaintiffs are entitled to any additional relief with respect to the Rule's effective date.

BACKGROUND

I. THE TOBACCO INDUSTRY AND THE DANGERS OF SMOKING

a. Congress enacted the Family Smoking Prevention and Tobacco Control Act in 2009, based on evidence compiled over decades about the health risks of tobacco products and the industry's deceptive marketing practices. That evidence established four key points: First, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). Congress found that "[e]ach year, 440,000 people die of diseases caused by smoking or other forms of tobacco use—that is about 20 percent of all deaths in our nation." 155 Cong. Rec. S6000 (2009) (statement of V. Admiral Richard H. Carmona, U.S. Surgeon General).

Second, tobacco's public-health harm is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.* The power of nicotine addiction is perhaps best illustrated by the failure rate of cessation efforts. In 2004, over 40% of adult smokers reported trying to quit; only 3-5% were successful. *Id.* at 69,529. The tobacco industry has long appreciated the importance of nicotine addiction to sales. In an internal memo, one of the Plaintiffs acknowledged that "a tobacco product is, in essence, a vehicle for the delivery of nicotine"—a "potent drug with a variety of physiologic effects"—and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." 146 Cong. Rec. H1847, H1849 (2000) (statement of Rep. Ganske) (quoting a 1972 memo from Plaintiff R.J. Reynolds).

Third, the tobacco industry has long depended on recruiting underage users who become addicted before age 18. Despite laws prohibiting sales to minors, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Leg. Finding 31, Pub. L. No. 111-31, § 2, 123 Stat. 1776, 1779 (2009) (codified at 21 U.S.C. § 387 (note)). Congress also found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." *Id.* at 1777, Leg. Finding 15.

Fourth, for decades, the tobacco industry—including some of these Plaintiffs—intentionally misled its own customers and the general public about the health risks and addictiveness of its products. In 1964, the Surgeon General began issuing reports on the health consequences of tobacco use and nicotine addiction. In response, tobacco companies undertook a coordinated campaign to deny these health hazards and attack those studies—even though they knew they were accurate. These efforts are "demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 855 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095, 1121 (D.C. Cir. 2009) (per curiam) ("28 years after Reynolds scientists declared the presence of carcinogenic compounds in cigarettes was 'now well established,' a Reynolds press release and newspaper advertisement declared the connection between smoking and disease 'an open controversy.'").

b. This unique industry has thus been built upon the twin pillars of a powerfully addictive product, and decades of deception—which allowed cigarettes to become deeply entrenched in American society. If tobacco products were considered drugs or devices under the Federal Food, Drug, and Cosmetic Act, the FDA would be required "to remove them from the market entirely," *Brown & Williamson*, 529 U.S. at 143, due to their deadly and wide-ranging health consequences.

Smoking remains addictive (by design), and death and disease caused by cigarettes are not a problem of the past. To this day, "[c]igarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year among cigarette smokers and those exposed to secondhand smoke." 85 Fed. Reg. at 15,638. And "[o]ver 16 million Americans alive today live with disease caused by smoking cigarettes." *Id.* at 15,652. Usage rates remain staggering: "approximately 34.2 million U.S. adults smoke cigarettes, and, among these adult smokers, the vast majority—74.6 percent, or approximately 25.5 million people—smoke every day." *Id.* FDA estimates that 860,000 high school students are smokers. *Id.*

As the Surgeon General put it, "[t]he tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes." 85 Fed. Reg. at 15,645.

II. STATUTORY BACKGROUND

Congress enacted the Federal Cigarette Labeling and Advertising Act ("the Labeling Act") in 1965. Pub. L. No. 89-92, 79 Stat. 282 (1965). Congress's stated "policy" and "purpose" was to establish a system of warnings on cigarette packages and advertisements through which "the public may be adequately informed about any adverse health effects of cigarette smoking[.]" 15 U.S.C. § 1331. Originally, the Labeling Act "required that a printed text-only warning appear on cigarette packages," 85 Fed. Reg. 15,640, which read: "Caution: Cigarette Smoking May Be Hazardous to Your Health." Pub. L. No. 89-92, § 4, 79 Stat. at 283. In 1970, Congress amended the warning statement to read: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87.

In the Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984), Congress expanded the warning requirement to apply to both labeling and advertising. 85 Fed. Reg. 15,640. Congress's stated purpose was "to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about

smoking." Pub. L. No. 98-474, § 2, 98 Stat. at 2200. To that end, Congress updated and replaced the 1969 warning with a rotating set of the following four statements:

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
>
> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Id. § 4, 98 Stat. at 2202. These warnings are colloquially known (including in this brief) as "the Surgeon General's warnings." To this day, every pack of cigarettes sold in the United States is required to bear one of these warnings, which have not changed in 35 years.

Recognizing that the Surgeon General's warnings had gone stale in the intervening decades, in 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA" or "the Act"), Pub. L. No. 111-31, 123 Stat 1776 (2009). Having found that "[t]he current Surgeon General warnings on tobacco products are ineffective in providing adequate warnings about the dangers of tobacco products," Congress decided to "require[] stronger and more specific health warnings immediately upon enactment," and to "give[] FDA the authority to enlarge them further and to incorporate color graphics." H.R. Rep. No. 111-58 at 4.

To that end, the Tobacco Control Act required FDA, within 24 months (*i.e.*, by June of 2011), to "issue regulations that require color graphics depicting the negative health consequences of smoking," which would "accompany" the "label statements" contemplated by the statute. Pub. L. 111-31 § 201(d) (codified at 15 U.S.C. § 1333(d)[1]).[1] Congress also authorized FDA to change the label requirements (including the text of the label statements), through rulemaking, upon a finding

[1] As Plaintiffs note, Pls.' Br. 1 n.1; *see also* 85 Fed. Reg. 15,641 n.4, two separate provisions of the Tobacco Control Act were codified as 15 U.S.C. § 1333(d). To avoid confusion, this brief (like Plaintiffs') will refer to those provisions as Sections 201(a) and 202(b) of the Tobacco Control Act, and will cite those provisions as § 1333(d)[1] and § 1333(d)[2], based on the order in which they appear in the statute.

"that such a change would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 202(b) (codified at 15 U.S.C. § 1333(d)[2]). Congress specified that the warnings (1) "shall comprise the top 50 percent of the front and rear panels" of any cigarette package, *id.* § 201(a)(2) (codified at 15 U.S.C. § 1333(a)(2));[2] (2) "shall comprise at least 20 percent of the area" of any cigarette advertisement, *id.* § 201(b)(2) (codified at 15 U.S.C. 1333(b)(2)); (3) "shall be randomly displayed . . . as equal a number of times as is possible on each brand" of cigarettes, *id.* § 201(c)(1) (codified at 15 U.S.C. § 1333(c)(1)); (4) and "shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes," *id.* § 201(c)(2) (codified at 15 U.S.C. § 1333(c)(2)).

III. REGULATORY BACKGROUND

A. FDA's Initial Approach to Pictorial Health Warnings

Immediately after the Tobacco Control Act was signed into law, FDA, as directed by Congress, got to work on "regulations that require color graphics depicting the negative health consequences of smoking" to "accompany" the "label statements" contemplated by the statute. 15 U.S.C. § 1333(d)[1]. "FDA promulgated the final set of nine images—one for each warning statement—by regulations issued on June 22, 2011." *R.J. Reynolds I*, 696 F.3d at 1209; *see* 76 Fed. Reg. 36,628. In the 2011 rule, in addition to the warning text-image pairs, "FDA also required each graphic image to bear the phone number of the National Cancer Institute's 'Network of Tobacco Cessation Quitlines,' which uses the telephone portal '1-800-QUIT-NOW.'" *R.J. Reynolds I*, 696 F.3d at 1209 (quoting 76 Fed. Reg. at 36,681).

The 2011 rule was invalidated by the D.C. Circuit. The panel majority interpreted FDA's objective in issuing the rule as reducing smoking rates—rather than informing consumers about the

[2] *See, e.g.*, 155 Cong. Rec. S13904 (2009) (Statement of Sen. Durbin) ("My colleague from North Carolina has improved the warning labels he would require on cigarettes. But they would not be strong enough. The Burr substitute would allocate 25 percent of the bottom front of the package to a warning label. In contrast, the Kennedy bill reflects the latest science on warning labels by requiring text and graphic warning labels that cover 50 percent of the front and back of the package. Clearly, a health warning that takes up the top half of the front and back of a package will be more noticeable and easier to read than one that takes up only a quarter of the bottom of the package—an area that may be hidden by the sales rack.").

health risks of smoking—and concluded that because the record did not demonstrate that the rule would result in meaningful behavioral change, it did not directly advance the government's interest. *See R.J. Reynolds I*, 696 F.3d at 1219. The original rule never went into effect.

B. FDA's Process for Developing New Warnings

After the D.C. Circuit's decision in *R.J. Reynolds I*, FDA went back to the drawing board. It commenced a years-long process to develop new cigarette health warnings—an effort that differed markedly from the agency's initial approach. Those differences started at the foundational level. When assessing the 2011 rule, the D.C. Circuit found that FDA's real interest was "in reducing smoking rates." *R.J. Reynolds I*, 696 F.3d at 1218. But in its second effort, FDA targeted a different goal, grounded in the TCA's text: promoting greater public understanding of the negative health consequences of smoking. That goal, in turn, shaped the steps the agency took in its iterative process for developing, testing, and selecting the eleven health warnings that were included in the Rule. That process included a thorough literature review, several qualitative studies (including focus groups), and two large-scale quantitative consumer research studies. Those quantitative consumer research studies "represent some of the largest experimental studies on cigarette warnings conducted to date." 85 Fed. Reg. at 15,663. Each of the two quantitative studies underwent external peer review, and FDA revised the lengthy reports it generated for each study to address the reviewers' feedback. All of those materials—FDA's initial study reports, the report of the peer reviewers, and FDA's responses and revised study reports—were already public, and are now part of the administrative record.

FDA's process began with a "careful[] review [of] the scientific literature on the health risks associated with cigarette smoking." 85 Fed. Reg. at 15,658. That review included "a focus on negative health effects that are less known, less understood, or about which the public holds misperceptions." 84 Fed. Reg. at 42,765. One reason for that review was to determine whether FDA should propose changes to the default text of the warnings set forth in the TCA. As noted above, Section 202(b) of the TCA allows FDA to change those warning statements if the agency finds "that such a change would promote greater public understanding of the risks associated with the use of tobacco products."

Pub. L. 111-31 § 202(b). Given the focus FDA placed on promoting understanding in this rulemaking, determining whether different language could better achieve that end was an important step.

Based on its consideration of the relevant research, FDA found that "consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings as well as more specific information about the negative health effects and their mechanisms." 84 Fed. Reg. at 42,766. Accordingly, FDA's next task was to identify warning statements that might better promote understanding of the risks of smoking. As part of that process, FDA held a series of qualitative focus groups—with adolescent smokers, adolescents at risk for starting smoking, and adult smokers—to gather further input on consumers' awareness of the health consequences of smoking and to gauge the participants' initial responses to both the TCA statements and a selection of revised statements FDA drafted. 84 Fed. Reg. at 42,767. The qualitative feedback generally indicated that FDA's revised statements did a better job of presenting new information than did the statements from the TCA. In light of that feedback, FDA identified 15 revised statements for further testing. *Id.*

FDA then conducted a large consumer research study (the "first quantitative study"), with 2,505 participants, "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." 85 Fed. Reg. at 15,658. This study played a role similar to that of a qualifying heat. FDA's ultimate aim, of course, was to develop and assess health warnings that included both text *and* an accompanying image. But first, it needed to decide which warning statements it would pair with images for its second (and final) quantitative study. FDA's first quantitative study found that 10 of the 15 statements it had drafted performed better than the TCA statements on key metrics of improved understanding. *See* 84 Fed. Reg. at 42,768. Accordingly, FDA selected those 10 statements, along with 5 statements from the TCA, to pair with images for further testing. *See id.* at 42,769.

At the same time that FDA was moving forward with its development and testing of warning statements, it was preparing concordant photorealistic images to be paired with those statements. To determine "what to depict in the photorealistic illustrations, FDA consulted the medical literature and medical experts to identify common, visual presentations of each health condition described by the

textual warning statements." 85 Fed. Reg. at 15,661. FDA "refined and reduced" its initial set of possible images after conducting another series of qualitative focus groups and interviews. *Id.* Based on that feedback, "FDA further refined some images for additional clarity and eliminated other images that were not well understood or where potential confusion could not be resolved through additional revisions." 84 Fed. Reg. at 42,771. These qualitative studies—like the first set of focus groups FDA conducted—were never intended to be "nationally representative" or to "yield data that can be generalized." 85 Fed. Reg. at 15,666. Rather, they were a piece of FDA's iterative research process to develop and refine elements of the warnings that would then be tested in its quantitative consumer research studies. Accordingly, at the conclusion of this development process, FDA prepared "16 statement-and-image pairings to test in the final quantitative consumer research study." 84 Fed. Reg. at 42,771.

That study (the "second quantitative study") was even larger than the first, including 9,760 participants. 85 Fed. Reg. at 15,658. It tested these "16 text-and-image pairings against the current Surgeon General's warnings" and was designed "to identify which," if any, of the warnings "increase understanding of the negative health consequences of cigarette smoking." *Id.* FDA collected data on ten different "outcome measures" to allow it to assess which warnings would promote increasing understanding. *Id.* at 15,658-59. None of those measures, however, sought to gauge the effect that the warnings would have on consumer behavior, intentions, or emotions. *See* AR 50772[3] ("The study is not designed, nor is it the intent of the study, to investigate the effect of these warnings on behavior, behavioral intentions, or emotional reactions.").

Of the ten measures FDA chose for the study, it identified two in particular to serve as the benchmark for determining which warnings (if any) to select for the proposed rule. Those measures were "new information" and "self-reported learning"—measures that FDA chose after surveying the relevant literature and finding that those metrics were most "predictive of improved understanding."

[3] Experimental Study of Cigarette Warnings, FDA Supporting Statement Part A, 2019 ("FDA Study Supporting Statement").

Citations to "AR XXXXX" are to the Bates-numbered pages of the administrative record.

See 84 Fed. Reg. at 42,769. Critically, FDA made that determination *before* it conducted the study. *See* 85 Fed. Reg. at 15,658. In other words, before FDA knew what the study would show, it tied its own hands by committing to select only warnings that outperformed the Surgeon General's warnings on both the "new information" and "self-reported learning" metrics. *See id.*

Most of the warnings FDA tested showed significant gains in improving understanding of the negative health consequences of smoking. For instance, more than *85%* of participants indicated that the warning for "Smoking causes bladder cancer, which can lead to bloody urine" was new information. 85 Fed. Reg. at 15,675. More broadly, all eleven of the warnings FDA ultimately chose for the Final Rule "outperformed the current Surgeon General's warnings on 8 of the 10 outcome measures, including the two that FDA determined were predictive of improved understanding (*i.e.*, 'new information' and 'self-reported learning')." *Id.* at 15,659. The three warnings that did not clear that bar were discarded. *See id.* at 15,658 (rejecting "3 of the 16 warnings that were tested because they did not outperform the current Surgeon General's warnings on both the 'new information' and 'self-reported learning' outcome measures"). The remaining 13 were the subject of FDA's proposed rule.

C. This Rulemaking

FDA published a Notice of Proposed Rulemaking on August 16, 2019.[4] 84 Fed. Reg. 42,754 (Aug. 16, 2019) ("NPRM" or the "Proposed Rule"). In the Proposed Rule, FDA recounted its iterative research process, explained how it arrived at the 13 warnings it was proposing to adopt, and sought public comment on those warnings.

FDA issued the Final Rule on March 18, 2020. 85 Fed. Reg. at 15,638.[5] Of the 13 warnings FDA included in the Proposed Rule, FDA ultimately selected eleven. *See id.* at 15,658. Those eleven

[4] The deadline for this proposed rule, along with the deadline for the final rule, were set after separate litigation in the District of Massachusetts. *See Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985-IT, 2019 WL 1047149, at *3 (D. Mass. Mar. 5, 2019).

[5] For ease of reference, and given their central role in this case, Defendants have attached the Proposed Rule and the Final Rule to this brief as Exhibits 1 and 2, respectively.

warnings comprise the following factual statements, each paired with a concordant, medically accurate, photorealistic image:[6]

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

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

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

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

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

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

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

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

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

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

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

85 Fed. Reg. at 15,708-09 (codified at 21 C.F.R. § 1141.10(a)(1)).

In the Rule, FDA meticulously walked through its reasoning for selecting each of the warnings, explaining why the evidence supported the conclusion that each warning would promote understanding of the harms of smoking and refuting claims that the warnings were inaccurate or misleading. *See* 85 Fed. Reg. at 15,671-84. FDA did so with a careful attention to detail and scientific accuracy. *See, e.g.*, *id.* at 15,673 (discussing different presentations of lung cancer in explaining why the image accompanying the warning that "Tobacco smoke causes fatal lung disease in nonsmokers" is medically accurate). FDA provided thorough responses to the public's comments, including to many from the tobacco industry that have reappeared, unaltered, in this case. *See, e.g.*, *infra* at 29-30.

[6] The final warnings are reproduced on FDA's website, at https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements. *See also* Pls.' Br. 9-10.

IV. PROCEDURAL HISTORY

Plaintiffs—four cigarette manufacturers from North Carolina (R.J. Reynolds Tobacco Company; Santa Fe Natural Tobacco Company, Inc.; ITG Brands, LLC; and Liggett Group LLC) (collectively, the "manufacturer Plaintiffs"), and five cigarette retailers from Texas (Neocom, Inc.; Rangila Enterprises Inc.; Rangila LLC; Sahil Ismail, Inc.; and Is Like You Inc.) (collectively, the "retailer Plaintiffs")—filed this action on April 3, 2020. ECF No. 1. The complaint names four Defendants: the United States Food and Drug Administration (FDA), the United States Department of Health and Human Services (HHS), Stephen M. Hahn (in his official capacity as the Commissioner of Food and Drugs), and Alex M. Azar II (in his official capacity as the Secretary of Health and Human Services). Plaintiffs bring a variety of First Amendment and statutory challenges to the Rule, as well as a similar First Amendment challenge to the provision of the Tobacco Control Act that directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333(d)[1].

LEGAL STANDARD

In resolving legal challenges to agency action, a court's role is "to apply the appropriate APA standard of review to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985) (citation omitted). FDA's "action[s], findings, and conclusions" must be upheld unless they are, *inter alia*, "arbitrary, capricious, an abuse of discretion, . . . contrary to constitutional right, . . . [or] in excess of statutory jurisdiction, authority, or limitations[.]" 5 U.S.C. § 706(2).

Plaintiffs do not mention this standard of review. But in a record-review case like this one, "[t]he administrative agency is the fact finder," and "[j]udicial review has the function of determining whether the administrative action is consistent with the law—that and no more." *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996) (citation omitted). When courts review agency findings, they "should not substitute [their] own judgment for the agency's." *Gulf Restoration Network v. U.S. Dep't of Transp.*, 452 F.3d 362, 368 (5th Cir. 2006). That deference is particularly warranted here because courts "are at [their] most deferential in reviewing the agency's findings" when the "agency's

particular technical expertise is involved." *Medina Cty. Envtl. Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). Indeed, in the specific "context of a challenge to the FDA's decisionmaking," courts should "'give[ ] a high level of deference' to the agency's scientific analysis of the evidence before it, and must avoid 'unduly second-guess[ing] [those] scientific judgments.'" *Pharm. Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (citations omitted).

Moreover, as the D.C. Circuit confirmed in assessing the tobacco industry's challenge to the prior health-warnings rule, the standard of review for agency findings of fact does not vary with the nature of the claim—*i.e.*, the agency's findings are entitled to the same deference in the context of a First Amendment claim as they are in the context of an arbitrary-and-capricious claim. *See R.J. Reynolds I*, 696 F.3d at 1217-18 (holding that "the Administrative Procedure Act governs [the] review of the record" for First Amendment claims); *see also POM Wonderful, LLC v. FTC*, 777 F.3d 478, 499-500 (D.C. Cir. 2015) ("Our precedents . . . call for reviewing the [agency's] factual finding of a deceptive claim under the ordinary (and deferential) substantial-evidence standard, even in the First Amendment context."). To be sure, courts must "make an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making." *Texas Office of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 410 (5th Cir. 1999) (quoting *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979)).[7] But although courts "of course 'do not defer to the Government's reading of the First Amendment,'" an agency's "evaluation of the underlying facts is entitled to appropriate weight[.]" *Trump v. Hawaii*, 138 S. Ct. 2392, 2422 (2018) (quoting *Holder v. Humanitarian Law Project*, 561 U.S. 1, 34 (2010)).

Accordingly, the factual findings at issue here—including the appropriateness of FDA's methodological choices, the medical accuracy of the warning text and images, the extent to which the public holds misperceptions about the health consequences of smoking, and the degree to which the

[7] In *Porter*, the court held that granting summary judgment in a First Amendment case was improper because there remained "several genuine issues of material fact" in a case where "agency fact-finding procedures were inadequate" and where the plaintiff had a "statutory right to a full evidentiary hearing in district court." 592 F.2d at 772. Here, by contrast, the parties agree that "judicial review is based solely on the administrative record," ECF No. 30 at 5 (citation omitted), and this Court's review of that record is limited to questions of law, *see Girling Health Care*, 85 F.3d at 215.

warnings correct those misperceptions—must be upheld unless they are arbitrary and capricious.[8] *See* 5 U.S.C. § 706(2).

ARGUMENT

I. THE RULE IS CONSISTENT WITH THE FIRST AMENDMENT.

There is no dispute that a requirement to include warnings on a product's package or in its advertisements regulates commercial speech—*i.e.*, speech "'linked inextricably' with the commercial arrangement that it proposes," *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (citation omitted)—which receives "more limited" constitutional protection than "most other speech," *Express Oil Change, LLC v. Miss. Bd. of Licensure for Prof'l Eng'rs & Surveyors*, 916 F.3d 483, 487 n.2 (5th Cir. 2019) (citation omitted). Courts generally assess restrictions of commercial speech under the intermediate scrutiny standard set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). But where, as here, "the challenged provisions impose a *disclosure* requirement rather than an affirmative limitation on speech," courts apply "the less exacting scrutiny described in" *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (emphasis added). Under *Zauderer*, compelled disclosures of "purely factual and uncontroversial information" are upheld as long as they are "reasonably related" to the government's interest and not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651; *see also Nat'l Inst. of Family & Life Advocates v. Becerra* ("*NIFLA*"), 138 S. Ct. 2361, 2372 (2018). The health warnings required by the Final Rule readily withstand review under that standard, and, indeed, under any other standard of First Amendment review.

In general, there is "no dispute about Congress's authority to require health warnings on cigarette packages," *Am. Meat Inst. v. USDA* ("*AMI*"), 760 F.3d 18, 31 (D.C. Cir. 2014) (en banc)

[8] Here, the relevant APA inquiry is whether the agency's factual findings were "arbitrary [and] capricious," rather than whether those findings were "unsupported by substantial evidence," because FDA's findings were made in the context of a notice-and-comment rulemaking, rather than in an on-the-record hearing. *See* 5 U.S.C. §§ 706(2)(A), (E); *see also Castillo v. Army & Air Force Exch. Serv.*, 849 F.2d 199, 203 n.1 (5th Cir. 1988) (per curiam) ("The 'substantial evidence' test of § 706(2)(E) generally applies where a formal administrative hearing is statutorily required." (emphasis omitted)).

(Kavanaugh, J., concurring in the judgment), which have appeared on product packages and advertisements since 1965, when Congress determined that they were needed to provide important health information to consumers. *See* Labeling Act, Pub. L. No. 89-92, § 4; Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222; *see also NIFLA*, 138 S. Ct. at 2376 (declining to "question the legality of health and safety warnings long considered permissible"). The warnings at issue here, which inform consumers of cigarette smoking's causal connection to serious but lesser-known health risks—including harm to children, fatal lung disease in nonsmokers, type 2 diabetes, amputation, blindness, bladder cancer, erectile dysfunction, head and neck cancer, heart disease and strokes, stunted fetal growth, and COPD—are supported by a substantial body of evidence compiled by Congress and FDA, and they readily withstand review.

A. The Rule Should Be Evaluated Under *Zauderer*.

Zauderer governs the inquiry into the constitutionality of cigarette health warnings generally, and the final warnings withstand review under that standard. The warnings, which address the negative health consequences of smoking, convey "purely factual and uncontroversial information" because scientific evidence establishes that cigarette smoking causes those harms. *Zauderer*, 471 U.S. at 651. Moreover, the warnings are "reasonably related to the [government's] interest in" promoting understanding of the harms of smoking and are not "unjustified or unduly burdensome disclosure[s]." *Id.* Plaintiffs, however, suggest that *Zauderer* should not apply to *any* cigarette health warnings because such warnings do not relate to consumer deception and because the government lacks any interest in informing consumers about the harms of smoking. Both arguments are meritless.

Plaintiffs' contention that cigarette health "warnings are not 'reasonably related to the State's interest in preventing deception of consumers,'" and therefore cannot be evaluated under *Zauderer*, is wrong as a matter of both law and fact. *See* Pls.' Br. 20 (quoting *Zauderer*, 471 U.S. at 651). On the legal question, every court of appeals that has directly considered the issue agrees: *Zauderer* is not limited to "cases in which the government points to an interest in correcting deception." *AMI*, 760 F.3d at 22; *see Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005); *Nat'l Elec. Mfrs.*

Ass'n v. Sorrell, 272 F.3d 104, 114 (2d Cir. 2001); *CTIA - The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019); *see also CTIA*, 873 F.3d 774, 775 (9th Cir. 2017) (Fletcher, J., concurring in the denial of rehearing en banc) (surveying circuit court cases applying *Zauderer*).

That conclusion follows from the reasoning of *Zauderer* itself. *AMI*, 760 F.3d at 22 ("The language with which *Zauderer* justified its approach . . . sweeps far more broadly than the interest in remedying deception."). In particular, *Zauderer* drew a direct contrast with the test outlined in *Central Hudson*, emphasizing the "material differences between disclosure requirements and outright prohibitions on speech." *Zauderer,* 471 U.S. at 650.[9] *Zauderer* also described a "speaker's interest in opposing forced disclosure" of purely factual and uncontroversial information as "minimal"—a characterization that "seems inherently applicable beyond the problem of deception." *AMI*, 760 F.3d at 22 (quoting *Zauderer*, 471 U.S. at 651). Accordingly, although *Zauderer* happened to involve a disclosure where the government's interest was in preventing deception, the framework *Zauderer* established for evaluating disclosure requirements is not limited to that context.

None of the cases Plaintiffs cite address this issue, much less come out the other way. *See* Pls.' Br. 20-22. Instead, although some of the cases quote from, apply, or distinguish the language of *Zauderer*, they never purport to *limit Zauderer* to the consumer-deception context. *See Hersh v. U.S. ex rel. Mukasey*, 553 F.3d 743, 766 (5th Cir. 2008) (quoting from *Zauderer* but not purporting to interpret it or to decide whether it applies); *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015) (applying *Zauderer* in a context where the required disclosure corrected deceptive speech); *see also Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146-47 (1994) (invalidating required disclaimer because it was an "unduly burdensome disclosure requirement," not because it was unrelated to consumer deception (citation omitted)); *Dwyer v. Cappell*, 762 F.3d 275, 282 (3d Cir. 2014) (declining to decide whether *Zauderer* applies because the disclosure requirement was "unconstitutional under even . . . *Zauderer*"); *Cent. Ill. Light Co. v. Citizens Util. Bd.*, 827

[9] That *Zauderer* drew this contrast with *Central Hudson* confirms that, contrary to Plaintiffs' suggestion, *Zauderer* is not "best read simply as an application of *Central Hudson*[.]" Pls.' Br. 46 (quoting *AMI*, 760 F.3d at 33 (Kavanaugh, J., concurring in the judgment)).

F.2d 1169, 1173 (7th Cir. 1987) (holding that *Zauderer* does not apply to a required disclosure of a third party's message). The remaining cases Plaintiffs cite are wholly removed from the *Zauderer* context because they do not involve compelled commercial disclosures. *See United States v. United Foods, Inc.*, 533 U.S. 405, 408-09 (2001) (striking down a requirement to financially contribute to a trade group's advertising, not a compelled commercial speech disclosure); *Allstate Ins. Co. v. Abbott*, 495 F.3d 151, 166 (5th Cir. 2007) (invalidating an attempt to *restrict* speech in an insurance script).[10]

Stepping back, if Plaintiffs were right that *Zauderer* applies in only one context—*i.e.*, when assessing "the lawfulness of a compelled disclosure necessary to make a commercial advertisement nonmisleading," Pls.' Br. 21—then a slew of run-of-the-mill disclosures would, in Plaintiffs' telling, become constitutionally suspect. After all, Plaintiffs maintain that for any disclosure "not subject to *Zauderer*, courts must apply strict scrutiny." Pls.' Br. 45. Under Plaintiffs' view of the First Amendment, courts should subject every warning label, ingredients list, and table of nutrition facts to strict scrutiny. Precedent and common sense foreclose that result. *See NIFLA*, 138 S. Ct. at 2376.

In any event, cigarette health warnings—including the ones at issue here—*are* "reasonably related to preventing consumer deception." *Disc. Tobacco*, 674 F.3d at 565. Broadly, the reason there remains a need to warn consumers about the health consequences of smoking is because the tobacco industry succeeded at getting millions of Americans addicted to cigarettes while lying about the health consequences of smoking. *See, e.g.*, 85 Fed. Reg. at 15,645 ("The tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes." (citation omitted)). And more specifically, a substantial portion of the population lacks accurate information about each of the eleven health consequences FDA addressed in the final warnings. *See infra* at 22-23, 34-35. By promoting understanding of those

[10] Three of the cases Plaintiffs cite—*Allstate Insurance*, *Dwyer*, and *Central Illinois Light Co.*—were cited in a petition for a writ of certiorari in *CTIA* as the basis for an alleged circuit split. *See* Pet'r's Br. 26-27, *CTIA*, 2019 WL 4897111 (U.S. Sept. 30, 2019). That the Supreme Court nonetheless denied the petition, and left undisturbed the Ninth Circuit's 2019 decision applying *Zauderer* beyond the consumer-deception context, is consistent with Defendants' reading of *Zauderer* and its progeny. *See CTIA*, 140 S. Ct. 658 (2019) (denying certiorari).

lesser-known health consequences, the warnings combat the misperception that smoking does not put one at risk for, *inter alia*, bladder cancer, blindness, and amputation. Accordingly, even if *Zauderer* were as limited as Plaintiffs suggest, it would still apply here.

Plaintiffs also err in suggesting that *Zauderer* cannot apply here because the government lacks an adequate interest in cigarette health warnings. Plaintiffs acknowledge that warnings about the scientifically proven consequences of smoking can "convey straightforward factual information about the risks of smoking." Pls.' Br. 1. And although Plaintiffs gesture at skepticism of the accuracy of the statements in the final warnings, *see, e.g.*, Pls.' Br. 23 (describing those statements as "purportedly factual"), they do not actually dispute that all eleven statements convey purely factual information. Plaintiffs nonetheless maintain that the government lacks *any* interest in promoting the public's understanding of the risks of cigarette smoking—both in general, and with respect to the specific risks addressed in the final warnings. *See* Pls.' Br. 30. That claim is baseless.

Under *Zauderer*, the government's interest need only be in "remedy[ing] a harm that is potentially real, not purely hypothetical." *NIFLA*, 138 S. Ct. at 2377.[11] Congress's judgment, decades of precedent, and the evidence in the record all confirm that the government has a real interest in "promoting greater understanding of the negative health consequences of cigarette smoking." 85 Fed. Reg. at 15,638. When Congress first enacted cigarette health warnings, it stated its goal clearly: to ensure that "the public [will] be adequately informed about any adverse health effects of cigarette smoking[.]" 15 U.S.C. § 1331. It reaffirmed that goal in 1984, revising the warnings to make "Americans more aware of any adverse health effects of smoking" and "to enable individuals to make informed decisions about smoking." Pub. L. No. 98-474, § 2. And in the TCA, Congress expressly linked any change in the text of the cigarette health warnings to a finding that "such a change would

[11] Although the Ninth Circuit has held that the government's interest must be "substantial," *CTIA*, 928 F.3d at 844, this Court need not decide whether *Zauderer* imposes that requirement because the government's interest in promoting understanding of the negative health consequences of smoking no doubt meets that bar. *See AMI*, 760 F.3d at 23 (holding that "the government's interest in country-of-origin labeling for food" is "substantial" and therefore declining to "decide whether a lesser interest could suffice under *Zauderer*."); *see also infra* at 46.

promote greater public understanding of the risks associated with the use of tobacco products." Pub. L. No. 111-31 § 202(b). Plaintiffs, accordingly, cannot question the sufficiency of the government's interest here without setting aside half a century's worth of congressional judgments. *See Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997) ("Even in the realm of First Amendment questions[,] . . . deference must be accorded to [Congress's] findings as to the harm to be avoided and to the remedial measures adopted for that end[.]").

Courts, similarly, have had no trouble recognizing the significance of the government's interest in promoting the public's understanding of the harms of smoking. The Sixth Circuit—evaluating the same statutory provisions at issue here—found that "[t]here can be no doubt that the government has a significant interest . . . in warning the general public about the harms associated with the use of tobacco products." *Disc. Tobacco*, 674 F.3d at 519. In *Cigar Association of America v. FDA*, 315 F. Supp. 3d 143, 168 (D.D.C. 2018), *appeal pending*, No. 18-5195 (D.C. Cir.) (argued Oct. 29, 2019), where the court upheld the constitutionality of health warnings on cigar packages, the court determined that "the FDA has . . . a substantial government interest" in "help[ing] consumers better understand and appreciate the risks and characteristics of tobacco products[.]" And in *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 284 (D.C. Cir. 2019), the D.C. Circuit held that "the government has a substantial interest in" requiring accurate risk statements about e-cigarettes "in order to protect consumers from buying a highly addictive product with a false sense of the risks it presents." None of these courts suggested the issue was even a close one.

Moreover, FDA's extensive research validated the need for improved understanding of the specific health risks addressed in the final warnings. FDA found "a pervasive lack of knowledge about and understanding of the many negative health consequences of smoking," particularly with respect to the "range of illnesses caused by smoking." 84 Fed. Reg. at 42,761-62; *see also, e.g.*, AR 5118[12] (finding that, "except for lung cancer, no specific smoking-linked illness could be named by more than half of our respondents"). FDA's quantitative research from this rulemaking provides additional

[12] Noah Weinstein, et al., *Public Understanding of the Illnesses Caused by Cigarette Smoking*, Nicotine & Tobacco Res., 6(2):349-355 (2004).

evidence of this deficit in public understanding. In FDA's second (and final) quantitative study, *all* of the warnings FDA selected in the Rule provided new information to a significant portion—ranging from 35.7% to 88.7%—of participants. 85 Fed. Reg. at 15,655; *see Cigar Ass'n*, 315 F. Supp. 3d at 168 (explaining that "the agency relied on evidence establishing widespread misperceptions regarding the true health hazards of cigars" and that this evidence "support[ed] the FDA's determination that there exists a need to educate the public about [those] health risks").

Despite this evidence, Plaintiffs do not accept that the government can have a real interest in promoting greater understanding of the harms of smoking; instead, they contend, the government can rely *only* on an interest in reducing smoking rates. *See* Pls.' Br. 30. Not so. The government plainly has an interest in ensuring that Americans fully understand the dangers of a product that may blind them, render them chronically ill, or result in amputation.[13] That conclusion is consistent with the foundational First Amendment "principle that 'people will perceive their own best interests if only they are well enough informed[.]'" *Pub. Citizen Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 219 (5th Cir. 2011) (quoting *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.,* 425 U.S. 748, 770 (1976)). To that end, courts have repeatedly upheld disclosure requirements based solely on the importance of the information being disclosed, rather than based on a prediction as to how the required disclosure might affect consumer behavior. For instance, in *Zauderer*, the Court held that it was constitutional to require that an attorney operating on contingency fees disclose that his clients would still have to pay litigation costs in the event of a loss, without evaluating whether such a disclosure would cause the contingency-fee attorney to lose clients. 471 U.S. at 652. In *Milavetz*, the Court upheld a disclosure

[13] The D.C. Circuit's decision in *R.J. Reynolds I* is not to the contrary. The court did not cast aside Congress's judgment about the importance of informing the public about risks of smoking; it merely emphasized that FDA could not claim an "interest in 'effectively' communicating information" in that particular case without "some barometer for assessing that effectiveness." *R.J. Reynolds I*, 696 F.3d at 1221 n.16. But *with* such a barometer, like the data-driven process FDA undertook here, *see infra* at 32-41, the government's interest in promoting understanding of the consequences of smoking is "an independent interest capable of sustaining the Rule." *R.J. Reynolds I*, 696 F.3d at 1221; *see also Cigar Ass'n*, 315 F. Supp. 3d at 170 (distinguishing *R.J. Reynolds I* and explaining that "FDA's stated interest in this case is . . . decidedly an objective one: To provide accurate information and to correct documented, widespread misperceptions about the health risks of cigar use").

law—which required debt relief agencies to reveal that their services might include filing for bankruptcy—without any inquiry into whether fewer people would avail themselves of the debt relief agencies' services. 559 U.S. at 232-33, 251. And in *Citizens United v. FEC*, 558 U.S. 310 (2010), the Supreme Court upheld a disclosure requirement for electioneering communications because "transparency enables the electorate to make *informed decisions* and give proper weight to different speakers and messages." *Id.* at 371 (emphasis added). The Court did not, by contrast, demand evidence that such disclosures would swing an election or lead shareholders to oust a corporate board; the importance of the disclosed information, standing alone, sufficed. *See also Am. Hospital Ass'n v. Azar*, No. 1:19-CV-03619 (CJN), 2020 WL 3429774, at *17 (D.D.C. June 23, 2020) (emphasizing that "transparency measures . . . are intended to enable consumers to make informed decisions").

To avoid this authority, Plaintiffs suggest that the government has no interest in warning about the *specific* health consequences addressed in the final warnings because "the public 'already know[s]' about the risks of smoking." Pls.' Br. 30. In other words, according to Plaintiffs, the information in the final warnings is "immaterial." *Id.* at 34 (emphasis omitted). Plaintiffs are wrong.

As an initial matter, Plaintiffs are wrong about the degree to which the public understands even the most common effects of smoking. For instance, FDA highlighted evidence that 33% of adult *smokers* are unaware that smoking is a proven cause of cancer. *See* 84 Fed. Reg. at 42,761; *see also* AR 5877.[14] And in another study cited by FDA, in which participants were asked to identify illnesses caused by smoking, fewer than half of the respondents identified cardiovascular disease. *See* 84 Fed. Reg. at 42,761; *see also* AR 5114.[15]

Plaintiffs are also wrong that FDA has "concede[d] that the public has an effectively universal awareness of the risks described in the Tobacco Control Act." Pls.' Br. 31. That consumers know so little about some of the lesser-known consequences of smoking, *see infra* at 34-35, does not mean they know *enough* about the more widely known risks. To that end, for the one warning statement from

[14] K.M. Cummings, et al., *Are Smokers Adequately Informed About the Health Risks of Smoking and Medicinal Nicotine?*, Nicotine & Tobacco Res., 6(Suppl. 3):S333-S340 (2004).

[15] Weinstein, et al., *supra* note 12.

the TCA that FDA selected in the Rule—that "tobacco smoke can harm your children"—FDA found that almost half of respondents (40.7%) reported this as "new information." 85 Fed. Reg. at 15,671. The fact that there is still so much room for improved understanding of risks that Plaintiffs contend are universally known reinforces how much of a knowledge deficit there is for lesser-known risks and, in turn, why the government's interest in correcting that deficit is substantial.

Plaintiffs' principal basis for contending that consumers are already saturated with knowledge about the health consequences of smoking is an analysis of the Population Assessment of Tobacco and Health (PATH) study—an analysis referred to in Plaintiffs' brief as the "Klick Report." *See* Pls.' Br. 30-31, 33. But FDA already considered that report during the rulemaking and found it wanting, particularly insofar as Plaintiffs use it to assess "PATH data for specific health outcomes." 85 Fed. Reg. at 15,655. FDA raised significant concerns about the Klick Report's reliability, highlighting its failure to include "a description of the methods [used] and [its] statistical approach." *Id.* Yet Plaintiffs do not say a word in defense of the Klick Report's methods. Nor do they dispute that the research underlying the Klick Report's additional claim that "the public actually *overestimates*" the risks of smoking, Pls.' Br. 31, comes from decades-old studies (commissioned and paid for by a tobacco-industry law firm), or that the research "has been criticized on methodological and other grounds in the public health and psychology literature." 85 Fed. Reg. at 15,655.

Setting aside the extent to which the public grasps that cigarettes are "harmful," Pls.' Br. 30, Plaintiffs' suggestion that the government has no interest in ensuring consumers know about *additional*, specific health risks from smoking is astounding. Apparently, once someone knows that smoking can be fatal and can cause diseases like lung cancer, further specifics are irrelevant. In Plaintiffs' telling, understanding the details of other cancers that smokers may contract, or of the appendages they may lose, is simply an intellectual exercise—a matter of morbid "consumer curiosity," *CTIA*, 928 F.3d at 844. Plaintiffs' only "evidence" on this point is the *ipse dixit* of Dr. Klick, who opines that, "[p]resumably, . . . for those who know smoking is deadly but are still inclined to smoke, risks like

blindness and erectile dysfunction are likely not material." AR 27934[16] (cited at Pls.' Br. 33). That assertion not only defies common sense—particularly given the rate at which adolescents, who may think about risks differently than adults, continue to take up smoking, *see* 85 Fed. Reg. at 15,652—it is also inconsistent with other contexts in which consumers are warned about risks to their health. It is difficult to imagine, for instance, that a patient considering surgery would shrug off a surgeon's failure to disclose a known risk of amputation or blindness, no matter how serious the other risks associated with the procedure. And prescription drug labeling would fail to serve its purpose if drug companies could omit a known risk of bladder cancer or erectile dysfunction from the list of warnings and precautions. *See* 21 C.F.R. § 201.57(c)(6) (requirement that prescription drug labeling include in the warnings and precautions section a description of "clinically significant adverse reactions," including ones that "are serious even if infrequent," if there is "reasonable evidence of a causal association" between the drug and the consequence); *see also id.* § 310.501 ("The safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and the risks involved in their use.").

At bottom, Plaintiffs' quibbles with the government's interest in cigarette health warnings rest on a misconception of the importance of information. They view it is a commodity, going so far as to fault FDA for not quantifying the monetary value of the increased understanding the Rule will bring about. *See* Pls.' Br. 33; *see also infra* at 50-51 (explaining that FDA's cost-benefit analysis was reasonable). But empowering individuals to make fully informed choices about their health is not useless just because its value might not be readily measured. Every person who smokes, or who is considering taking up the addictive habit, deserves to know the risks to which they are exposing themselves and others so that they can "perceive their own best interest[.]" *Pub. Citizen*, 632 F.3d at 219 (5th Cir. 2011) (citation omitted). The government has a real interest in ensuring that they do.

[16] Statement of Jonathan Klick, Ph.D., J.D. (attached as Exhibit C to RAI Services comment).

B. The Rule Should Be Upheld Under *Zauderer*.

1. The Warnings Are Purely Factual and Uncontroversial.

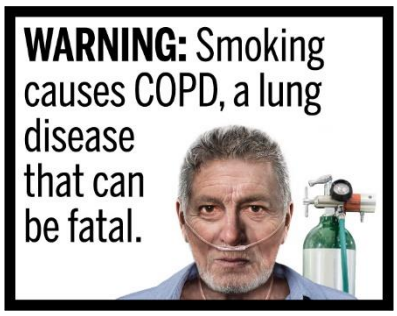
FDA's final warnings satisfy *Zauderer's* threshold requirement because they are "purely factual and uncontroversial." 471 U.S. at 651. Warnings generally are "factual" if they convey "facts [that] are directly informative of intrinsic characteristics of [a] product," and "uncontroversial" so long as they are not "so one-sided or incomplete" as to be misleading or inaccurate. *AMI*, 760 F.3d at 27. The final warnings easily satisfy this threshold requirement.

The statements in the final warnings address only health conditions where "the causal link between cigarette smoking and the negative health consequences . . . is rated at the highest level . . . provided in the Surgeon General's Reports." 85 Fed. Reg. at, 15,669. All eleven statements are factually accurate, and Plaintiffs have offered no evidence to the contrary. *See supra* at 21.

The final warnings—with their concordant text and image pairs—are just as accurate as the warning text. The warnings were the product of a "science-based, iterative research process." *Id.* at 15,658. And throughout that process, FDA took the D.C. Circuit's admonishment in *R.J. Reynolds I* to heart. It did not craft warnings "to evoke an emotional response." *R.J. Reynolds I*, 696 F.3d at 1216. Nor did it include images—like a "'T-shirt emblazoned with the words 'I QUIT'"'—that "do not offer any information about the health effects of smoking." *Id.* Instead, FDA "used a certified medical illustrator to design [the] images," included "common visual presentations of the health conditions," and presented "the health conditions in a realistic and objective format devoid of non-essential elements." 85 Fed. Reg. at 15,646. For instance, to illustrate the warning that "Smoking causes head and neck cancer," FDA chose to depict a woman with a medically accurate cancerous mass in her neck. *See* 85 Fed. Reg. at 15,674.

Plaintiffs hardly dispute that these images are medically accurate—*i.e.*, that they are accurate representations of the health conditions the warnings describe. That omission is telling, as it means that Plaintiff take issue with the accuracy of *neither* the text nor the text-image pairings. In other words, FDA achieved its goal of "develop[ing] high quality, factually accurate photorealistic images." 85 Fed. Reg. at 15,646.

Plaintiffs do, however, contend that the warnings are "misleading." Pls.' Br. 26; *see also id.* at 26-27. In fact, they begin with the sweeping claim that *all* photorealistic images are misleading because they "are inherently susceptible to multiple, subjective interpretations and lack precise meaning." *Id.* at 23. That argument relies on viewing the images in a vacuum; in context, the images have an obvious, "precise" meaning: the warning statement with which they are paired. Plaintiffs point to no evidence that the *combined* text-image warnings are less precise than other common health warnings. Indeed, it is easy to imagine Plaintiffs leveling the same arguments they raise here against the current Surgeon General's warnings—even though Plaintiffs have conceded those warnings "convey straightforward factual information." Pls.' Br. 1. For instance, under Plaintiffs' logic, the warning "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health" is misleading because the adverb "greatly" and the adjective "serious" could prompt different "subjective interpretation[s]." If anything, photorealistic images *add* clarity because they "impart information directly," *Zauderer*, 471 U.S. at 647, and provide concrete context—like "symptoms as they are typically experienced" for a disease that may otherwise be unfamiliar to a consumer, 85 Fed. Reg. at 15,646; *see also Zauderer*, 471 at 648 (rejecting an argument that "the use of illustrations in advertising . . . creates unacceptable risks that the public will be misled, manipulated, or confused"). The warning FDA selected for COPD illustrates this point, pairing a disease that consumers may not know about with an image that provides a clear understanding of one consequence of the disease—a need for supplemental oxygen:



Plaintiffs then turn to the alleged misleadingness of the individual warnings. *See* Pls.' Br. 26-27. Their contentions on this front provide perhaps the clearest illustration of why it matters that Plaintiffs have ignored the standard of review. *See Bellion Spirits, LLC v. United States*, 393 F. Supp. 3d 5, 18-19 (D.D.C. 2019), *appeal docketed*, No. 19-5252 (D.C. Cir. Sept. 25, 2019) (holding that a determination about whether a "proposed claim[] [is] misleading" is a "factual—not legal—one[]," even when such a determination "is dispositive" in a First Amendment case). For not only have Plaintiffs failed to demonstrate that the agency's findings about the warnings' accuracy are arbitrary and capricious, they have failed to even acknowledge those findings in the first place. FDA devoted more than a dozen full pages of the Federal Register to defending the accuracy of each individual warning, often against the same charges of misleadingness that Plaintiffs regurgitate here. *Compare* 85 Fed. Reg. at 15,671-84 (Final Rule's discussion of the individual warnings), *with* Pls.' Br. 26-27 (failing to cite any of that discussion). For brevity's sake, Defendants highlight the following representative examples:

- **"Tobacco smoke can harm your children."** Plaintiffs claim the image for this warning "exaggerates" because children are "rarely" hospitalized for a tobacco-smoke-induced asthma attack. Pls.' Br. 26. But FDA found that "it is not rare or atypical for children with chronic asthma resulting from secondhand smoke exposure to receive nebulizer treatments in either an emergency department or inpatient setting." 85 Fed. Reg. at 15,672. In fact, "children with asthma *and* secondhand smoke exposure are nearly twice as likely to be hospitalized with asthma exacerbations compared to children with asthma but *without* secondhand smoke exposure." *Id.* (emphasis added).

- **"Tobacco smoke causes fatal lung disease in nonsmokers."** In their brief, Plaintiffs repeat a claim about the image accompanying this warning that FDA already addressed in the Rule. *Compare* Pls.' Br. 26 (claiming that "the lungs do not look like a non-smoker's lungs" because the image includes an unusual "amount of black pigmentation"), *with* 85 Fed. Reg. at 15,673 (recounting same comment). In the Rule, FDA explained that the image it selected for this warning was accurate because the "discoloration caused by vascular congestion (*i.e.*, blood in the lower lungs causing a darker coloration) [is] consistent with the appearance of postmortem lungs in a nonsmoking patient with fatal

lung disease." 85 Fed. Reg. at 15,673. FDA also described how lung cancer presents differently in the lungs of smokers versus nonsmokers, including variations in the location and degree of discoloration that were taken into account in developing the image. *See id.*

- **"Smoking causes reduced blood flow to the limbs which can require amputation."** Plaintiffs' only criticism of this warning is that it "depicts a condition that could affect, at most, one in 1,000 smokers." Pls.' Br. 26. Even accepting the curious premise that this "critique" would somehow render the image "misleading," Plaintiffs' statement is false. Although Plaintiffs do not the name the "condition" in their brief, the declaration they cite (which was attached to R.J. Reynolds's comments on the Proposed Rule) indicates that Plaintiffs are positing that the image refers to Buerger's disease. *See* AR 28127.[17] Buerger's disease is indeed a very rare condition. *See id.* But, again, FDA already addressed this precise issue in the Rule. The agency explained, citing peer-reviewed literature, that the image is consistent with "a person who had several toes amputated due to tissue damage resulting from [peripheral arterial disease] . . . and is *not* specific to Buerger's disease." 85 Fed. Reg. at 15,681 (emphasis added). Peripheral arterial disease is far more common, affecting roughly 13.5% of the population. *Id.* For those with particularly severe artery blockages caused by peripheral arterial disease, an astounding 25% have amputations *each year*. *Id.* Smoking is "the most powerful risk factor predisposing individuals to this condition." *Id.*

- **"Smoking causes head and neck cancer."** Plaintiffs take no issue with the truth of this warning statement or with the medical accuracy of the accompanying image. Rather, their only criticism is that "a cancerous mass of that size" would have been caught by "a reasonable person" who would "have had an opportunity to seek treatment[.]" Pls.' Br. 27. FDA took on this critique directly in the Rule. *See* 85 Fed. Reg. at 15,674. It cited research indicating that, among other factors, "lack of health insurance coverage, lack of financial resources, lack of transportation, and lack of cancer knowledge" contribute to "late-stage diagnosis for head and neck cancer." *Id.* FDA then reasonably concluded that "it is not unusual for patients from underserved communities to present at advanced stages for head and neck cancer as depicted in the warning's image." *Id.* If it is Plaintiffs' contention that a cancer patient in such circumstances is not "a reasonable person," they have pointed to no evidence in the record supporting that claim.

The findings that Plaintiffs ignore are dispositive of the warnings' accuracy. *See* 85 Fed. Reg. at 15,671-84. Plaintiffs might prefer that this Court discard its role as a "reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality," and instead act as a "chemist, biologist, or statistician" in the first instance—but those are roles that courts "are qualified neither by training nor experience" to assume. *Gulf Restoration Network v. U.S. Dep't of Transp.*, 452 F.3d 362, 368 (5th Cir. 2006) (citation omitted). Even then, FDA's thorough findings would hold

[17] Decl. of Robert Wagmeister (attacked as Exhibit K to RAI Services comment).

up. But on this record, and in light of the applicable standard of review, the result is even clearer: FDA's findings that each warning is accurate and non-misleading must be upheld.

Perhaps in light of the record evidence in support of the warnings' accuracy, Plaintiffs call into question FDA's motives, suggesting the warnings are "intended to evoke an emotional response" and to "shock the viewer." Pls.' Br. 22 (citation omitted); *see also id.* at 25 (noting speech that "is *intended* to stir controversy" is not uncontroversial (emphasis added)). Plaintiffs' brief, however, cites no evidence of such intent. They claim that "[t]he most natural inference" from the "inclusion of the images" in the warnings is that "the images are being used not to *convey facts*, but to scare consumers." *Id.* at 23. But the purpose of the images, as the record reflects, was to promote understanding of the health consequences addressed in the warnings.

Plaintiffs do not dispute that the communication-science literature indicates that "messages that are accompanied by images closely linked to the message content (*i.e.*, concordant) are shown to increase the likelihood that consumers will comprehend the message." 84 Fed. Reg. at 42,764. Nor do they explain why, if FDA's goal was to *shock* consumers, it devoted so much time and energy studying how to *inform* them. What is Plaintiffs' explanation, for instance, for FDA's decision to select "new information" and "self-reported learning" as the make-or-break measures for the final warnings? There is no reason to believe those measures correlate with images designed to shock; in fact, according to Plaintiffs, the opposite should be true. Plaintiffs point to evidence that warnings that elicit "[a] high level of fear . . . may cause the audience to 'emotionally block the message by tuning out, perceiving it selectively, or denying its argument outright.'" Pls.' Br. 35 (citation omitted). But if fear causes an audience to block out a message, then the fact that the participants in FDA's second quantitative study indicated that they learned new information from the warnings suggests that the warnings do not provoke the response that Plaintiffs assume.

Other choices the agency made throughout the rulemaking process confirm that FDA's aim was to inform, not to frighten. For instance, one comment recommended changing the image that accompanies the "Smoking during pregnancy stunts fetal growth" warning to make it more disturbing, suggesting that the image should "feature a small infant in an incubator attached to various tubes and

lines[.]" 85 Fed. Reg. at 15,676. But FDA declined to make that change because, while a premature infant "would likely require . . . interventions such as an incubator, oxygen, [and] feeding tube," the agency determined that "[s]tunted fetal growth does not necessarily result in premature birth[.]" 85 Fed. Reg. at 15,677. In other words, the agency chose a more medically accurate depiction of stunted fetal growth over one recommended as more shocking.[18]

To be sure, some people may find medically accurate depictions of the consequences of smoking upsetting. If so, that is a reflection of the harms of smoking, not of an agency decision to shock consumers. The possibility that "a disclosure . . . provokes a visceral response" does not mean the disclosure "fall[s] outside *Zauderer's* ambit." *Disc. Tobacco*, 674 F.3d at 569. Rather, "whether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience[.]" *Id.*; *see also CTIA*, 928 F.3d at 847 (upholding required disclosure about cell-phone radiation that "may not be reassuring, but . . . is hardly inflammatory"). Plaintiffs draw on cherry-picked quotes from the qualitative studies and news articles to play up the fear these warnings allegedly will cause. *See* Pls.' Br. 23-25. But such concerns are belied by the agency's larger quantitative consumer studies, where FDA found that all of the warnings it tested "were perceived as being factual by the vast majority of participants[.]" 85 Fed. Reg. at 15,646; *see also id.* at 15,666 (highlighting commenter's observation "that a potential pitfall with qualitative studies is to place 'too much emphasis on a single quote or comment that sparks interest'").

2. The Rule Reasonably Relates to the Government's Interest in Promoting Understanding of the Negative Health Consequences of Smoking.

Determining whether the Rule is "reasonably related to the [government's] interest in" promoting understanding of the harms of smoking, *Zauderer*, 471 U.S. at 651, is straightforward here. In undertaking that inquiry, courts may consider a range of evidence to identify a sufficient link between a regulation of speech and a government interest, including "studies and anecdotes"—even

[18] Plaintiffs' hypotheticals about "shock and awe" warnings for other products are red herrings because they rest on the apparent assumption that the government would be *trying* to frighten or shock consumers. *See* Pls.' Br. 24-25.

ones that "pertain[] to different locales altogether"—as well as "history, consensus, and 'simple common sense.'" *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (citation omitted). Here, however, the task is simple because FDA studied the precise question at issue. The agency's second quantitative study, which involved 9,760 participants, applied rigorous scientific methods to evaluate whether 16 pictorial health warnings, including all 11 of the warnings selected in the Final Rule, promote understanding of the negative health consequences of cigarette smoking. FDA found that all eleven of the final warnings did precisely that, and to a statistically significant degree. Specifically, the final warnings all outperformed the current Surgeon General's warnings on the two metrics that FDA selected in advance as predictive of promoting understanding—"new information" and "self-reported learning"—as well as six other measures on which the agency collected data. *See* 85 Fed. Reg. at 15,658. Those findings must be upheld unless Plaintiffs demonstrate that they were arbitrary or capricious. *See supra* at 15-17. To that end, the choices FDA made in designing the second quantitative study and analyzing its results were sound, and, at a minimum, reasonable in light of the "extreme degree of deference" FDA is owed for decisions that "involve complex judgments about sampling methodology and data analysis that are within the agency's technical expertise." *Kennecott Greens Creek Min. Co. v. Mine Safety & Health Admin.*, 476 F.3d 946, 956 (D.C. Cir. 2007) (citation omitted).

Plaintiffs have not made the showing necessary for this Court to discard FDA's careful work. Most strikingly, Plaintiffs do not meaningfully contest the key takeaway from FDA's second quantitative study: that all eleven warnings outperformed the current Surgeon General's warnings on eight of the ten measures the agency selected to assess understanding, including the two that FDA determined were predictive of improved understanding. *See* 85 Fed. Reg. at 15,659. Instead, Plaintiffs undertake a scattershot critique of FDA's research, leveling disjointed charges and ignoring many of the agency's responses to identical criticisms that were submitted during the comment period. Plaintiffs' critiques fall broadly into three categories. First, Plaintiffs suggest that several of the warnings were unnecessary because they address health consequences that are already known. Second, Plaintiffs question the metrics the agency used as predictors of improved understanding. Third,

Plaintiffs raise a handful of miscellaneous quibbles. Each of these criticisms fails on its own terms, and none overcomes the deference owed to FDA's predictive and methodological judgments.

First, Plaintiffs claim that the Rule does not promote understanding of the health consequences of smoking because six of the Rule's eleven warnings allegedly "describe well-known risks." Pls.' Br. 32.[19] As an initial matter, that means Plaintiffs concede that the public lacks sufficient information about the five other health consequences the warnings address—namely, that smoking causes bladder cancer, reduces blood flow (which can cause erectile dysfunction), causes type 2 diabetes, causes cataracts (which can lead to blindness), and reduces blood flow to the limbs (which can require amputation). For the remaining six, Plaintiffs' argument suffers from an overarching flaw: a failure to even mention, much less dispute, the results of FDA's second quantitative study. Those results demonstrate that a significant percentage of respondents found all eleven warnings—including the six about health consequences that Plaintiffs claim are well known—to provide new information, suggesting the public is *not* adequately informed. *Cf. Flyers Rights Educ. Fund Inc. v. U.S. Dep't of Transp.*, 957 F.3d 1359, 1363 (D.C. Cir. 2020) (emphasizing that a determination as to whether a given "quantum of evidence of consumer confusion . . . warrants a rulemaking falls within [an agency's] discretion"). Specifically, the results for each of the warnings that Plaintiffs single out are as follows:

- **"Tobacco smoke can harm your children."** This warning was reported to be new information by **40.7%** of participants who viewed it. 85 Fed. Reg. at 15,671.
- **"Tobacco smoke causes fatal lung disease in nonsmokers."** This warning was reported to be new information by **41.9%** of participants who viewed it. *Id.* at 15,672-73.
- **"Smoking causes head and neck cancer."** This warning was reported to be new information by **80.9%** of participants who viewed it. *Id.* at 15,673-74.
- **"Smoking can cause heart disease and strokes by clogging arteries."** This warning was reported to be new information by **52.1%** of participants who viewed it. *Id.* at 15,669.
- **"Smoking during pregnancy stunts fetal growth."** This warning was reported to be new information by **40%** of participants who viewed it. *Id.* at 15,676.

[19] Plaintiffs claim this criticism applies to "seven . . . risks," but their brief lists only six. *See* Pls.' Br. 32.

- **"Smoking causes COPD, a lung disease that can be fatal."** This warning was reported to be new information by **35.7%** of participants who viewed it. *Id.* at 15,678.

Additionally, each of these warnings outperformed the current Surgeon General's warnings, to a statistically significant degree, on at least seven other measures that bear on the extent to which the warnings promote understanding. Plaintiffs provide no basis for questioning the accuracy of these results. Nor do Plaintiffs provide a reason to ignore the results of FDA's rigorous quantitative study in favor of the other data they cite. *See* Pls.' Br. 32. Many of those citations rest on apples-to-oranges comparisons, like Plaintiffs' attempt to elevate the results of FDA's first *qualitative* study, which used different stimuli and featured only 146 participants, over FDA's second quantitative study. *See* AR 23288-89.[20] But in light of the findings of FDA's second quantitative study, FDA had more than enough evidence to determine that the warnings would better promote understanding of all eleven of the negative health consequences that FDA selected.

Second, Plaintiffs take issue with some of the measures FDA selected to assess whether the warnings it tested will, in fact, promote understanding about smoking's negative health consequences. Although FDA collected data on ten measures, it determined that two particular measures—whether a warning was "new information" and whether participants learned something ("self-reported learning")—were the best predictors of improved understanding. 85 Fed. Reg. at 15,658. FDA selected these measures for three principal reasons. First, in order to *understand* a risk, a consumer needs to be *aware* of it first, and the record established that the "new information" measure helps target areas of knowledge where there are "opportunities to improve understanding through increased awareness." 84 Fed. Reg. at 42,769. Second, the record also established that "people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning." *Id.* Third, FDA reasonably concluded that other possible measures, such as "thinking about the risks" or "health beliefs," were not likely to change after participants had only limited exposure to the warnings. Those measures were thus not as "predictive of improved understanding

[20] Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions, July 2015.

in the way the 'new information' and 'self-reported learning' measures were" for purposes of the experiment. *Id.*

Notably, FDA prioritized these two measures *before* it conducted the study, leaving itself no wiggle room in the event the warnings performed poorly. The agency determined that "individual warnings *must* demonstrate statistically significant improvements, as compared to the control condition, on both the two outcomes of New Information and Self-Reported Learning" in order to be eligible for inclusion as final warnings. AR 50772 (emphasis added).[21]

In any event, Plaintiffs' critique of FDA's measures falls short. For starters, Plaintiffs do not dispute that "new information" and "self-reported learning" are, as FDA found, measures that encapsulate a necessary component of understanding a message. *See* 84 Fed. Reg. at 42,769. Moreover, although Plaintiffs dismiss these measures as having "questionable validity," Pls.' Br. 37, FDA "was guided by communication and social science theories" in selecting them. AR 39705;[22] *see also id.* (citing support in the literature for selection of "new information" and "self-reported learning" as measures of understanding).[23] Indeed, several peer reviewers expressly endorsed the agency's choice of the outcomes it measured. *See* AR 54097, 54105 (Peer Review Report). And where, as here, "specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, [the reviewing court] might find contrary views more persuasive." *Medina Cty.*, 602 F.3d at 699.

Plaintiffs next contend that FDA should not have used "new information" and "self-reported learning" as its key metrics, because those measures capture an *initial* step in the process of understanding a message, rather than the entirety of the process. *See* Pls.' Br. 37. But here, Plaintiffs

[21] Experimental Study of Cigarette Warnings, FDA Supporting Statement Part A, 2019.

[22] Experimental Study of Cigarette Warnings: Study 2 Report, 2020 ("Revised Second Quantitative Report").

[23] FDA's citations to the relevant literature address the criticism from one of the peer reviewers that Plaintiffs cite. The reviewer agreed that "[t]he primary outcomes of 'new information' and 'self-reported learning' have some fac[ial] validity as potential indicators of understanding," but noted that "[t]he [study] report would be stronger if it provided citations separately for each measure used[.]" AR 54059 (the "Peer Review Report"). FDA did precisely that in its revised report. *See* AR 39705 (Revised Second Quantitative Report).

conflate the role of these two measures—which is to be "*predictive* for promoting understanding of the risks associated with cigarette smoking"—with the goal of the warnings themselves—which is to actually promote that understanding. 85 Fed. Reg. at 15,658-59 (emphasis added). FDA "prioritize[d] the outcomes that provide the best assessment of initial reactions" because "more 'delayed' outcomes . . . are unlikely to change after only brief exposure to a warning." *Id.* at 15,662. In other words, measuring an early indicator of understanding makes sense in the context of a study that has a limited time horizon. And again, decisions regarding "methodology and data analysis" fall squarely within "the agency's technical expertise." *Kennecott Greens Creek Min. Co.*, 476 F.3d at 956 (citation omitted).

Even if Plaintiffs could overcome the high bar necessary to set aside FDA's selection of "new information" and "self-reported learning" as the most predictive measures, there would be no basis for upsetting the agency's conclusion that the final warnings promote understanding of smoking's negative health consequences. That is because all eleven warnings also "surpassed the Surgeon General's warnings on six *other* measures"—specifically, the warnings "led to more thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness [in] understanding health effects; attracted more attention; and were better recalled." 85 Fed. Reg. at 15,658 (emphasis added). Those findings put to rest many of Plaintiffs' remaining concerns. For instance, Plaintiffs speculate that a warning might convey "new information" in a "confusing" way (and thus fail to promote better public understanding). Pls.' Br. 37. But the eleven final warnings are not confusing; all eleven outperformed the Surgeon General's warnings on "perceived informativeness" and "perceived understandability." 85 Fed. Reg. at 15,659. Plaintiffs likewise hypothesize that a warning might convey "new information" in a way that is "not credible" or is "offensive." Pls.' Br. 37. But all eleven final warnings also outperformed the Surgeon General's warnings on "perceived helpfulness in understanding health effects," "self-reported learning," and "thinking about risks," 85 Fed. Reg. at 15,658—results at odds with Plaintiffs' claimed fear that consumers will respond to the warnings in a manner that impedes understanding.

The only measures where the final warnings were not across-the-board better than the current Surgeon General's warnings are "perceived factualness" and "health beliefs." While Plaintiffs dwell

on these two measures, *see* Pls.' Br. 34-38, nothing about them changes the reasonableness of the agency's bottom-line conclusions. In fact, that the Surgeon General's warnings generally outperformed the final warnings on the "perceived factualness" measure is fully consistent with the conclusion that the final warnings are better at promoting understanding. As FDA explained in the Rule—in analysis that Plaintiffs ignore, *see* Pls.' Br. 38—it "is common in pre-implementation studies that test warnings about health effects for which there are low levels of consumer awareness" for those warnings to test comparatively poorly on measures of perceived factualness. 85 Fed. Reg. at 15,660 (citing comment from Professor David Hammond, located at AR 28785). That stands to reason, as the literature on this issue confirms: "individuals presented with new information may view it with skepticism and even consider the new information less factual than information they have seen before." 85 Fed. Reg. at 15,660. In other words, the very reason these warnings are needed—*i.e.*, because of their "'novelty' or newness," *id.* at 15,663—is a reason they may not *seem* as factual as the Surgeon General's warnings to a study participant.

That leaves "health beliefs" as the measure on which Plaintiffs must hang their critique of FDA's second quantitative study. Plaintiffs assume, without citing any evidence in the record, that "altering participants' beliefs about smoking risks" is "the best measurement of whether the warnings would promote greater public understanding of [the] risks" FDA selected. Pls.' Br. 16. Plaintiffs then take that assumption and try to redefine the goals of FDA's research, suggesting that FDA expected to find that the warnings "chang[ed] study participants' beliefs about smoking" and "moved the goalposts" when that result did not come to pass. *Id.* at 35, 37. That is false. FDA selected "new information" and "self-reported" learning as the make-or-break measures for the warnings *before* it conducted the second quantitative study. *See* AR 50772 (FDA Study Supporting Statement). And as noted above, FDA did *not* expect health beliefs to change because such a result is "unlikely . . . after only brief exposure to a warning." 85 Fed. Reg. at 15,662. Plaintiffs do not contest that conclusion, asserting instead that FDA should somehow have "design[ed] a longer-term study." Pls.' Br. 37. But they point to no evidence indicating what such a study might have looked like, much less evidence that FDA was unreasonable in choosing a more feasible methodological approach.

In any event, Plaintiffs' focus on "health beliefs" overlooks that the warnings performed remarkably well on that measure in the second quantitative study. Nine of the final eleven warnings "demonstrated statistically significant improvements over the Surgeon General's warnings between Session 1 of the study and Session 2," and six of the final eleven warnings "demonstrated statistically significant improvements over the Surgeon General's warnings" between Session 1 and Session 3, even though Session 3 was approximately 17 days later. 85 Fed. Reg. at 15,659. To put that in perspective, seven of the warnings were so effective at changing participants' health beliefs that the effects still lingered, to a statistically significant degree, more than two weeks after just "two brief exposures" to the warnings. *Id.* Plaintiffs cite no research indicating that FDA could, or should, have hoped for the warnings to perform better.

In sum, FDA's selection of measures for the second quantitative study was appropriate and well-grounded in the literature, and Plaintiffs' criticisms of those measures misperceive the methodological evidence in the record and misconstrue the study's robust results.

Third, Plaintiffs throw out several miscellaneous criticisms of the second quantitative study, none of which has merit. They suggest FDA did not demonstrate "*meaningful* gains in consumers' knowledge" because FDA used the current Surgeon General's warnings as the control condition. Pls.' Br. 38. But Plaintiffs fail to propose a different control, and FDA's methodological choice is supported by the record. *See* AR 54070 (Peer Review Report) (explaining that "the current standards for warnings" were "an appropriate control group[]" for the second quantitative study). Additionally, Plaintiffs do not contest the agency's findings that—in absolute terms—a large percentage of study participants reported that the eleven warnings were new information. *See* 85 Fed. Reg. at 15,655 (warnings provided new information to between 35.7% and 88.7% of study participants). It is not clear what more Plaintiffs are looking for.

Next, Plaintiffs assert that the second quantitative study is not "reliable" because the sample was not nationally representative. Pls.' Br. 38. But once again, that charge fails to engage with FDA's thorough discussion of this issue in the Rule. As the agency explained, "an experimental design does not require a nationally representative sample to demonstrate a valid and reliable effect." 85 Fed. Reg.

at 15,663; *see also id.* (explaining how the agency set "specific recruitment targets for the number of study participants in each age group and tobacco-use category to be recruited into the study population"). All studies require tradeoffs in their design and execution, and FDA's selection of participants was reasonable and consistent with best scientific practices. *See* AR 54055 (Peer Review Report) (finding that FDA's selection of the "study population represents a good trade off" because although the sample is not nationally representative, it is "diverse," "easily recruitable," and "appropriate to address the research questions").

Finally, Plaintiffs describe FDA's first and second quantitative studies as "self-contradictory." Pls.' Br. 38-39. This is a fitting critique on which to close because it illustrates many of the flaws that plague Plaintiffs' failure to carefully engage with FDA's research. For instance, it shows how Plaintiffs target other portions of the record as a roundabout way of calling into the question the key portion—*i.e.*, FDA's second quantitative study. For although Plaintiffs apply the "self-contradictory" label to *both* quantitative "studies," they cite data from only the *first* (which tested only text statements, without images). *See id.* More insidiously, the argument rests on the alleged identity between a "new information" measure and an "informative[ness]" measure. *See id.* at 39 (citing AR 10865, 10868).[24] But the measures are different. Whereas "new information" reflects the knowledge that participants reported gaining, "informativeness" gauges participants' subjective assessment of the warning—specifically, whether participants "*considered* the [FDA-generated] statement to be more informative." AR 10863, 10868 (emphasis added). It is not contradictory—in fact, it is unsurprising—that participants would report learning more new information from a warning they nonetheless *perceived* to be less informative. This is consistent with how FDA described another subjective measure from one of its studies, highlighting that "[w]hen individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known." 85 Fed. Reg. at 15,663. Plaintiffs, once again, ignore FDA's analysis.

[24] Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report, 2018. The revised version of this report on FDA's first quantitative study, which incorporates feedback provided by peer reviewers, is at AR 39292-424.

Ultimately, Plaintiffs provide no reasoned basis to question that the second quantitative study's "consistent pattern of findings for each individual required warning *and* across all the required warnings is highly supportive" of FDA's conclusion that the eleven final warnings promote understanding of the negative health consequences of smoking. 85 Fed. Reg. at 15,660 (emphasis in original). That failure is all the more pronounced in light of the deference owed to FDA in its exercise of scientific expertise. FDA set out to determine whether its proposed warnings further the exact interest the government advances in this litigation. For the eleven warnings the agency selected, the answer was an unequivocal yes. The Court should not disturb that reasoned judgment.

3. The Rule Is No Broader than Reasonably Necessary.

There is likewise no merit to Plaintiffs' argument that the Rule is "unduly burdensome." Pls.' Br. 39-45. Under *Zauderer*, the Rule need only further the government's interest in a manner that is "no broader than reasonably necessary." *NIFLA*, 138 S. Ct. at 2377. This inquiry into "fit" is a lenient one, and considerably less searching than a least-restrictive-means test. *See AMI*, 760 F.3d at 26-27 (*Zauderer* requires no more than a "'reasonable fit' between means and ends"). That is particularly true given that cigarettes are a uniquely dangerous and addictive product. Commercial speech "is 'linked inextricably' with the commercial arrangement that it proposes," and as a result, the regulatory tools the government has at its disposal vary with "the State's interest in regulating the underlying transaction[.]" *Edenfield*, 507 U.S. at 767 (citation omitted). Where, as here, the underlying transaction is the sale of a deadly, addictive product, the government's authority to regulate commercial speech about that product is at its zenith. *See Pearson v. Shalala*, 164 F.3d 650, 656 & n.6 (D.C. Cir. 1999) (explaining that products where "the potential [for] harm presumably is much greater" are "in an entirely different category" from products that have not been shown to present safety concerns).

Plaintiffs maintain that the Rule is insufficiently tailored, and they broadly divide their arguments on this point into two categories: (1) that the size and location of the required warnings is too burdensome, *see* Pls.' Br. 41, and (2) that FDA had other alternatives available, *see id.* at 42-45. But

both Congress and FDA reasonably determined that warnings like the ones required under the Rule are necessary, and this Court should uphold that determination.

Plaintiffs take issue with the size of the warnings (50% of the front and back of cigarette packages, 20% of advertisements) and their placement at the top of packages and advertisements. *See* Pls.' Br. 39-41. Those requirements, however, come directly from the TCA, and it is squarely within Congress's "traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Turner Broad. Sys.*, 520 U.S. at 196. Accordingly, "deference must be accorded to [Congress's] findings as to the harm to be avoided and to the remedial measures adopted for that end." *Id.*

Deference is particularly appropriate here because Congress is not new to the business of requiring health warnings on cigarettes. Congress first required such warnings in 1965, *see* Pub. L. No. 89-92, modified them in 1970, Pub. L. No. 91-222, updated them in 1984 in light of a need to make Americans "more aware of any adverse health effects of smoking," Pub. L. No. 98-474, § 2, and revamped them once more in 2009 through the TCA. Congress knows how to draw reasonable lines with respect to such warnings, and it knows whether its prior efforts have achieved their desired ends. *See Schirmer v. Edwards*, 2 F.3d 117, 122 (5th Cir. 1993) (upholding the Louisiana legislature's decision to double the "campaign-free zone" around polling locations after an earlier law proved "inadequate"). Here, the question is not *whether* to mandate warnings—indeed, Plaintiffs concede that existing warning requirements are constitutional. *See* Compl. ¶ 1. Rather, the question is what specifications for the warnings are appropriate. And the nuances of that question—such as whether the warning should take up slightly less space, or be oriented differently—is not one "of 'constitutional dimension.'" *Burson v. Freeman*, 504 U.S. 191, 210 (1992) (plurality op.) (citation omitted).

Set against this backdrop, Plaintiffs' arguments about the size and location of the warnings fall short. They mirror the arguments raised before, and rejected by, the Sixth Circuit in *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012)—in which R.J. Reynolds was also a

plaintiff[25]—where the court upheld the same TCA requirements for cigarette health warnings that are at issue here. The Sixth Circuit relied on "abundant evidence" that "larger warnings incorporating graphics promote a greater understanding of tobacco-related health risks[.]" 674 F.3d at 565. And it found that the manufacturers had "not shown that the remaining portions of their packaging are insufficient for them to market their products," highlighting that such an argument was "undercut by Plaintiffs' claim that the warnings will not reduce the use of their tobacco products." *Id.* at 567. "If that is true," the court reasoned, "then the [warning] provision is certainly not unduly burdening Plaintiffs' speech." *Id.*; *see also Cigar Ass'n*, 315 F. Supp. 3d at 173-74 (upholding a requirement for warning labels that take up 30% of cigar packaging and 20% of cigar advertisements and emphasizing the lack of evidence that "the size of the warnings will dampen the industry's enthusiasm to engage in commercial speech or cause manufacturers or importers to pull products from the marketplace").

The same analysis applies here, only with greater force in light of FDA's record-based findings. FDA found that "the scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are *necessary* to ensure that consumers notice, attend to, and read the messages conveyed by the warnings[.]" 85 Fed. Reg. at 15,650-51 (emphasis added). FDA also found that "placement of the warnings at the top 50 percent of the front and rear panels of the packages and at least the top 20 percent of advertisements will better ensure noticeability of the warnings." *Id.* at 15,651. And the agency specifically addressed a concern that Plaintiffs reiterate here—namely, that "the rule will render cigarette packages indistinguishable from one another because of certain display cases that show only the top portions of cigarette packages[.]" 85 Fed. Reg. 15,647; *see also* Pls.' Br. 40-41. "[T]here is no requirement that display cases be configured" in that manner, and moreover, such "cases generally do not display only cigarette package facings, but commonly feature a large amount of 'header,' 'flipper,' and other cigarette advertising" (for which any warning would occupy only 20% of the space). 85 Fed. Reg. 15,647. In any event, the constitutionality of a requirement to

[25] The judgment from *Discount Tobacco*, accordingly, has preclusive effect at least with respect to R.J. Reynolds's claims about the constitutionality of the TCA's cigarette health warnings requirements.

warn consumers about risks as serious as cancer, blindness, and amputation does not turn on the configuration of a retail display case.

Plaintiffs challenge none of these record-based findings. Instead, they pivot to alternatives they would have preferred FDA pursue. First, they suggest FDA should have pursued "a public-education campaign[.]" Pls.' Br. 42. But FDA already conducts such campaigns. *See, e.g.*, FDA's Youth Tobacco Prevention Plan, *available at* https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan. And in any event, Plaintiffs' argument—that a public health campaign would allow FDA to use more communication channels, change information more quickly, and better target particular groups—sweeps too broadly. If public health campaigns are the easy fix, that would call into question not only the current Surgeon General's warnings, but also *every* compelled health warning on any potentially dangerous product. *See* Pls.' Br. 42. Fortunately, there is no need to "question the legality of health and safety warnings long considered permissible," *NIFLA*, 138 S. Ct. at 2376, because although "voluntary public education campaigns can provide effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette package and cigarette advertisement warnings," 85 Fed. Reg. at 15,648. The decision to ensure that every person who picks up a pack of cigarettes or sees a cigarette advertisement be informed of the negative health consequences of smoking reflects a decades-long policy judgment by Congress. *See id.* The wisdom of that decision was confirmed by the research FDA performed in support of the Rule, which found that "pictorial cigarette warnings placed directly on products convey the risks to those who look at packages and advertisements with more immediacy and noticeability." *Id.* In light of this evidence, FDA reasonably concluded that public health campaigns were not a sufficient substitute for pictorial health warnings.

Plaintiffs' remaining arguments on the issue of burden are, in essence, a series of "what ifs": What if FDA had tested slightly smaller warnings? What if FDA had tested revised text-only warnings? What if FDA had tested warnings on only *one* side of cigarette packages? And so on. *See* Pls.' Br. 43-45. It is not clear how far down this rabbit hole Plaintiffs would have FDA descend,

though it is hard to resist the prediction that for every "n" studies FDA conducts, Plaintiffs would have FDA conduct at least "n + 1." In any event, and contrary to Plaintiffs' suggestion, FDA *did* consider many of the alternatives floated by Plaintiffs. Most notably, FDA thoroughly considered the arguments in favor of text-only warnings. *See* 84 Fed. Reg. at 42,762-65; 85 Fed. Reg. at 15,648. But it rejected that option because "the scientific literature strongly supports that pictorial cigarette warnings promote greater public understanding about the health consequences of smoking" for several reasons, including that they "increase knowledge and learning of the negative health consequences of smoking, and "benefit subpopulations that have disparities in knowledge about the negative health consequences of smoking." *Id.* Among other things, FDA considered the value of images with respect to the wide variability in the general public's ability to read and understand health information, 84 Fed. Reg. at 42,769-70, and to communicate information to youth, *id.* at 42,764. FDA did not need to add *another* study to its lengthy process to confirm what the literature already reflects.

In sum, FDA appropriately balanced Congress's judgment, the relevant scientific literature, and the findings of its own studies on the degree to which the final warnings promote understanding of the harms of smoking. It charted a regulatory path that was "no broader than reasonably necessary," *NIFLA*, 138 S. Ct. at 2377, and the Rule should therefore be upheld under *Zauderer*.

C. The Warnings Are Also Constitutional Under *Central Hudson*.

For the foregoing reasons, this Court should apply *Zauderer* to the Rule and uphold it under that standard. But in the event the Court finds that *Zauderer* does not apply, or defers resolving that threshold question, the Rule should be upheld under *Central Hudson*. As the D.C. Circuit has held in multiple cases involving the tobacco industry, commercial speech regulations that are not evaluated under *Zauderer* are subject to the intermediate scrutiny of *Central Hudson*. *See R.J. Reynolds I*, 696 F.3d at 1217 (citing *Philip Morris*, 566 F.3d at 1142-43).[26] That result makes sense: "commercial speech receives a lower level of protection under the First Amendment," *id.*, and a regulation targeting *only*

[26] Plaintiffs suggest the Fifth Circuit disagreed with this view in *Hersh*. *See* Pls.' Br. 7 n.4, 45. But the court merely held that the statutory provision at issue *satisfied* strict scrutiny. *Hersh*, 553 F.3d at 764-68. The court did not consider, much less resolve, whether strict scrutiny applies to any regulations of commercial speech.

commercial speech should therefore not receive the strictest form of scrutiny. That is how the Supreme Court approached the issue in *Milavetz*. There, after finding that "the challenged provisions regulate only commercial speech," the Court examined whether *Central Hudson* or "the less exacting scrutiny described in *Zauderer*" applied. 559 U.S. at 249. The Court did not even consider strict scrutiny. *See id.* at 249-50.

Under *Central Hudson*, courts "ask whether the asserted governmental interest [in regulation] is substantial" and "whether the regulation [at issue] directly advances the governmental interest asserted[.]" *Cent. Hudson*, 447 U.S. at 566. If so, the regulation survives so long as it is "not more extensive than . . . necessary" to further the government's interest. *Id.* Because those steps are similar to the analysis under *Zauderer*, and because the above discussion demonstrates how the rule not only meets, but surpasses, the *Zauderer* standard, the foregoing analysis is largely dispositive.

First, FDA's interest in warning consumers about the health consequences of cigarette smoking is substantial, as Congress and courts have repeatedly recognized. *See supra* at 21-26. That information is important because it enables consumers "to make informed decisions and give proper weight" to the serious risks to which they might otherwise unknowingly subject themselves. *Citizens United*, 558 U.S. at 371. Indeed, the government's interest here is even more significant when measured against other interests that courts have found to be substantial. The government has a substantial interest in, among other things, promoting "fair and efficient" energy rates, *Central Hudson*, 447 U.S. at 569, "promoting an educational rather than commercial atmosphere on [college] campuses," *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 475 (1989), and "resolving [a] dispute between Dallas and Fort Worth" over local airports, *Cramer v. Skinner*, 931 F.2d 1020, 1034 (5th Cir. 1991). *Cf. Kansas v. United States*, 16 F.3d 436, 443 (D.C. Cir. 1994) (recounting "the pedestrian nature of those interests affirmed as substantial"). Whether the government has a substantial interest in promoting greater understanding of the health risks posed by a product that today causes disease in roughly 16 million Americans is not, by comparison, a close question.

Second, FDA's research—in particular, its second quantitative study—establishes a direct link between the government's interest and the warnings required by the Rule. *See supra* at 32-41. When

courts assess the extent to which a commercial speech regulation furthers a government interest, they often look to empirical evidence of consumer perception. *See Express Oil Change*, 916 F.3d at 492 (finding that "evidence from [a] public opinion survey showing that [consumers] are misled" was sufficient to "support[] a holding" that the restriction at issue "directly advances the [government's] asserted interest"). Here, FDA conducted a study tailor-made for that inquiry. Because that study found the warnings promote understanding of the negative health consequences of smoking, it demonstrates the Rule directly furthers the government's interest.

Third, "the government's burden on the final *Central Hudson* factor is to show a 'reasonable fit[]' . . . between means and ends." *AMI*, 760 F.3d at 26 (citation omitted). FDA demonstrated that the Rule furthers the government's interest and explained why alternative measures would not have been as effective. *See supra* at 41-45. FDA considered the very alternatives that Plaintiffs claim would be "just as effective," Pls.' Br. 47, and explained why the agency's research and Congress's findings show Plaintiffs are wrong. *See* 85 Fed. Reg. at 15,648-49. *Central Hudson* does not require more.

D. Strict Scrutiny Does Not Apply, but the Rule Nonetheless Satisfies It.

Plaintiffs seek to pluck this case from the familiar world of commercial speech regulation and subject the Rule to strict scrutiny. They suggest that FDA's requirement that tobacco companies depict and describe the harms their products undisputedly cause amounts to being "coerced into betraying their convictions," and that the Rule must therefore undergo the same inquiry as forced subsidization of a union or other compelled political speech. Pls.' Br. 19 (quoting *Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, 138 S. Ct. 2448, 2464 (2018)). Plaintiffs are wrong.

As noted above, *Central Hudson* offers the most searching form of scrutiny applied to laws that target only commercial speech. *See supra* at 45-46. That is because compelled commercial speech does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." *Zauderer*, 471 U.S. at 651 (citation omitted). Rather, such disclosures "prescribe what shall be orthodox in commercial advertising" and labeling,

and here, that "prescription has taken the form of a requirement that [plaintiffs] include in [their] advertising purely factual and uncontroversial information about" their products. *Id.*

Even if strict scrutiny applied, however, the Rule would satisfy it because it is "narrowly tailored" to serve a "compelling interest." *Reed v. Town of Gilbert*, 576 U.S. 155, 171 (2015). The Rule provides the public with critical information about lesser-known risks of cigarette smoking, and it does so through warnings that were carefully tested to ensure that they are effective at promoting understanding. The Rule, accordingly, furthers a compelling government interest through means that are narrowly tailored to the problem it addresses.

If there were any doubt on this point, consider the following: Suppose that a new product was introduced into the market, and suppose that the product caused all of the negative health consequences—as confirmed by the highest degree of scientific evidence—that are addressed in the final warnings (*e.g.*, bladder cancer, head and neck cancer, COPD, type 2 diabetes, harm to children, *etc.*). Further, imagine that, prior to regulating the manufacturer's speech about this lethal new product, the government tested a series of warnings and found that all of them provided new information to a substantial percentage of consumers—say, between 35% and 88%. It blinks at reality to suggest that the government would not have a compelling interest in requiring that the product carry the tested warning labels. And it is similarly difficult to fathom that, in the face of the need to warn consumers about these risks, the government's efforts would be struck down as insufficiently tailored.

Cigarettes, of course, are not a new product. But that fact just illustrates how concerning it is that millions of Americans may pick up smoking, or continue to smoke, without knowing many of the serious risks to which they are exposing themselves and their loved ones. FDA's decision to help correct that perverse information asymmetry through truthful, medically accurate warnings, focused especially on lesser-known risks, is permissible—irrespective of the level of scrutiny this Court applies.

II. THE TCA'S REQUIREMENTS FOR PICTORIAL HEALTH WARNINGS ARE FACIALLY CONSTITUTIONAL.

Facially invalidating a statute "frustrates the intent of the elected representatives of the people," *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 329 (2006) (citation omitted), and is

therefore a measure of last resort. Plaintiffs' half-hearted facial attack on the TCA fails to support such broad relief. To prevail, Plaintiffs must demonstrate that "'no set of circumstances exists under which [the statute] would be valid' . . . or that the statute lacks any 'plainly legitimate sweep.'" *United States v. Stevens*, 559 U.S. 460, 472 (2010) (citations omitted). But they have not even attempted to make that showing. Instead, they assert only that certain features of the warnings required by the TCA "are designed to shock viewers." Pls.' Br. 48. As evidence of that design, Plaintiffs cite a statement made by a single senator and statements taken from FDA's 2011 rulemaking and the D.C. Circuit decision invalidating it. *See id.* These provide no basis for invalidating an Act of Congress on its face.

In any event, the Sixth Circuit upheld these same statutory warning requirements against a similar challenge in *Discount Tobacco*, and this Court should reject Plaintiffs' argument for the same reasons. There, the court rejected the claim that images included in cigarette health warnings under the TCA necessarily "provoke a visceral response in the audience." *Disc. Tobacco*, 674 F.3d at 569. Such a requirement, the court explained, is "simply not in the statute." *Id.* In addition, the court rejected a facial challenge to the statutory size and placement requirements, *see supra* at 42-43, concluding that "there is more than substantial evidence to support the conclusion that larger warnings incorporating graphics would promote greater public understanding of the health risks of using tobacco," *id.* at 566, and that "[a]mple evidence supports the size requirement for the new warnings," *id.* at 567. FDA's findings reinforce this conclusion. As discussed above, replacing the stale Surgeon General's warnings with new, larger warnings accompanied by supporting images directly furthers the government's interest in promoting consumer understanding of the health risks of smoking. *See supra* at 32-41, 46-47. The statute is thus consistent with the First Amendment.

III. FDA COMPLIED FULLY WITH THE APA IN PROMULGATING THE RULE.

A. FDA's Decision to Promulgate the Rule Was Not Arbitrary or Capricious.

Under the APA, the Rule must be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under this "narrow standard of review, . . . a court is not to substitute its judgment for that of the agency," *FCC v. Fox*

Television Stations, Inc., 556 U.S. 502, 513 (2009) (internal citations omitted), but instead to assess only whether the decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment," *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). In other words, the APA requires that the agency "examine[] the relevant data and articulate[] a satisfactory explanation" for its action, "including a rational connection between the facts found and the choice made." *U.S. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (citation omitted).

For all of the reasons described in depth in the First Amendment section above, FDA's decision to promulgate the Rule was the product of reasoned decision-making. Nearly all of Plaintiffs' arguments to the contrary are repackaged versions of their analysis under the First Amendment. And as with their earlier iterations, these arguments ignore the APA's deferential standard of review, as well as the voluminous record that supported FDA's reasoning. *Compare, e.g.*, Pls.' Br. 49 ("[T]he Rule lacks *any* evidence demonstrating that the warnings will further FDA's only asserted interest"), *with* 85 Fed. Reg. at 15,671-84 (evidence demonstrating that each warning furthers FDA's interest in promoting understanding of the negative health consequences of smoking).

The one new point Plaintiffs develop is a claim that FDA acted unreasonably by declining to quantify the Rule's benefits and using a "break-even" approach instead. Pls.' Br. 50. But Plaintiffs overlook two key threshold points. First, whether an agency's cost-benefit analysis is reviewable under the APA depends on the text of the authorizing statute. *Michigan v. EPA*, 135 S. Ct. 2699 (2015); *see Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 510 (1981) ("When Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute."). Here, the TCA imposes no obligation to conduct a cost-benefit analysis for this rulemaking, and thus "the agency was not required [by statute] to undertake a cost-benefit analysis when it implemented" the warnings in the first place. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 400-01 (D.D.C. 2017). Second, contrary to Plaintiffs' suggestion, FDA did not invoke its cost-benefit analysis as a reason for the Rule, *see* Pls.' Br. 50 (emphasis added), but simply reported the results of the analysis required by "E.O.s 12866 and 13563," 85 Fed. Reg. at 15,697—both of which expressly preclude judicial review, *see* EO 12,866, § 10 (Sept. 30, 1993); EO 13,563, § 7(d) (Jan. 18, 2011); *Air Transp.*

Ass'n of Am. v. FAA, 169 F.3d 1, 8 (D.C. Cir. 1999) (challenge to cost-benefit analysis under EO 12,866 "not subject to judicial review"). There is therefore no basis for APA review of that analysis here.

In any event, the agency's analysis—including its decision to use a "break-even" approach—was reasonable. *See Nicopure*, 266 F. Supp. 3d at 406 (upholding FDA's use of a "break even" analysis). In *Nicopure*, the court held that even if some consideration of costs and benefits were required, FDA did not need to "monetarily" quantify a rule's benefits because the agency "provided substantial detail on the benefits of the rule, and the reasons why quantification was not possible." *Id.* FDA did the same here. It explained that a break-even analysis was justified in light of the "high level of uncertainty around quantified economic benefits." AR 39629 (Final Regulatory Impact Analysis). Given that the aim of the Rule is to promote understanding of the risks of smoking, FDA concluded that "a per-package break-even estimate" would help decision-makers "understand the magnitude of non-quantified benefits[.]" *Id.* at 39630-31. That conclusion was reasonable.

B. FDA Complied with the APA's Requirements for Notice-and-Comment Rulemaking.

The APA "prescribes a three-step procedure for so-called 'notice-and-comment rulemaking.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). "First, the agency must issue a '[g]eneral notice of proposed rulemaking,' ordinarily by publication in the Federal Register." *Id.* (quoting 5 U.S.C. § 553(b)). Second, "the agency must 'give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.'" *Id.* (quoting 5 U.S.C. § 553(c)). "Third, when the agency promulgates the final rule, it must include . . . 'a concise general statement of [its] basis and purpose.'" *Id.* (quoting 5 U.S.C. § 553(c)). The Supreme Court has "held that generally speaking this section of the [APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures." *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). Although "[a]gencies are free to grant additional procedural rights in the exercise of their discretion," "reviewing courts are generally not free to impose them if the agencies have not chosen to grant them." *Id.*

Plaintiffs advance two notice-and-comment arguments. First, they assert that FDA "failed to provide meaningful notice," Pls.' Br. 52, because its publication of certain studies as part of its notice of proposed rulemaking—including hundreds of pages of reports summarizing and analyzing those studies, including their design, methodology, and results—did not also include all of the underlying raw data from each study. *See id.* at 52-54. Second, Plaintiffs argue that, although FDA provided a 15-day extension of the initial (60-day) comment period after publishing additional study reports later in the rulemaking process, 15 days was an inappropriately "tight timeframe," *id.* at 56, for additional comments. *See id.* at 54-56. Both arguments are meritless.

1. FDA had no obligation to publish all of the raw data from all of its studies with its "general notice of proposed rulemaking."

1. FDA's notice of proposed rulemaking spanned 45 pages of the Federal Register. 84 Fed. Reg. 42,754-98. In Section V, titled "Data Concerning Cigarette Health Warnings," FDA summarized the state of the scientific literature on the continuing effectiveness (or lack thereof) of the Surgeon General's warnings, and the potential for updated, more noticeable warnings to promote greater public understanding of the negative health consequences of smoking. *Id.* at 42,759-65. In Section VI, "FDA's Process for Developing and Testing the Proposed Cigarette Health Warnings," the agency described in detail the quantitative and qualitative studies that it carried out to develop its proposal—including summaries of key data, findings, and the studies' designs and methodology. *Id.* at 42,765-72. And in Section VII, "FDA's Proposed Required Warnings," FDA presented its proposed new warnings, and explained the scientific bases for its determination that the warnings would promote greater public understanding of the negative health consequences of smoking. *Id.* at 42,772-77. FDA also published detailed reports, totaling hundreds of additional pages, summarizing its two quantitative studies, and cited 220 publicly available sources (including peer-reviewed journal articles, congressional findings and reports, Surgeon General's reports, and more). *See id.* at 42,789-96.

FDA later published additional reports about its qualitative studies. The agency had not released these materials with the notice of proposed rulemaking because it "did not rely on these studies as part of the rulemaking." 84 Fed. Reg. at 60,997. But FDA acknowledged that "the

qualitative studies were used to inform further research, namely, the quantitative consumer research studies"—on which it *had* relied. *Id.* For that reason, FDA decided to make "these additional materials available," *id.*, whether or not it had any obligation to do so. It "reopen[ed] the comment period for the proposed rule for 15 days to allow comment on the additional materials." *Id.*[27]

As is typical, FDA did not immediately publish all of the raw data sets for each of its studies—which were immense.[28] But those datasets have now been provided to Plaintiffs as part of the administrative record, because the standard for compilation of the administrative record is broader. *See, e.g.*, *Exxon Mobil Corp. v. Mnuchin*, No. 3:17-cv-1930-B, 2018 WL 4103724, at *2 (N.D. Tex. Aug. 29, 2018) ("all documents and materials directly or indirectly considered by [the] agency").

2. Plaintiffs' primary notice-and-comment argument—that FDA failed to provide meaningful notice because it did not release all underlying data for public comment—presumes that the APA obligates agencies to solicit comments on virtually every piece of potentially relevant factual information. But the APA—and Fifth Circuit precedent interpreting it—impose no such standard.

While it is true that "interested parties should be able to participate meaningfully in the rulemaking process," it is also settled that "the public 'need not have an opportunity to comment on every bit of information influencing an agency's decision.'" *Texas Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 325-27 (5th Cir. 2001) (quoting *Texas v. Lyng*, 868 F.2d 795, 800 (5th Cir. 1989)). That

[27] Plaintiffs' brief, at times, arguably leaves the incorrect impression that some or all of these reports were *never* published for comment. Pls.' Br. 53 ("But FDA did not release the underlying data for the qualitative studies, or even the study reports."); *id.* (alleging "FDA's failure to release these reports"). To be clear, by November 12, 2019, FDA had published detailed reports—and provided an extended opportunity to comment—on *all* of its relevant studies, qualitative and quantitative. *See* 84 Fed. Reg. 42,793 (NPRM Ref. 129: FDA, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study Report* (April 2018)); *id.* at 42,794 (NPRM Ref. 153: FDA, *Experimental Study of Cigarette Warnings: Study Report* (May 2019)); *id.* at 60,968 (Nov. 12, 2019) (qualitative study reports).

[28] FDA's first quantitative study included 2,505 participants, each providing data for more than 300 items, for a total of approximately 850,000 individual data points. FDA's second quantitative study included 9,770 participants, each providing data for more than 300 items (across three survey time points) for a total of nearly 2.2 million individual data points. And the raw data from FDA's qualitative studies included more than two thousand pages of verbatim transcripts from focus groups and interviews.

should come as no surprise: the APA's text contemplates only a "*[g]eneral* notice of proposed rule making," including "either the terms or *substance* of the proposed rule or a *description* of the *subjects and issues*."[29] 5 U.S.C. § 553(b) (emphases added); *cf. id.* § 706 (calling for judicial review based on "the *whole* record," which is generally assembled only after agency action is challenged in litigation) (emphasis added). The text of 5 U.S.C. § 553(b)—which is phrased at a high level of generality, and makes no mention of studies or data—does not fit with Plaintiffs' apparent expectation that *all* of the raw data collected in *all* of FDA's quantitative and qualitative studies *must* have been disclosed *before* the comment period. Nor does it square with the Supreme Court's admonition that courts are not to require more of agencies than the APA explicitly provides for. *See Vermont Yankee*, 435 U.S. at 524.

To be sure, courts have sometimes required that an agency solicit comments—as FDA did here—on key *reports* about studies "that served as the technical basis for [a] rule." *Texas v. EPA*, 389 F. Supp. 3d 497, 503-06 (S.D. Tex. 2019) (requiring disclosure of "the Final Connectivity Report" because it was among "the most critical factual materials used to support the Final Rule," but making no mention of underlying data). By contrast, the Fifth Circuit has rejected claims, like this one, asserting that an agency violated the APA's notice-and-comment requirements by failing to make available for comment all potentially relevant underlying *data*—particularly where, as here, the data were already summarized for comment.

Chemical Manufacturers Association v. EPA is instructive. There, the plaintiffs argued that the EPA had violated the APA's notice-and-comment requirements by "relying on economic data . . . that were never made available to the public for comment." 870 F.2d 177, 200 (5th Cir.), *clarified on other grounds on reh'g*, 885 F.2d 253 (5th Cir. 1989). The Fifth Circuit found that there was no error (and that any error would have been harmless, *see infra*, Section III.B.3), because the notice of proposed rulemaking had "adequately advised interested parties of the method the EPA had followed, the

[29] Plaintiffs state that "[t]he APA requires that agencies publish a general notice of proposed rulemaking that includes 'a description of the subjects and issues involved' in the proposed rule." Pls.' Br. 52 (quoting part of 5 U.S.C. § 553(b)(3)). In fact, the full statutory subsection confirms that the agency need 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) (emphases added). Here, FDA did both.

financial data it proposed to rely on, and its intention to develop an economic-impact study"—even though the agency "did not reveal the new . . . data." *Id.* at 201-02; *see also Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212-13 (5th Cir. 1991) (stating that the agency "probably did not violate the notice requirement of 5 U.S.C. § 553" even though it "failed to give notice to the public . . . that it intended to use 'analogous exposure' data to calculate the expected benefits of certain product bans"); *Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 842 (5th Cir. 1978) (similar).

None of this Fifth Circuit precedent appears in Plaintiffs' brief, which instead relies heavily on out-of-circuit dicta. But none of Plaintiffs' authority would lead to a different result, even if it were controlling in Texas. For example, the government has no quarrel with the proposition that a notice of proposed rulemaking must contain "sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019) (cited in Pls.' Br. 52). But the government is aware of no authority, from the Fifth Circuit or elsewhere, for the view that an agency's otherwise-robust notice-and-comment process is tainted by a failure to disclose all underlying data—especially with respect to studies that were indisputably described and analyzed, at length, in agency documents that were available for comment.[30]

3. Lacking precedential support for their maximalist position about the opportunity to comment on raw data, Plaintiffs fall back on a variety of other disclosure-related grievances. But most have little (if any) connection to the APA's notice-and-comment obligations. For example, Plaintiffs complain that FDA's original public notice regarding its quantitative studies—issued pursuant to the

[30] The D.C. Circuit and Ninth Circuit cases cited by Plaintiffs are not to the contrary. *See, e.g.*, *N. Am.'s Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 301 (D.C. Cir. 2017) (stating in dicta that an agency should "identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules," but holding that: (1) any error had been rendered harmless by subsequent publication of the data for comment, thus avoiding a ruling on the issue of whether there was any error at all; and (2) OSHA's "fail[ure] to disclose the basis for" certain "assumptions" underlying its decision did not provide "grounds for questioning OSHA's conclusion that [it] provided the best available evidence" during the comment period); *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1076, 1080 (9th Cir. 2006) (citing similar D.C. Circuit dicta about disclosure of "the technical basis for a proposed rule," but holding that, because the agency "used the new studies merely to refine and expand on its pre-existing data," it "was *not* required to reopen the public comment period" upon their belated publication) (emphasis added).

Paperwork Reduction Act, 44 U.S.C. § 3506(c)(2)(A)—"failed to include the text and graphics that made up the warnings themselves." Pls.' Br. 53; *see also Experimental Study of Cigarette Warnings*, 83 Fed. Reg. 48,625 (Sept. 26, 2018). But the APA does not require an agency to publish *anything* in advance of a notice of proposed rulemaking, and Plaintiffs offer no argument to the contrary. That FDA offered preliminary descriptions of some of its study designs earlier in the process—in the interest of transparency, and consistent with the requirements of the Paperwork Reduction Act—cannot fairly be held against it here. As a legal matter, what matters is that the notice of proposed rulemaking itself included the proposed text-and-image warnings, on which Plaintiffs commented extensively.[31]

2. FDA provided sufficient time for comments on the qualitative study reports.

The original comment period was 60 days long—which is typical for FDA rules, *see* 21 C.F.R. § 10.40(b)(2), and which Plaintiffs do not challenge here. Then, after FDA published additional qualitative study reports, it offered an additional 15-day comment period. Plaintiffs argue that 15 days was too short (though they do not say how long the comment period should have been).[32]

This argument fails. As a threshold matter, this is exactly the sort of procedural minutiae that the APA entrusts to an agency's reasonable discretion. The APA "does not specify a minimum time for submission of comments in an informal rulemaking," *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984)—some "opportunity to participate is all that the APA requires," *Phillips Petroleum Co. v. EPA*, 803 F.2d 545, 559 (10th Cir. 1986). Therefore, courts generally lack the authority to arbitrarily impose some minimum required comment-period length. *See id.* (citing *Vermont Yankee*, 435 U.S. at 543).

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[31] Plaintiffs also profess late-breaking dissatisfaction with FDA's response to a three-year-old Freedom of Information Act (FOIA) request submitted by Plaintiff R.J. Reynolds. *See* Pls.' Br. 53. But FOIA allows an aggrieved party to sue within 20 days of any unsatisfactory response. *See* 5 U.S.C. § 552. R.J. Reynolds has not done so. Accordingly, although FDA disagrees with Plaintiffs' characterizations about the handling of this FOIA request, they have no bearing on this lawsuit.

[32] Plaintiffs state that "FDA failed to provide a coherent explanation about why it had failed to release these reports along with the Proposed Rule." Pls.' Br. 55. FDA disagrees, *see* 84 Fed. Reg. 60,697, but that is irrelevant now—what matters is that FDA published the reports, solicited public comment, and took those comments into account before finalizing the Rule. The only live disputes are whether 15 days was too short and, if it was, whether the length of time was prejudicial.

In any case, under these circumstances, 15 days was entirely reasonable. Again, Plaintiffs do not challenge the length of the original 60-day comment period—during which they apparently had no trouble reviewing, analyzing, and commenting in detail on thousands of pages of scientific, technical, and legal analysis. In fact, during those 60 days, Plaintiffs went so far as to commission, complete, and report results from two of their *own* studies, one of which included a consumer survey. *See* Iyengar Report, ECF No. 43-21; Klick Report, ECF No. 34-21. It is hard to imagine that preparing comments on one new set of reports to the rulemaking record (totaling a bit less than 600 pages) could have required 25% of the entire time they spent preparing comments on the overall notice. By this point, Plaintiffs were well-steeped in these subjects, having already commented extensively, and having been engaged in litigation and non-litigation advocacy on these issues for much of the past decade. Plaintiffs' complaints about the "tight timeframe" for comments, Pls.' Br. 56—which was longer than, for example, the default period of time to respond to a motion in this district, *see* Local Rule CV-7(e)—are thus of no moment.

Even if FDA had been inclined to offer a longer period for additional comments, it was constrained by factors beyond its control: namely, a court order from separate litigation in the U.S. District Court for the District of Massachusetts, which required FDA to submit the Final Rule for publication in the Federal Register no later than March 15, 2020. *Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985-IT, 2019 WL 1047149, at *3 (D. Mass. Mar. 5, 2019). Given that reality, it was especially important that FDA minimize unnecessary procedural delay.

Courts have looked to similar considerations of context and practicality in upholding comment periods of similar length. *See, e.g.*, *Omnipoint Corp. v. FCC*, 78 F.3d 620, 629-30 (D.C. Cir. 1996) (rejecting a challenge to a 7-day comment period "given the urgent necessity for rapid administrative action under the circumstances" in light of a "congressional mandate" to move quickly, and the fact that interested parties already had some knowledge of the forthcoming rulemaking) (internal quotations and citation omitted); *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 534 (D.C. Cir. 1982) ("We cannot say that the NRC's choice of a [30-day] comment period was unreasonable. Neither statute nor regulation mandates that the agency do more. While the technical complexity of the

regulations is such that a somewhat longer comment period might have been helpful, the NRC had been exploring without complete success the problem of fire protection at nuclear plants with members of the industry for over five years."). Plaintiffs offer no reason for the Court to chart a different course here.

3. Any notice-and-comment error was harmless.

In any event, Plaintiffs fail to show they were harmed by any alleged notice-and-comment flaw. The APA provides explicitly that "due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706. Under that rule, procedural errors that do not cause "substantial prejudice" are to be excused. *Chem. Mfrs. Ass'n*, 870 F.2d at 202; *accord PDK Labs. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand."); *see also Texas Office of Pub. Util. Counsel*, 265 F.3d at 326-27 ("[T]he petitioners must show how they were prejudiced by the FCC's failure to solicit additional comments, and how they would have responded had they been given the opportunity to submit additional responses."). As explained above, there was no notice-and-comment error at all. But even if the Court disagrees, Plaintiffs have still failed to carry their burden to show that any such error caused "substantial prejudice," *Chem. Mfrs. Ass'n*, 870 F.2d at 202.

1. Raw Study Data. With respect to lack of earlier access to FDA's raw study data, the Fifth Circuit has applied the APA's harmless-error rule to reject similar notice-and-comment claims. *See Chem. Mfrs. Ass'n*, 870 F.2d at 202 ("[W]e fail to discern any substantial prejudice from the EPA's use of the 1981-86 Dun & Bradstreet data to supplement the other information on which it relied. We therefore decline to overturn the regulations because of the EPA's use of undisclosed supplementary economic data from Dun & Bradstreet."); *Lyng*, 868 F.2d at 800 ("Appellants presumably had access to most of the information relied on by witnesses before the task force . . . . [F]ailure to allow public comment after issuance of the task force report was harmless.").

As explained above, all of FDA's studies were described in hundreds of pages of reports, which provided more than enough detail for interested parties to analyze and comment on the agency's

work. In fact, Plaintiffs did just that—offering extensive commentary before the agency (and now again in this Court) about what they believe to be shortcomings with FDA's studies. Plaintiffs never offer any coherent explanation as to how their comments would have differed—let alone how *the outcome of the rulemaking* would have differed—in a world in which the full datasets were available during the comment period, in addition to FDA's detailed reports about that data.

Outside experts also found the absence of the raw study data to be no obstacle to meaningful analysis and commentary on FDA's studies. During the rulemaking, six peer reviewers, selected by an independent contractor, were charged with "provid[ing] input on the clarity of the documents describing [FDA's] studies and the soundness of the design and analysis of the studies." AR 54057 (Peer Review Report). Each was asked the following question: "Is sufficient information provided about the study design, stimuli, sample, methods, analysis, and results?" *Id.* None of the peer reviewers raised any concern with the amount of data that had been provided, nor did any of them request *any* of the raw data. *See, e.g.*, *id.* at 26 ("Yes, I thought that there was plenty of detailed information about the design, stimuli, sampling methods, and analysis both in the two documents that made up Study 1 plus the supplementary materials."); *id.* at 57 ("Yes. The methods section was through and detailed."); *see also id.* at 43 ("The document is exceedingly clear in its purpose and in its style of communicating. . . . Level of detail, particularly as it relates to the analytic plan and results, are crystal clear—supporting transparency of this endeavor."). Plaintiffs had access to all of the same information. If experts in the field did not need additional data to offer meaningful commentary, neither did Plaintiffs.

Plaintiffs argue that, because of the absence of the raw study data, "FDA has still not explained basic aspects of their studies or reasoning." Pls.' Br. 54. First of all, that is hardly a notice-and-comment argument—if anything, it is an argument that the Rule is arbitrary and capricious for lack of a reasoned explanation. But, either way, Plaintiffs are mistaken. FDA *has* explained "why it chose to "highlight[] certain diseases over others." Pls.' Br. 54; *see* 84 Fed. Reg. 42,767. FDA *has* explained why it chose to test "consumers' self-reported belief that they learned something new," Pls.' Br. 54, instead of other metrics that industry would prefer. *See* 85 Fed. Reg. 15,661-62. And FDA *has*

explained why it used language like "causes" instead of "can cause." *See* AR 23,281-23,379 (July 2015 Qualitative Study Report, at 6). Plaintiffs may disagree with those explanations, but that is no basis to set aside the rule—and it is certainly no basis for an argument that Plaintiffs' ability to comment on the raw study data would somehow have changed the outcome. FDA was aware that commenters had raised questions like these, which is why it fully responded to them in the Final Rule. Any notice-and-comment error with respect to the raw study data was therefore harmless.

2. Length of Additional Comment Period. Plaintiffs similarly suffered no "substantial prejudice," *Chem. Mfrs. Ass'n*, 870 F.2d at 202, from FDA's providing a 15-day period to solicit new comments on the qualitative study reports. Among other reasons, that is because Plaintiffs (and others) actually submitted another round of lengthy comments during that additional comment period. *See, e.g.*, AR 36856, 36886, 36893, 36943 (supplemental comments of RAI Services (R.J. Reynolds), Marissa G. Hall, *et al.*, Altria (Philip Morris), and Professor Hammond); *see also Fla. Power & Light*, 846 F.2d at 772 (finding "no evidence that petitioners were harmed by the short comment period," where the agency received extensive comments anyway); *Conference of State Bank Sup'rs v. Office of Thrift Supervision*, 792 F. Supp. 837, 844 (D.D.C. 1992) (rejecting argument that 30-day comment period was inadequate, "especially in light of the comments that [aggrieved plaintiffs] and other interested parties submitted").

Here, Plaintiffs offer only two arguments for prejudice. First, they note that R.J. Reynolds's experts had already "analyzed whether the proposed warnings were misleading or provoked negative emotions," but claim that, if they had more time, those experts "could have used the qualitative study reports to deepen that analysis." Pls.' Br. 56. But even setting aside Plaintiffs' failure to explain why this "deepening" could not have been accomplished within 15 days, they have now had the reports for *months*, yet *still* fail to explain what more, exactly, they would have said during a longer comment period. *See, e.g.*, *Air Transp. Ass'n of Am. v. Civil Aeronautics Bd.*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984) (error harmless where plaintiff "does not explain what it would have said had it been given earlier access to the staff studies"); *Alfa Int'l Seafood v. Ross*, 264 F. Supp. 3d 23, 57 (D.D.C. 2017) ("Plaintiffs have done no more than say that they *might* have data or other information that *may* have had an effect

on the agency's disposition."). Moreover, it is entirely speculative to imagine that FDA would have changed course upon reading a "deeper" version of the analysis already provided by R.J. Reynolds's experts—which FDA has already explained is scientifically flawed in material respects, *see* 85 Fed. Reg. 15,668 (responding to Iyengar Report); *id.* at 15,655 (responding to Klick Report). Courts often reject such speculative claims of prejudice. *See, e.g.*, *Alfa*, 264 F. Supp. 3d at 57 ("[Plaintiffs] have not, for instance, put forward any data or information that would cast doubt on any particular priority species designation.").

Second, according to Plaintiffs, if they had more time, "Reynolds's survey expert could have tested additional questions in her consumer survey, such as whether the word 'causes' is less believable than 'can cause.'" Pls.' Br. 56. But the APA does not guarantee that a hired expert will have unlimited time to ask every conceivable survey question—it requires only that the agency "give interested persons an opportunity to participate in the rule making" via their comments. 5 U.S.C. § 553(c). FDA more than discharged that obligation. In any event, measures like "perceived believability" or "perceived factualness" have "nothing to do with the *actual* factual accuracy" of the warnings, and "FDA unequivocally found that each of the warning statements is factual and uncontroversial, based on extensive scientific evidence." 85 Fed. Reg. at 15,663. No additional data from R.J. Reynolds about what consumers consider to be more or less "believable" could have changed FDA's science-based conclusions about the factual accuracy of any of the warning statements. Thus, whether on the merits or for lack of prejudice, Plaintiffs' notice-and-comment claim should be rejected.

IV. THE RULE IS AUTHORIZED BY THE TOBACCO CONTROL ACT.

In the Tobacco Control Act, Congress authored an original set of nine default textual warning statements. *See* 15 U.S.C. § 1333(a)(1). Then, in a provision titled "Change in Required Statements," Congress also authorized FDA to "adjust the format, type size, color graphics, and text of any of the label requirements," so long as any such change: (1) is carried out "through a rulemaking," and (2) the agency "finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2]. FDA has now exercised that authority. Although

Plaintiffs all but concede that FDA may make substantive changes to the Act's default warning statements—despite taking the opposite position before the agency—they now argue that this authority springs to life only *after* issuance of an original rule that uses the default warning statements. But that position finds no support in the statute's text. Even if this statutory-interpretation question were a close one, at a minimum, FDA's reasonable resolution of any lingering ambiguity in the Tobacco Control Act warrants *Chevron* deference.

A. The Tobacco Control Act unambiguously authorizes the Rule's adjustments to the text and number of the default warning statements.

1. When interpreting a statute, "[t]he always primary, and here decisive, interpretive tool is the text itself." *Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286, 292 (5th Cir. 2020). In the Tobacco Control Act, Congress amended the Labeling Act to give FDA specific authority to revise cigarette warnings. This new authority includes two separate provisions, which differ in important ways:

> **Section 201(a): GRAPHIC LABEL STATEMENTS**
> . . . [T]he Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.
>
> **Section 202(b): CHANGE IN REQUIRED STATEMENTS**
> The Secretary through a rulemaking conducted under section 553 of title 5, United States Code, may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

15 U.S.C. § 1333(d). As is clear from their text and from the statutory scheme as a whole, these provisions are addressed to two different types of changes.

Section 201(a)'s second sentence—which does not require a substantive factual finding about promoting greater public-health understanding—is focused only on "the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2)." *Id.* § 1333(d)[1]. Those statutory

cross-references all relate to the *formatting* of "the label statements specified in" the statute. *See id.* § 1333(a)(2) (discussing the "Placement; typography; etc." of warning labels, including use of "capital letters," "17-point type," and other matters of "layout" and "color"); *id.* § 1333(b)(2) (discussing "Typography, etc." of warning labels, including "format," "location," "capital letters," "conspicuous and legible type," a "rectangular border," and "typeface"). In other words, read in context and as a cohesive set, the adjustments authorized by the second sentence of section 201(a) focus on the placement, typography, clarity, conspicuousness, and legibility of the label statements—that is, changes that go to the visual presentation or *formatting* of the warnings, rather than their substance. *See Yates v. United States*, 574 U.S. 528, 543 (2015) (discussing "the principle of *noscitur a sociis*—a word is known by the company it keeps"). Unsurprisingly, Congress broadly authorized those less significant changes "as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible, and appear within the specified area," 15 U.S.C. § 1333(d)[1]—with no requirement for a factual finding about promoting understanding.

Section 202(b), by contrast, gives the agency more significant authority to "adjust the format, type, size, color graphics, *and text* of *any of the label requirements*"—although that broader authority may only be exercised (1) through "a rulemaking conducted under section 553 of title 5, United States Code," and (2) after a substantive factual finding by the agency "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] (emphases added). Section 202(b) therefore authorizes adjustments to "any of the label requirements" of the statute—including their "text"—rather than only the formatting or style adjustments cross-referenced in 15 U.S.C. § 1333(a)(2) and (b)(2).

2. Plaintiffs appear to no longer meaningfully dispute this general understanding of the statutory scheme, or that FDA may make substantive revisions to the text of the warning statements. Instead, Plaintiffs now press the argument that FDA may use the broader adjustment authority in

Section 202(b) "only *after* FDA has issued a valid graphic-warnings rule and the textual warnings contemplated by the Act have taken effect." Pls.' Br. 57.[33]

The biggest problem with Plaintiffs' timing argument is that it is entirely atextual—there is simply no statutory provision that requires FDA to first issue warnings with the Act's default statements, and then wait 15 months or more for such warnings to be implemented before the Agency may embark on any effort to revise the warning statements. Instead, Congress authorized FDA to modify the Act's warning statements—including their substance—as long as FDA does so (1) through a rulemaking, and (2) after making the requisite factual finding. *See* 15 U.S.C. § 1333(d)[2]. Adopting Plaintiffs' position would rewrite the statute to impose a third requirement that Congress did not include: a 15-month-or-more waiting period for Section 202(b) modifications. That is enough to dispose of this argument; it is this Court's "duty to respect not only what Congress wrote but, as importantly, what it didn't write." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1900 (2019).

Plaintiffs argue that FDA's interpretation—*i.e.*, that Section 202(b) modifications, like Section 201(a) modifications, are permissible either before or after issuance of a final rule—"would render the narrower modification provision" in Section 201(a) "superfluous." Pls.' Br. 58. That is mistaken: because only Section 202(b) modifications require a substantive factual finding by FDA about promoting greater understanding of the risks of smoking, both provisions continue to have independent force under FDA's interpretation (before or after issuance of a final warnings rule). Section 201(a) adjustments—generally limited to comparatively minor changes of formatting, typeface, and the like—are broadly permissible, at any time, "as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and

[33] During the rulemaking process, some of the Plaintiffs took the position that FDA lacked authority to make substantive modifications to the text of warnings *at all*. *See, e.g.*, Ex. 2 to Pls.' Compl., ECF No. 1-4, R.J. Reynolds Comment at 36-37 (arguing that "the term 'adjust'" is "more naturally read to refer to typographic changes than to substantive changes"). That argument was refuted by FDA in the Final Rule, *see* 85 Fed. Reg. 15,641-42, and Plaintiffs have seemingly abandoned it here. *See* Pls.' Br. 56-58. In any case, the argument is now forfeited by Plaintiffs' failure to develop the argument in their opening brief (which included only one conclusory sentence even arguably on point, *see id.* at 57). *See, e.g.*, *Nichols v. Scott*, 69 F.3d 1255, 1287 (5th Cir. 1995).

appear within the specified area." 15 U.S.C. § 1333(d)[1]. By contrast, Section 202(b) adjustments—which may include substantive changes to warning content—require FDA to find, through a rulemaking, "that such a change would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2] (emphases added). FDA's understanding of this two-tiered statutory structure—in which it is easier to make formatting changes but harder to make substantive changes—is entirely sensible, and results in no problematic surplusage.

Plaintiffs further argue that FDA's "ability to adjust the 'color graphics' shows that Section 202(b) applies only after FDA has issued a valid graphic-warnings rule"—on Plaintiffs' view, "if FDA had not done so, there would be no color graphics to adjust." Pls.' Br. 57. But Section 202(b) does not require FDA to wait until *all* relevant label features—format, type size, color graphics, and text—have been specified in an earlier rulemaking before it may adjust *any* of those features. In other words, once there is something to be modified, there is a process for making the modification. It is therefore irrelevant that, before a final rule, there were no images to "adjust" (as there are no "default" images in the statute) because there *was* text to adjust via rulemaking: the statute's default textual warnings. Indeed, Section 202(b)'s heading is "Change in Required *Statements*," 15 U.S.C. § 1333(d)[2] (emphasis added), reinforcing that Congress expressly empowered FDA to change the text of these warnings.

Plaintiffs profess uncertainty as to why, on FDA's reading, Congress "bothered to include nine textual warnings" if FDA could change them. Pls.' Br. 58. But Congress's purpose is easy enough to discern: the default warning statements serve as a starting point, and are only subject to substantive modification if FDA makes the necessary findings through APA rulemaking. Having made the requisite findings, through the requisite procedures, FDA's modifications to the default warning statements are consistent with—indeed, explicitly authorized and contemplated by—the statute's text.

3. Plaintiffs separately argue that "FDA also violated the Act by changing the total number of warnings from nine to eleven." Pls.' Br. 58. But again, Section 202(b) authorizes FDA to change "any of the label requirements." 15 U.S.C. § 1333(d)[2]. Plaintiffs offer no explanation (let alone a citation to statutory language) for the proposition that Congress silently prohibited the addition of new or modified warnings as part of that broad delegation of authority.

Other nearby statutory provisions confirm FDA's reading. Section 202(a), which amended the Labeling Act's preemption provision, provides 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 4 of [the FCLAA, now amended by the Tobacco Control Act], shall be required on any cigarette package." 15 U.S.C. § 1334(a)) (emphasis added). Congress's neighboring reference to "*additional or different*" statements, *id.* (emphasis added), cannot be squared with Plaintiffs' view that Congress (silently) mandated that the number of warnings must be permanently fixed at nine. And in the statute's operative section, Congress mandated the use of "one of the following labels" on cigarette packaging, 15 U.S.C. § 1333(a)(1)—not, say, "one of these *nine* labels," or something to that effect.

The most that can be said for Plaintiffs' nine-is-the-magic-number argument is that, arguably, the statute is silent or ambiguous with respect to the number of warnings. But even if that were right, under *Chevron*, FDA's reasonable resolution of any such ambiguity would be entitled to deference.

B. At a minimum, FDA's reasonable interpretation of any ambiguity in the Tobacco Control Act is entitled to deference.

Under the *Chevron* framework, "[w]hen a court reviews an agency's construction of the statute which it administers, it is confronted with two questions." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). "First, applying the ordinary tools of statutory construction, the court must determine 'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 296 (2013) (quoting *Chevron*, 476 U.S. at 842-43)). "But 'if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.'" *Id* (quoting *Chevron*, 476 U.S. at 843).[34]

[34] There is no question that *Chevron* applies here, because FDA's interpretation was published in the Federal Register as part of notice-and-comment rulemaking. *See United States v. Mead Corp.*, 533 U.S. 218, 230 (2001); 85 Fed. Reg. 15,641-43 (expressly considering and rejecting these and other statutory-interpretation arguments raised in comments, including from some of these Plaintiffs).

For all the reasons discussed above, here, the Court need not proceed beyond *Chevron*'s first step: "Congress has directly spoken to the precise question at issue," *Chevron*, 476 U.S. at 842-43, by authorizing exactly these sorts of adjustments to cigarette labeling requirements, so long as FDA (1) proceeds via rulemaking, and (2) makes the requisite factual finding about promoting greater understanding. It did both, so "that is the end of the matter." *Id.* at 842.

At a minimum, however, FDA's interpretation "is a reasonable one," *Chevron*, 467 U.S. at 845—and that is enough under *Chevron* step two. FDA's interpretation is comfortably grounded in the text and structure of the Tobacco Control Act and the Labeling Act. Plaintiffs' arguments, by contrast, rely on a counterintuitive and atextual gloss on the statutory language, and vague allusions to legislative purpose. Under *Chevron*, then, Plaintiffs' statutory arguments must fail.

V. PLAINTIFFS' REQUESTS FOR RELIEF ARE OVERBROAD.

For the reasons set forth above, Plaintiffs' claims lack merit, and summary judgment in favor of Defendants is therefore appropriate on all claims. But to the extent the Court disagrees, Plaintiffs' requested relief is overbroad. First, both the Tobacco Control Act and the Rule contain robust severability clauses, which this Court should respect by severing any unlawful portions while leaving the rest in place—as both Congress and FDA plainly intended. Second, the Court need not issue any additional order regarding the Rule's effective date. Third, Article III and general principles of equity require that any relief be limited to these Plaintiffs. Fourth, the motion for a preliminary injunction should be denied, among other reasons because it is now unnecessary, as this case can be litigated to final judgment on the same timeline, and before Plaintiffs suffer any alleged First Amendment harm.

A. Any unlawful portions of the Rule should be severed.

Defendants are confident that the Rule is lawful in its entirety. In any case, at an absolute minimum, and as explained at length above, *see supra*, Section I, the lawfulness of the warning statements themselves—*i.e.*, of the warnings' *text*—for example, cannot be reasonably disputed. Accordingly, to the extent the Court concludes that only some portions of the Rule are unlawful, it

should still decline Plaintiffs' bold invitation—mentioned only in a footnote, Pls.' Br. 3 n.2—to vacate the Rule in its entirety.

Typically, "[w]hether the offending portion of a regulation is severable depends upon [1] the intent of the agency and [2] upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001); *accord Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1033 (5th Cir. 2019) (vacating only "the portions of the final rule" that the court decided were unlawful). The Rule easily satisfies those requirements. But here, Congress resolved any doubt by specifying in the Tobacco Control Act itself that the Rule's requirements are severable. *See* 21 U.S.C. § 387 (note).

1. In Section 5 of the Tobacco Control Act—titled "SEVERABILITY"—Congress included a broad severability clause that not only covered challenges to the statute, but also specifically considered the possibility that portions of FDA *regulations* issued *pursuant to* the statute might be subject to litigation. Congress expressed a clear intent in favor of maximal severability:

> **SEVERABILITY**
> If any provision of this division, of the amendments made by this division, or of the regulations promulgated under this division (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this division, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

21 U.S.C. § 387 (note). That is enough to resolve the severability question.

2. As for the intent of the agency, Plaintiffs state that "the various warnings and elements of the warnings are sufficiently 'intertwined' with each other that there is no reason to be confident that FDA would have adopted any different version of the Rule." Pls.' Br. at 3 n.2. But Plaintiffs' description of FDA's supposed intent omits one glaring, inconvenient fact: there is an entire section at the end of the Rule, titled "Severability," that is uncommonly explicit that, "in a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect." 85 Fed. Reg. 15,695; *see also id.* ("FDA intends for the various requirements established by this rulemaking to be severable."); *id.* ("FDA has concluded that the individual aspects of this rule

are workable on their own and should go forward in the event that some are invalidated."). FDA could hardly have been clearer about its intent, going so far as to list specific (non-exhaustive) examples in which a severability analysis might be relevant:

> As the proposed rule indicated, if a court were to invalidate some of the cigarette health warnings (*i.e.*, text-and-image pairings), but some of the pairings remained valid, FDA intends that the remaining required warnings would go into effect. As another example, if a court were to invalidate some but not all of the images within the cigarette health warnings, FDA intends that those images would be severed and the corresponding textual warning statements would go into effect without the invalidated images, along with the remaining cigarette health warnings that pair a textual warning statement with an image. As a third example, if a court were to invalidate all of the images within the cigarette health warnings, FDA intends for the invalidated images to be severed and all the warnings to go into effect with only their textual warning statements.

Id. Given the clarity of these statements from the Agency (not to mention Congress), there can be no reasonable dispute: "the intent of the agency" is clear that, if necessary, any unlawful portions of the Rule should be severed. Plaintiffs' conclusory statements to the contrary are baseless.

3. The final question is "whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters*, 236 F.3d at 22. Here again, FDA made explicit findings: "FDA has considered each provision independently and concluded that the individual portions of this rule are workable on their own." 85 Fed. Reg. at 15,695. That conclusion is entitled to deference and, in any event, is sensible. Although FDA believes that the Rule as a whole will best serve the government's goal of promoting greater public understanding of the negative health consequences of smoking, even portions of the Rule—for example, fewer warning statements—would be an improvement over the status quo, given Congress's and FDA's well-documented conclusions that "the current 1984 Surgeon General's warnings ha[ve] become ineffective in providing adequate warnings about the dangers of tobacco products." 85 Fed. Reg. 15,644 (citing congressional findings). Indeed, FDA determined that *each* warning "demonstrate[s] statistically significant improvements, as compared to the current Surgeon General's warnings" with respect to FDA's key "new information" and "self-reported learning" metrics (and "also led to more thinking about risks; were higher on

perceived informativeness, perceived understandability, and perceived helpfulness [in] understanding health effects; attracted more attention; and were better recalled"). 85 Fed. Reg. 15,658. And one warning statement does not depend on the others for its meaning or its effectiveness. Therefore, vacating a portion of the Rule would still "leave a sensible regulation in place," *MD/DC/DE Broadcasters*, 236 F.3d at 22—albeit one that falls short of FDA's and Congress's full intent.[35]

B. The Rule should take effect on October 16, 2021.

The Rule is currently slated to take effect on October 16, 2021. ECF No. 33. Plaintiffs separately argue that "[b]ecause the Rule is legally invalid, the Court should order that the textual warnings and related requirements cannot take effect until fifteen months after FDA issues a legally valid rule." Pls.' Br. 59. Obviously, FDA believes that the rule *is* valid—and if the Court does too, the rule (and any related requirements) will take effect on October 16, 2021, as planned. Alternatively, if the Court determines that any portion of the rule violates the First Amendment, the offending portion should be stricken, and the remainder of the Rule (along with any related requirements) should take effect on October 16, 2021. Only if the Court determines that no aspect of the warnings may stand would neither the Rule nor any related requirements take effect at all, unless and until FDA issued a new rule (which would come with its own new effective date). So, to the extent Plaintiffs are requesting any separate relief with respect to the effective date of the Rule, that request should be denied as both legally meritless and practically unnecessary.

[35] Although Plaintiffs included a separate challenge in their complaint to the relevant provision of the Tobacco Control Act, they do not say anything at all about severability with respect to their statutory claim. In any case, the governing principles with respect to statutory severability are more or less the same as with respect to regulatory severability, so the key question is one of congressional intent. *See, e.g.*, *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 685 (1987) ("[T]he unconstitutional provision must be severed unless the statute created in its absence is legislation that Congress would not have enacted."). So, for example, if the Court determined that the statutory requirement that the warnings include color graphics is facially unconstitutional, the Court could strike the statute's (and thus the Rule's) "color graphics" requirement, *see* 15 U.S.C. § 1333(d); 21 C.F.R. 1141.10(a)(2)—but leave everything else in place. Plaintiffs have offered no argument to the contrary.

C. Nationwide relief is inappropriate.

Ordering nationwide relief that would run to the benefit of those who are not parties to this case—whether through vacatur under the APA, a preliminary injunction, or a permanent injunction—would exceed this Court's authority under Article III, longstanding equitable doctrine, and the text of the Tobacco Control Act. Instead, any relief should be limited to Plaintiffs.

1. "Article III of the Constitution limits the exercise of the judicial power to 'Cases' and 'Controversies.'" *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (citation omitted). A federal court may entertain a suit only by a plaintiff who has suffered a concrete "injury in fact," and the court may grant relief only to remedy "the inadequacy that produced [the plaintiff's] injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1929 1930 (2018) (citations omitted). In short, neither standing nor remedies are "dispensed in gross." *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996).

Principles of equity reinforce those constitutional limitations imposed by Article III. A court's equitable authority to award relief is generally confined to relief "traditionally accorded by courts of equity" in 1789. *Grupo Mexicano de Desarrollo, S. A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 319 (1999). In that tradition, injunctive relief may "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" in that case. *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

Nationwide injunctions are irreconcilable with those constitutional and equitable limitations. By definition, a nationwide injunction extends relief to parties that were not "plaintiff[s] in th[e] lawsuit, and hence were not the proper object of th[e court's] remediation." *Lewis*, 518 U.S. at 358.[36]

2. Nationwide relief would be particularly inappropriate where, as here, litigation in other districts is not merely hypothetical but presently ongoing, and the regulatory scheme at issue is important and complex. FDA is currently defending a nearly identical lawsuit in the U.S. District

[36] To be sure, the Fifth Circuit has previously held that "[i]t is not beyond the power of a court, in appropriate circumstances, to issue a nationwide injunction." *Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015). But in *Texas*, the Fifth Circuit expressly relied on the Constitution's separate requirement of a "uniform Rule of Naturalization," U.S. Const. art. I, § 8, cl. 4 (emphasis added), and Congress's separate directive that "the immigration laws of the United States should be enforced vigorously and uniformly," Pub. L. No. 99-603, § 115(1), 100 Stat. 3359, 3384 (emphasis added). *See* 809 F.3d at 188. This case does not present the same concerns.

Court for the District of Columbia. *See Philip Morris USA Inc. v. FDA*, No. 1:20-cv-01181-KBJ (D.D.C., filed May 6, 2020). Courts have recognized the importance of allowing such legal questions to percolate through the federal judiciary. *See, e.g.*, *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011) (nationwide relief may be "inappropriate where a regulatory challenge involves important or difficult questions of law, which might benefit from development in different factual contexts and in multiple decisions by the various courts of appeals") (citing *Yamasaki*, 442 U.S. at 702); *Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393-94 (4th Cir. 2001) (holding that district court order enjoining agency's unconstitutional regulation on nationwide basis was abuse of discretion where it was broader than necessary to afford relief to the plaintiff and would thwart development of the law in other circuits). Preventing that percolation "take[s] a toll on the federal court system." *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring).

For example, should FDA prevail in the *Philip Morris* case, ordering nationwide relief here would effectively deprive the United States of the benefit of that victory—even in the District of Columbia, and even with respect to a litigation adversary that (by hypothesis) FDA defeated in court on more or less the same claims. The potential for that bizarre and inequitable result illustrates one of the many practical problems with nationwide injunctions, particularly in the context of litigation against the federal government. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 601 (2020) (Gorsuch, J., concurring) ("If a single successful challenge is enough to stay the challenged rule across the country, the government's hope of implementing any new policy could face the long odds of a straight sweep, parlaying a 94-to-0 win in the district courts into a 12-to-0 victory in the courts of appeal."); *see also United States v. Mendoza*, 464 U.S. 154 (1984) (holding, for similar reasons, that the doctrine of nonmutual offensive collateral estoppel does not apply to the federal government).

3. Plaintiffs' inclusion of APA claims does not justify a departure from these principles. Nothing in the APA's directive to "set aside" unlawful "agency action" mandates that "agency action" shall be set aside globally, rather than as applied to the plaintiffs. 5 U.S.C. § 706(2). And Congress enacted the APA against a background rule that statutory remedies should be construed in accordance with "traditions of equity practice." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). While Congress

"may intervene and guide or control the exercise of the courts' discretion," courts should "not lightly assume that Congress has intended to depart from established [equity] principles." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982).

In fact, here, Congress *did* "intervene" to "control the exercise of the courts' discretion," *id.*—in the Tobacco Control Act itself. In the statute's severability clause, Congress specified that, even if "the application of any [] provision [of the TCA] to *any person* or circumstance is held to be invalid, the remainder of [the TCA] . . . and the application of such provisions to *any other person* or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note) (emphases added). Accordingly, this Court need not even wade into the broader debate about the overall propriety of nationwide injunctions, nor feel constrained by the APA's "set aside" language, 5 U.S.C. § 706(2). Instead, the Court should be guided by the more specific, and more recent, statutory language in the TCA, which precludes nationwide relief that would run to non-parties. *See, e.g.*, *Brown & Williamson*, 529 U.S. at 133 ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.").

D. Plaintiffs' motion for a preliminary injunction should be denied.

By this point, the reader can be excused for having forgotten that there is also a pending request for a preliminary injunction, which is being briefed simultaneously with the parties' cross-motions for summary judgment. That is because it no longer makes any practical sense to decide this case in a preliminary-injunction posture: it can be litigated to final judgment on the same timeline, and before Plaintiffs will suffer any irreparable First Amendment harm. Plaintiffs' request for a preliminary injunction should therefore be denied—both because Plaintiffs have failed to carry their burden to demonstrate entitlement to this "extraordinary remedy never awarded as of right," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), and because it is now unnecessary.

1. A preliminary injunction is unnecessary, because this case can be litigated to final judgment before Plaintiffs suffer any irreparable harm.

It will be no easier for this Court to decide the preliminary-injunction motion than the parties' summary-judgment motions—all will ultimately turn on the same legal arguments. A preliminary

injunction, then, is not just unnecessary, it is inappropriate: assuming Plaintiffs persuade this Court on the merits—as they must for any of these remedial questions to matter[37]—there is *not* "a substantial threat of irreparable injury if the injunction is not issued," *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (citation omitted). Instead, the Court will simply enter judgment for Plaintiffs.

Relatedly, a preliminary injunction is only ever necessary if a plaintiff is going to suffer significant irreparable harm *during the litigation*. *See, e.g.*, *Parks v. Dunlop*, 517 F.2d 785, 787 (5th Cir. 1975). Here, Plaintiffs will not, which independently dooms their request. Plaintiffs primarily rely on a First Amendment injury, fearing that they "*will* be required to engage in compelled speech." Pls.' Br. 60 (emphasis added). But even assuming that Plaintiffs *will* suffer a valid First Amendment injury, no plaintiff will suffer any such injury until the Rule takes effect in October of 2021—more than a year away, and likely well after this Court's judgment will issue.

The manufacturer Plaintiffs also argue that they will face significant compliance costs, and that at least some of those costs will be unrecoverable and will come due before the Rule takes effect. Defendants do not dispute that manufacturers will bear expenses as they prepare to comply with the Rule, *see* Pls.' Br. 61-62 (citing declarations), and FDA acknowledged as much during the rulemaking, *see* 85 Fed. Reg. at 15,639. But the manufacturer Plaintiffs' critical factual claim—that significant and unrecoverable costs are coming due *immediately*—is supported primarily by the statements of litigation counsel in Plaintiffs' brief. *None* of Plaintiffs' declarations justifies the assertion that the Rule "requires the Plaintiffs to commence extraordinary compliance measures almost immediately, as the costly changes it requires are ongoing and escalating." Pls.' Br. 63. Although Plaintiffs' declarations focus primarily on the *amount* of costs that will be incurred, to the extent some of the declarations include time estimates at all, those estimates often *undermine* the assertion that Plaintiffs cannot wait for the

[37] The motion for a preliminary injunction can also be denied solely on the basis that Plaintiffs are unlikely to succeed on the merits. *See, e.g.*, *Def. Distributed v. Dep't of State*, 838 F.3d 451, 457 (5th Cir. 2016).

Court to resolve the parties' summary-judgment motions (even accepting the validity of those estimates at face value)—especially given that the effective date of the rule is more than a year off.[38]

2. The public interest disfavors injunctive relief.

This lawsuit is only the most recent in a long history of tobacco industry efforts to resist (or at least delay) disclosure of information about their deadly products. This Court should not indulge that project further. Instead, the Court can and should recognize "that the public interest involved in this dispute" sweeps well "beyond the immediate interests of the named litigants" and includes "the consumers upon whose behalf" Congress and FDA have acted, *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 626 (5th Cir. 1985), by requiring effective and accurate disclosures of important factual information about the dangers of smoking—particularly those dangers that are lesser known. Generations of Americans, past and present, have been ravaged by nicotine addiction and smoking-related disease, often with an inadequate appreciation of those risks until it was far too late—due in part to deliberate deception by some of these Plaintiffs and their competitors. And regardless of cause, consumers continue to suffer from a pervasive lack of knowledge about many of the negative health consequences of smoking. Neither the First Amendment nor the APA prohibits Congress and FDA from working together to try to narrow the remaining information gap, thereby helping current and future smokers (or potential smokers) better understand these matters of life and death.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' cross-motion for summary judgment, deny Plaintiffs' motion for summary judgment, and deny—as moot or on the merits—Plaintiff's motion for a preliminary injunction.

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[38] *See, e.g.*, Huckabee Decl., ECF No. 34-5, ¶ 11 ("[T]he work to engrave the cylinders will take several months and must begin within ten months after the Rule is published."); Reed Decl., ECF No. 34-6, ¶ 10 (same); Wall Decl., ECF No. 34-7, ¶ 19 (estimating that "the engraving process would take approximately five or six months"); Huckabee Decl. ¶ 12 (estimating that graphic design tasks "will take several months to complete"); *id.* ¶ 16 ("RJRT and SFNTC will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date."); Reed Decl. ¶ 10 ("[T]he work to engrave the cylinders will take at least five months and must begin within ten months after the Rule is published.").

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