IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
BRUNSWICK DIVISION

PHILIP MORRIS USA INC.; DHALIWAL & ASSOCIATES, INC.; STEWART CANDY COMPANY, d/b/a STEWART DISTRIBUTION; and GEORGIA ASSOCIATION OF CONVENIENCE STORES, INC.,	)	
Plaintiffs,	)	
v.	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT M. CALIFF, in his official capacity as Commissioner of the United States Food and Drug Administration; and XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,	)	**Civil Action No.: 2:24-cv-00143**
Defendants.	)	

COMPLAINT

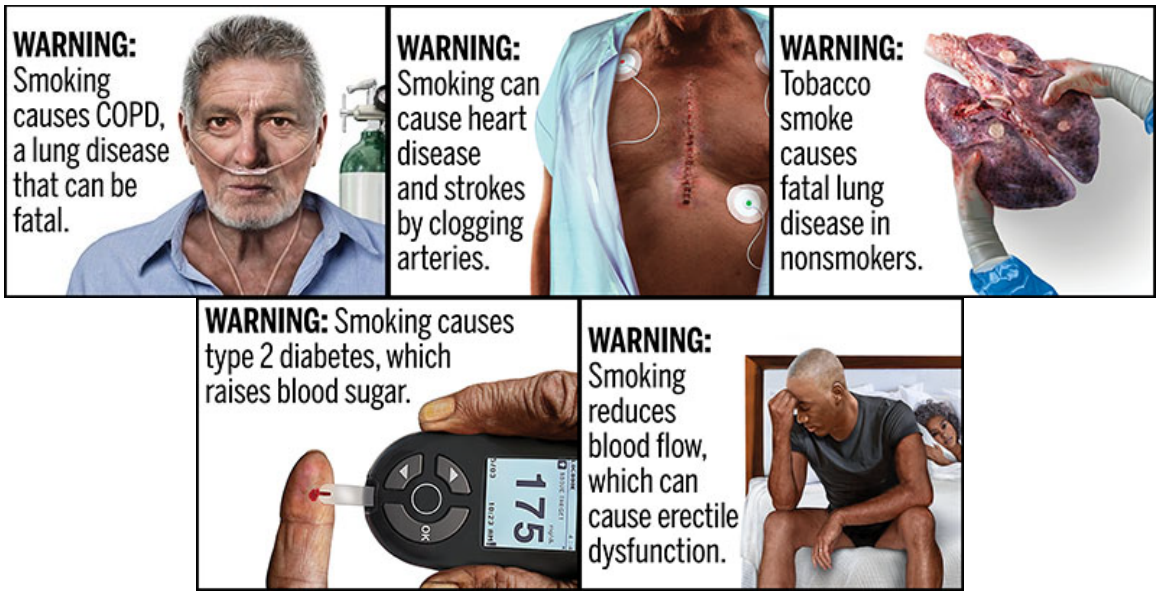
INTRODUCTION

1. This is a clear case of administrative rulemaking gone awry, violating essential administrative-law protections and the First Amendment. The Food and Drug Administration ("FDA") has issued an unprecedented rule compelling cigarette manufacturers to feature massive graphic warnings on their packaging and advertisements, and prohibiting distributors and retailers from selling or advertising cigarettes absent the graphic warnings. *See* Final Rule, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638

(Mar. 18, 2020) (codified at 21 C.F.R. pt. 1141) (the "Rule"). Cigarette packaging and advertisements have long featured text-only Surgeon General's warnings about the health consequences of smoking, but FDA's Rule would represent a sea change that would revolutionize cigarette packaging and advertisements.

2. FDA promulgated the Rule pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), a statute that requires FDA to replace the text-only Surgeon General's warnings with a set of 9 graphic warnings on statutorily specified risks. The TCA grants FDA limited authority to "adjust the format, type size, color graphics, and text" of those prescribed warnings if doing so would improve "public understanding." 15 U.S.C. §§ 1333(d)[2].

3. FDA's Rule ultimately requires cigarette manufacturers to display 11 warnings across 50% of every cigarette package and across 20% of every advertisement:



4. The Rule also requires every convenience store in the nation, including Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff Georgia Association of Convenience Stores' ("GACS") members, to display these warnings on in-store advertisements for cigarette products and on the packages of cigarettes they sell, rendering their stores unwelcoming, especially to children. And the Rule prohibits distributors, like Plaintiff Stewart Distribution, from distributing or advertising cigarettes to retailers absent the graphic warnings, on pain of civil penalties or even criminal prosecution.

5. FDA's Rule is profoundly unlawful. To start, FDA's rulemaking is replete with Administrative Procedure Act ("APA") violations. *See* 5 U.S.C. §§ 551-559, 701-706. FDA's Rule contravenes the TCA. Congress in the TCA prescribed nine and only nine warnings. FDA nonetheless adopted 11. Congress in the TCA gave FDA the authority only to "adjust the … text of" Congress' warning statements and even then only if the agency "finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2]. But FDA did far more than "adjust" Congress' warnings: FDA engaged in wholesale rewrites, additions, and deletions. And because FDA misdefined "public

understanding," FDA overhauled Congress' warnings without making the congressionally-required finding that the agency's new warnings would promote public understanding better than Congress'.

6. FDA also engaged in arbitrary decision-making. FDA never coherently explained why the agency chose to focus on particular smoking-related risks over others. Some of FDA's featured consequences (like smoking-related lung conditions and the risks of smoking during pregnancy) are extremely well-known; others (like bloody urine from bladder cancer) are more obscure. There appears to be no rhyme or reason to the set of health consequences FDA's pre-selected at the outset of its rulemaking. Nor did FDA ever consider featuring different consequences, no matter how badly its proposed warnings performed in ensuing studies.

7. FDA also arbitrarily assessed public understanding—the agency's sole stated interest in promulgating the rule. Rather than directly measure consumer understanding, FDA considered only certain precursors to understanding that it knew its warnings performed well on and, to the chagrin of its peer reviewers, refused to consider others. FDA ignored countless red flags in its own studies suggesting that its warnings did not in fact improve consumer understanding and may actually backfire. As the highly critical peer review of FDA's studies underscores, FDA repeatedly ignored study feedback that the graphic warnings were confusing, unclear, did not teach new information, or were not believable.

8. To top it all off, FDA shielded its shoddy decision-making from public scrutiny. FDA thwarted meaningful notice and comment by refusing to disclose crucial studies and data during the rulemaking. FDA failed to timely disclose the internal studies it relied on to craft its graphic warnings or to disclose raw data, and withheld a November 2019 peer-review report containing substantial critiques of FDA's quantitative studies until FDA issued the Final Rule.

9. FDA's Rule also violates the First Amendment, which safeguards private actors' right to speak messages of their own choosing and strictly limits the government's ability to compel speech. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA)*, 585 U.S. 755, 766 (2018). The Rule commandeers 50% of manufacturers' packaging and 20% of cigarette advertising, drowning out manufacturers', distributors', and retailers' ability to speak their own message. The Rule moreover forces Plaintiffs and Plaintiff GACS' members to speak against their own products via provocative images that may mislead consumers. Today's graphic cigarette warnings could be tomorrow's graphic junk food or climate change warnings.

10. Given these flaws, it is little surprise that the Rule has never taken effect. Soon after the Rule was promulgated in March 2020, a group of cigarette manufacturers and retailers led by R.J. Reynolds challenged the Rule in the Eastern District of Texas, raising both First Amendment and APA challenges. That district court postponed the Rule's effective date nationwide for two years as that challenge played out, and ultimately vacated the rule on First Amendment grounds without addressing the APA issues.

11. In March 2024, the Fifth Circuit reversed, but remanded for the district court to consider the APA claims. In June, the government agreed to a special enforcement policy as to the *R.J. Reynolds* plaintiffs, promising not to enforce the Rule against them until fifteen months after their Supreme Court challenge ended (now February 25, 2026).

12. In September 2024, however, FDA adopted a disparate enforcement policy for all others, including Plaintiffs and Plaintiff GACS' members here, subjecting them to enforcement of the Rule beginning on December 12, 2025—months before the *R.J. Reynolds* plaintiffs. Under this unequal enforcement regime, half the cigarette packages and advertisements on the market will display FDA's graphic warnings while the rest continue to utilize the text-only Surgeon

General's warnings. So, despite the Rule treating all cigarettes as equally likely to cause the identified health risks, consumers will face disparate messaging that risks misinforming them that R.J. Reynolds' cigarettes are less risky than others'.

13. This case is the poster child for delayed enforcement pending resolution of the merits. Plaintiffs are likely to succeed on the merits, given the Rule's multitude of flaws. And without swift relief Plaintiffs and Plaintiff GACS' members face imminent, significant, and unrecoverable costs as they work to submit compliance plans by February 2025 and ultimately comply with the rule by December 12, 2025. By next month, Plaintiff Philip Morris USA Inc. ("PM USA") will have incurred almost $7 million dollars in design and tooling costs. PM USA also faces a point of no return on January 1, 2025—after that point it will face more than $2 million in unrecoverable tooling costs. What is more, PM USA anticipates engraving costs exceeding $200,000 per month from now through August 2025. Distributors like Plaintiff Stewart Distribution must incur additional overhead estimating orders to ensure they do not distribute packages or retain inventory of packages that would violate the Rule after the enforcement guideline. So too for retailers like Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff GACS' members—who must incur extra overhead to ensure they do not sell any noncompliant packaging or retain inventory which would violate the Rule. FDA cannot claim harm from further delay of this already-years-delayed Rule, especially given that FDA has repeatedly agreed to other delays over the years.

14. Plaintiffs thus respectfully request that this Court: (1) delay enforcement of the Rule under 5 U.S.C. § 705 or preliminarily enjoin the Rule until 15 months after the resolution of this litigation (2) declare that the Rule violates the APA, (3) declare that the Rule and the TCA

violate the First Amendment, (4) enjoin the TCA's size and placement requirements, and (5) vacate the Rule in its entirety.

15. Plaintiffs also ask this Court to declare unlawful, enjoin, and vacate FDA's September 12, 2024 enforcement guidance dictating that the Rule's new textual and graphic warnings for cigarette packaging and advertising will be enforced on a disparate timeline for some manufacturers and not for others. At a minimum, the Court should preliminarily delay or preliminarily enjoin enforcement of the Rule for long enough to put Plaintiffs and Plaintiff GACS' members on the same timeline as the *R.J. Reynolds* plaintiffs as the Court resolves this litigation.

PARTIES

16. Plaintiff Philip Morris USA Inc. is a Virginia corporation with corporate offices located in Richmond, Virginia. Since 1983, PM USA has been the leading manufacturer of cigarettes in the United States. PM USA sells cigarettes under a number of leading brands, including Marlboro, Parliament, Virginia Slims, and L&M.

17. Plaintiff Dhaliwal & Associates, Inc., is incorporated in Georgia and its headquarters is located at 493 East Parker Street, Baxley, GA 31513. Dhaliwal & Associates owns and operates three convenience stores in South Georgia: (1) Petro Station #7, 493 East Parker Street, Baxley, GA 31513; (2) Joe's Qwik Stop, 495 Bay Street, Baxley, GA 31513; and (3) Jackets Corner, 67 South Tallahassee Street, Hazlehurst, GA 31539. Dhaliwal & Associates' convenience stores carry a full line of convenience store products, including cold drinks, beer and wine, health and beauty items, dog food, fishing supplies, and novelties like hats and t-shirts. Dhaliwal & Associates' convenience stores also sell fuel, deli sandwiches, and hot food. Dhaliwal & Associates' stores also sell cigarettes, including cigarettes manufactured by Plaintiff PM USA, in addition to many other cigarette manufacturers. Dhaliwal & Associates' stores order most of the products they sell, including cigarettes, from wholesaler Plaintiff Stewart Distribution.

18. Plaintiff Stewart Candy Co., d/b/a Stewart Distribution, is a Georgia corporation with corporate offices located in Blackshear, Georgia. Stewart Distribution distributes a full-line of convenience store products, include cigarettes, to approximately 1,200 convenience stores in Georgia, Florida, Alabama, and South Carolina.

19. Plaintiff Georgia Association of Convenience Stores is a member-based organization that advocates for convenience stores located throughout Georgia. GACS also works with regulatory agencies to ensure the interests of convenience stores are adequately represented and keeps members abreast of significant regulatory changes, like FDA's graphic warnings rule. GACS is headquartered in Dallas, Georgia.

20. Defendant United States Food and Drug Administration is a federal agency of the United States, within the United States Department of Health and Human Services ("HHS"). FDA regulates tobacco products marketed in the United States under the TCA and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, pursuant to authority delegated to it by HHS. *See id.* § 387a(e). FDA's headquarters are located in Silver Spring, Maryland.

21. Defendant HHS is a federal agency of the United States. Under the TCA and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, HHS is responsible for regulating tobacco products, including cigarettes, marketed in the United States. *See, e.g.*, *id.* § 387a; 15 U.S.C. § 1333(b)(4). HHS's headquarters are located in Washington, D.C.

22. Defendant Dr. Robert M. Califf is the Commissioner of FDA. Commissioner Califf oversees the implementation and day-to-day enforcement of the Rule. Plaintiffs sue Commissioner Califf in his official capacity.

23. Defendant Xavier Becerra is the Secretary of HHS, the parent agency of FDA. Secretary Becerra oversees FDA's activities and is responsible for the implementation and enforcement of the Rule. Plaintiffs sue Secretary Becerra in his official capacity.

JURISDICTION AND VENUE

24. This Court has subject-matter jurisdiction over this action under 28 U.S.C. §§ 1331, 2201, and 5 U.S.C. §§ 701-706.

25. Venue is proper in this district under 28 U.S.C. § 1391(e) because at least one Plaintiff's principal place of business is in this district and division.

26. An actual controversy currently exists between the parties concerning the constitutionality and legality of the Rule and the TCA, and the legality of FDA's disparate enforcement policy. That controversy is justiciable: Plaintiffs and Plaintiff GACS' members already are suffering injury, and speedy relief is necessary to preserve Plaintiffs' rights and those of the Plaintiff GACS' members.

27. A declaratory judgment will end the uncertainty and controversy between the parties.

28. A preliminary delay of the Rule's effective date will preserve the status quo and protect Plaintiffs' rights and those of the Plaintiff GACS' members pending judicial resolution of Plaintiffs' claims.

29. A preliminary injunction preserving the status quo and prohibiting Defendants from taking action to enforce the Rule will protect Plaintiffs' rights and those of the Plaintiff GACS' members pending judicial resolution of Plaintiffs' claims.

30. A permanent injunction preserving the status quo and prohibiting Defendants from taking action to enforce the Rule will protect Plaintiffs' rights and those of the Plaintiff GACS' members.

31. A permanent injunction preserving the status quo and enjoining FDA from enforcing the TCA's size-and-placement restrictions will protect Plaintiffs' rights and those of the Plaintiff GACS' members.

32. Vacatur of FDA's Final Rule will preserve the status quo and protect Plaintiffs' rights and those of the Plaintiff GACS' members.

FACTUAL ALLEGATIONS

A. Federal Warnings Requirements for Cigarettes

33. Federal law recognizes the lawfulness of selling cigarettes, but since 1965 Congress has required manufacturers to relay factual, text-only warnings developed by the Surgeon General concerning smoking-related health risks. *See* Pub. L. No. 89-92, 79 Stat. 282 (1965). After multiple iterations, in 1984, Congress again updated the required Surgeon General's warnings. *See* Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201-02 (codified at 15 U.S.C. § 1333). Congress mandated the following four rotating label statements, which manufacturers have featured for decades on all cigarette packaging and advertising:

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

34. These warnings have led to high levels of consumer knowledge regarding the warned-against health risks, which cover several of the most common health consequences of smoking. As FDA has acknowledged, the health effects highlighted in the Surgeon General's warnings are not areas "where there are significant gaps in public understanding about the negative health consequences of cigarette smoking." 85 Fed. Reg. at 15,653; *cf.* Statement of Dr. Jonathan Klick fig.1, Ex. C to RAI Servs. Co. Cmt., Docket No. FDA-2019-N-3065 (Oct. 11, 2019), https://tinyurl.com/u85jd4f (vast majority of respondents to FDA study believe cigarettes are either "extremely" or "very" harmful to health). Further, FDA acknowledges, smoking rates are at all-time lows, having "generally declined over the past several decades." 85 Fed. Reg. at 15,652.

35. In 2009, Congress enacted the TCA, which overhauled the health warning requirements for cigarette packaging and advertising. *See* Pub. L. No. 111-31, § 201(a), 123 Stat. 1776 (2009) (codified in part at 15 U.S.C. § 1333). As relevant here, the TCA replaces the factual, text-only Surgeon General's warnings with a list of 9 new textual warning statements to be accompanied by graphics. These requirements apply to manufacturers, distributors, and retailers. 15 U.S.C. § 1333(a)(1).

36. Those 9 TCA mandated textual warning statements cover a range of smoking-attributable health consequences:

- "**WARNING:** Cigarettes are addictive."
- "**WARNING:** Tobacco smoke can harm your children."
- "**WARNING:** Cigarettes cause fatal lung disease."
- "**WARNING:** Cigarettes cause cancer."
- "**WARNING:** Cigarettes cause strokes and heart disease."
- "**WARNING:** Smoking during pregnancy can harm your baby."

- "**WARNING:** Smoking can kill you."
- "**WARNING:** Tobacco smoke causes fatal lung disease in nonsmokers."
- "**WARNING:** Quitting smoking now greatly reduces serious risks to your health."

15 U.S.C. § 1333(a)(1).

37. The TCA further directs the Secretary of HHS to issue regulations mandating "color graphics depicting the negative health consequences of smoking" to accompany these 9 textual warning statements. *Id.* § 1333(d)[1].[1] The Secretary has delegated rulemaking authority to FDA.

38. The TCA vests FDA with authority to alter certain aspects of the graphic-warnings requirements. Section 202(b) permits FDA, through a rulemaking, to "adjust the format, type size, color graphics, and text of any of the label requirements … if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2].

39. The resulting, FDA-mandated graphic warnings must cover "the top 50 percent of the front and rear panels of" all cigarette packaging and the top 20% of all cigarette advertising. *Id.* § 1333(a)(2), (b)(2). Congress did not make any findings in the statute regarding the need for those size and placement requirements or the First Amendment implications of that mandate.

40. The TCA also requires manufacturers, retailers, and distributors to "randomly display[]" the graphic warnings on cigarette packaging "in as equal a number of times as is possible on each brand of the product" in a 12-month period. *Id.* § 1333(c)(1). The graphic warnings must be "rotated quarterly in alternating sequence" in cigarette advertisements. *Id.* § 1333(c)(2).

[1] There are two subsections designated (d) in the United States Code. The first codifies part of TCA section 201(a), while the second codifies TCA section 202(b). For the Court's convenience, we cite those provisions as § 1333(d)[1] and § 1333(d)[2], respectively.

Manufacturers, distributors, and retailers must submit compliance plans for these requirements to FDA for pre-approval. *Id.* § 1333(c)(1)-(2).

41. The TCA included a June 22, 2011 deadline for FDA to issue regulations implementing these requirements, and provided that the graphic-warnings requirements would take effect "15 months after the issuance of" FDA's graphic-warnings rule. 123 Stat. at 1845 (15 U.S.C. § 1333 note).

B. Further Restrictions on Tobacco Advertising and Sales

42. Since 1971, federal law has severely limited the channels by which cigarettes may be advertised, for instance by banning advertising cigarettes on television or the radio. *See* 15 U.S.C. § 1335. Federal law also bans manufacturers, distributors, and retailers from distributing or selling promotional items bearing cigarette brand names or other product identification. *See* 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34.

43. In addition, since November 1998, many cigarette manufacturers, including PM USA, have been parties to a Master Settlement Agreement with 46 State Attorneys General, the District of Columbia, and five U.S. territories, which further restricts manufacturers' advertising, and which applies to the other four states under separate agreements. For instance, manufacturers cannot engage in outdoor or transit advertising of their products; pay for their products to be featured in television and movies; or advertise their products in sports stadiums and arenas. *See* Master Service Agreement § III (Nat'l Ass'n of Att'ys Gen. Jan. 2019 prtg.) (Nov. 1998), https://www.naag.org/wp-content/uploads/2020/09/2019-01-MSA-and-Exhibits-Final.pdf.

44. The 2009 TCA imposed many additional advertising restrictions. For example, it prevents cigarette manufacturers, distributors, and retailers from giving out "free samples of cigarettes." 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d). The TCA also prohibits manufacturers and distributors from marketing cigarettes with any other product regulated by

FDA. 21 U.S.C. § 321(rr)(4). The TCA further allows even more stringent restrictions on the "advertising and promotion" of tobacco products, *id.* § 387p, including outright bans "on the time, place, and manner" of cigarette advertising and promotion, TCA § 203, 123 Stat. 1846 (adding 15 U.S.C. § 1334(c)).

C. FDA's Vacated 2011 Graphic-Warnings Rule

45. FDA issued its first rule implementing the TCA's graphic-warnings requirements on June 22, 2011. *See Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141). FDA justified the 2011 Rule by asserting a "substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products." *Id.* at 36,629.

46. FDA's 2011 Rule crafted graphic warnings by taking the exact 9 textual warnings set forth in the TCA and creating graphic images to illustrate those warnings. *Supra* ¶ 36. FDA formulated "attention-grabbing" warnings that would make viewers feel "'depressed,' 'discouraged,' and 'afraid'" to buy cigarettes. 76 Fed. Reg. at 36,638, 36,654. The 2011 warnings portrayed:

- A man with a hole in his throat smoking through a tracheotomy tube;
- A baby with a plume of smoke approaching its face;
- Two sets of lungs: one healthy, one diseased;
- A mouth with discolored teeth and a cancerous lesion on the lower lip;
- A man with an untied necktie breathing through an oxygen mask;
- An animation depicting a distressed baby in an incubator;
- A body on an autopsy table with an incision running from the collarbones down to the abdomen that had been stapled shut;
- A weeping woman; and

- A man wearing a T-shirt depicting a "no smoking" symbol and the declaration "I QUIT."

See Compl. 23-26, *R.J. Reynolds Tobacco Co. v. FDA*, No. 11-cv-01482 (D.D.C. Aug. 16, 2011), ECF No. 1 (reproducing warnings). FDA candidly acknowledged that these images would transform all cigarette packs and advertisements into "mini billboard[s]" carrying the government's anti-smoking message. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C. Cir. 2012) (citation omitted), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

47. R.J. Reynolds Tobacco Company and other manufacturers challenged the 2011 Rule on First Amendment and APA grounds. The D.C. Circuit ruled that the 2011 Rule violated the First Amendment. *R.J. Reynolds*, 696 F.3d at 1208, 1222.

48. The D.C. Circuit first held that the compelled-speech framework in the Supreme Court's *Zauderer* decision—which applies to only "purely factual and uncontroversial disclosures"—did not govern the First Amendment inquiry. *Zauderer v. Off. of Disciplinary Coun.*, 471 U.S. 626, 651 (1985); *accord NetChoice, LLC v. Att'y Gen., Fla.*, 34 F.4th 1196, 1227 (11th Cir. 2022), *vacated and remanded on other grounds sub nom. Moody v. NetChoice, LLC*, 603 U.S. 707 (2024). The D.C. Circuit held that FDA's warnings were not aimed at imparting factual information, were "primarily intended to evoke an emotional response, or, at most, shock the viewer," and could be "misinterpreted by consumers" by "suggesting" that certain unlikely outcomes were in fact "common consequence[s] of smoking." *R.J. Reynolds*, 696 F.3d at 1216. Because the warnings did not qualify for *Zauderer* review, the D.C. Circuit applied intermediate scrutiny, which the warnings failed. The D.C. Circuit vacated the 2011 Rule and remanded the matter to FDA for further consideration. The government decided not to seek Supreme Court review.

D. FDA Rushes to Issue the New Proposed Rule

49. In 2016, various anti-tobacco nonprofits sued FDA, claiming that FDA had "unlawfully withheld or unreasonably delayed" issuing a new graphic warnings rule. *See* Compl. ¶ 82, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. Oct. 4, 2016), ECF No. 1. FDA defended its delay by stating that this rulemaking would be "a time-consuming process that requires extensive resources," and involved particular "complexities" and challenges, including that graphic warnings were unprecedented in the United States. Decl. of Mitchell Zeller ¶ 10, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. May 26, 2017), ECF No. 33-2 ("Zeller Decl."). As of May 2017, FDA estimated that, to perform the necessary rulemaking steps properly, FDA would need until July 2021 to finalize a rule. *See id.* ¶ 37. In January 2018, FDA revised its estimate to November 2021. 1st Suppl. to Def.'s Statement of Undisputed Material Facts 2, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. Jan. 22, 2018), ECF No. 42.

50. In March 2019, the U.S. District Court for the District of Massachusetts issued an injunction dictating an accelerated timetable for FDA's rulemaking. *See Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985, 2019 WL 1047149 (D. Mass. Mar. 5, 2019). The court ordered FDA to expedite its proposal for a new graphic-warnings rule and issue it no later than mid-August 2019. *Id.* at *3. Though FDA requested 13 months to review and respond to comments, the court gave FDA only 7 months, ordering FDA to issue a final rule by March 15, 2020, *id.*—i.e., 20 months sooner than FDA had represented was feasible.

E. FDA's Proposed Rule

51. Pursuant to the court-ordered schedule, FDA published its new proposed graphic-warnings rule on August 16, 2019. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019) (the "Proposed Rule").

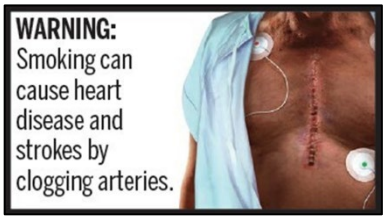
52. As with FDA's 2011 Rule, FDA proposed to force cigarette manufacturers to display massive graphic warnings featuring provocative, disturbing, and grotesque images, purportedly to illustrate negative health consequences of smoking. Likewise, FDA again planned to compel cigarette manufacturers to prominently display these warnings on the top 50% of their packaging and the top 20% of all advertisements. FDA also would require manufacturers, distributors, and retailers to ensure "random display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements." *Id.* at 42,755. Manufacturers, distributors, and retailers would have to submit plans for implementing those requirements to FDA for pre-approval before they could sell or advertise their products once the Final Rule took effect. *Id.*; *see also id.* at 42,787.

53. Unlike FDA's 2011 Rule, the Proposed Rule did not purport to affect consumer behavior or decrease smoking rates. Rather, FDA asserted an interest in "promot[ing] greater public understanding of the negative health consequences of cigarette smoking," especially "less-known or less understood" consequences. *Id.* at 42,755, 42,767.

54. This time, FDA's proposed graphic warnings did not track the 9 TCA warning statements. Rather, FDA proposed to mandate the following 13 graphic health warnings:

55. In all, only 2 of FDA's proposed graphic warnings (the harm to children and nonsmoker lung disease warnings) incorporated the TCA's textual statements. The remaining 11 warnings contained FDA-drafted statements. Six of those 11 FDA-drafted statements—the fetal growth, COPD, heart disease and strokes, bladder cancer, and head and neck cancer warnings—covered categories of health conditions that the TCA mentions in some fashion. The remaining 5 FDA-drafted statements—the erectile dysfunction, amputation, diabetes, cataracts, and age-related macular degeneration warnings—pertained to new health conditions on which the TCA is silent.

56. Many of FDA's proposed (and ultimately adopted) graphic warnings bear close resemblance to the warnings the D.C. Circuit previously held violated the First Amendment:

Barred by D.C. Circuit	FDA's New Warnings
	
	
	

57. The Proposed Rule justified FDA's new graphic warnings based on a series of studies performed at FDA's direction. FDA first conducted a series of qualitative studies—studies that are "used to understand how a research topic is experienced from the perspective of the study participants" through interviews, observation, or focus groups. 85 Fed. Reg. at 15,651. FDA's qualitative evaluations used focus-group interviews to gauge participants' reactions to proposed textual statements, warning images, and text-image pairings. *See* 84 Fed. Reg. at 42,767, 42,769-71. FDA claimed that "feedback" from the qualitative studies "informed FDA's selection and refinement" of the warning statements and images in order to "ensure that all proposed warnings are unambiguous, are unlikely to be misinterpreted or misunderstood by consumers, and do convey warning information." *Id.* at 42,778. But FDA did not release study reports or other underlying data regarding the qualitative studies' results with the Proposed Rule.

58. FDA's Proposed Rule also relied upon quantitative studies from April 2018 and May 2019. Those quantitative studies focus on gathering numerical or statistical data, as opposed to textual or narrative data, from study participants. FDA's April 2018 quantitative study had participants compare the TCA's 9 textual warning statements with longer, more specific, FDA-drafted warning statements. FDA's May 2019 quantitative study—the only study to examine the specific warnings FDA seeks to impose—asked participants to compare the 4 current, text-only Surgeon General's warnings with 15 color, graphic health warnings covering 50% of a mock package and 20% of a mock advertisement. FDA released preliminary study reports summarizing methodologies and results, but did not release the underlying data. FDA promised to subject the quantitative studies to peer review, but the Proposed Rule issued before peer review was complete.

F. Initial Comments to FDA

59. During FDA's 60-day comment period, Altria, owner of PM USA, submitted to FDA extensive comments on behalf of PM USA laying out legal deficiencies in the Proposed Rule that would render it invalid under the First Amendment and APA. *See* Altria Client Servs., Cmt. (Oct. 15, 2019) ("Altria Cmt."), attached hereto as Exhibit 1 (and attachments to Altria's letter are also attached hereto as Exhibits 1-1 and 1-2). Other commenters, ranging from cigarette manufacturers to tobacco retailer associations to pro-graphic-warnings health groups, echoed many of these concerns.[2]

60. Several organizations of health professionals likewise commented that FDA's proposed graphic warnings were inaccurate and likely to mislead the public. For example, the American Diabetes Association urged FDA to alter its diabetes warning because the graphic "could

[2] All referenced comments were filed on FDA Docket No. FDA-2019-N-3065, https://tinyurl.com/ycyn6xvb.

be confusing for people with diabetes" and "misconstrue[d]." Am. Diabetes Ass'n, Cmt. 3 (Oct. 15, 2019), https://tinyurl.com/rxv9bmq. The American Optometric Association similarly objected that FDA's diabetes warning, by singling out the effect of "raise[d] blood sugar," "fail[ed] to effectively convey the gravity" of the health condition. Am. Optometric Ass'n, Cmt. 3-4 (Oct. 15, 2019), https://tinyurl.com/tnwedvg. The New York State Department of Health objected to the bladder cancer warning because its focus on bloody urine could "mislead" the public about the nature of the relevant risks. N.Y.S. Dep't of Health, Cmt. 1 (Oct. 15, 2019), https://tinyurl.com/rnchexy. Other medical professionals similarly objected to the accuracy and misleading nature of FDA's warnings. *See* Exs. G-K to RAI Cmt, https://tinyurl.com/u85jd4f.

G. FDA's Belated Disclosure of the Qualitative Study Reports and Supplemental Comment Period

61. On November 12, 2019, nearly a month after the initial comment period closed and after nearly 200 comments were submitted, FDA announced that it had published four additional reports to the public docket and gave the public just 15 days to comment. FDA, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966, 60,967-68 (Nov. 12, 2019). Those four reports comprised 600 pages summarizing the internal qualitative studies that FDA discussed in the Proposed Rule. All of those reports were complete long before the initial comment period began.

62. FDA acknowledged that it "used" these newly disclosed studies to "inform" the development of its Proposed Rule. 84 Fed. Reg. at 60,967. Yet FDA justified its initial failure to disclose the study reports by instead claiming that FDA "did not rely" on the studies as part of the rulemaking because they were "not … nationally representative" and did "not yield data that can be generalized." *Id.*

63. The newly disclosed materials still did not contain the underlying data—datasets from FDA's quantitative studies or notes, participant worksheets, and transcripts from FDA's qualitative studies—necessary to fully evaluate FDA's decision-making. Nor did FDA at this juncture disclose information regarding FDA's promised peer review of its quantitative studies.

64. Specifically, the four study reports summarized the results of qualitative studies that FDA undertook between July 2015 and April 2018:

- The July 2015 qualitative study examined participants' reactions to proposed textual warning statements. *See* RTI Int'l, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions* (July 2015) ("July 2015 Study Rpt."), https://www.regulations.gov/document?D=FDA-2019-N-3065-0485. FDA used this study to select and refine textual warning statements for further testing.
- The March 2016 qualitative study evaluated the reaction of 9 Spanish speakers to Spanish versions of proposed textual warning statements. *See* RTI Int'l, *Mem.: Findings from Cognitive Testing of Spanish Warning Labels* (Mar. 22, 2016) ("March 2016 Study Rpt."), https://www.regulations.gov/document?D=FDA-2019-N-3065-0486.
- The June 2016 qualitative study gauged participants' reaction to a group of proposed images designed to illustrate certain smoking-attributable health consequences. *See* Siegel+Gale, *FDA Graphic Health Warning Image Concept Testing Findings Report* (June 2016) ("June 2016 Study Rpt."), https://www.regulations.gov/document?D=FDA-2019-N-3065-0487. FDA used this study to again select and refine images for further testing.
- The April 2018 qualitative study assessed participants' reactions to proposed images as well as text-image pairings. *See* RTI Int'l, *Qualitative Study on Consumer Perceptions of Cigarette Health Warning Images* (Apr. 27, 2018) ("April 2018 Qualitative Study Rpt."),

https://www.regulations.gov/document?D=FDA-2019-N-3065-0488. FDA relied on this qualitative evaluation to select the text-image pairings that FDA tested in its final quantitative study.

65. Altria filed a supplemental comment on behalf of Plaintiff PM USA on November 27, 2019. *See* Altria Client Servs. Suppl. Cmt. Letter on Proposed Rule "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," Docket No. FDA-2019-N-3065 (Nov. 27, 2019) ("Altria Suppl. Cmt."). Altria pointed out that FDA's continued failure to disclose information and data underlying its studies prevented interested parties from meaningfully testing the validity of FDA's study conclusions, or checking whether the data reveals other findings undercutting the Proposed Rule that FDA did not disclose. Altria also explained that the limited study information FDA had belatedly disclosed undermined FDA's consumer-education justification for the Rule, as well as FDA's selection of individual warnings. *See id.* attach. 1.

H. The Final Rule

66. FDA published the final graphic-warnings rule on March 18, 2020. *See* Final Rule, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638. Notwithstanding the numerous comments highlighting severe problems with FDA's approach, FDA's Final Rule did not alter basic aspects of the proposed graphic-warnings regime.

67. The Rule's sole justification is instead FDA's interest in "greater" and "more effective" promotion of "public understanding of the negative health consequences of smoking," and especially those risks that are "less known or less understood by consumers." *Id.* at 15,643, 15,654. FDA's Final Rule repeatedly disavows that its final graphic warnings were designed to or in fact would affect consumer behavior or smoking rates. FDA emphasized that its "interest in this rule is not to reduce smoking rates," *id.* at 15,660, again disavowed that its interest "lies in

reducing smoking rates," *id.* at 15,644, and stressed that "increased smoking cessation and decreased initiation are not the [Rule's] purpose," *id.* at 15,650.

68. The Final Rule settled on 11 warnings, eliminating two of the graphic warnings from the Proposed Rule: the warning for age-related macular degeneration and one of the two COPD warnings. *Id.* at 15,684-85, 15,688. The Final Rule also modified the fetal harm image by "increas[ing] the contrast and size of the weight display." *Id.* at 15,677. The Final Rule mandates that cigarette packaging and advertising display the remaining graphic warnings, with the same text and image pairings as in the Proposed Rule. *See supra* ¶ 3.

69. As applied to cigarette packages, the Final Rule requires that the graphic warnings be displayed on "at least the top 50 percent" of both the front and back of the packages. 85 Fed. Reg. at 15,709. The top of cigarette advertisements must contain a graphic warning in "at least 20 percent of the area of the advertisement in a conspicuous and prominent format." *Id.*

70. FDA estimated the Rule's cost as between $1.2 and $1.6 billion. *Id.* at 15,639. FDA admitted that the Rule's benefits are not readily quantifiable, but nevertheless valued the warnings at $0.01 per package, which meant that the Rule's benefits "would equal or exceed the estimated annual costs." *Id.* FDA did not explain how it arrived at that per-package valuation.

71. If the Rule takes effect, it will be unlawful for manufacturers, distributors, and retailers to distribute cigarettes packages or advertisements that do not bear FDA's required graphic-health warnings. *See* 85 Fed. Reg. at 15,694. Retailers are excepted from many of the Rule's requirements if the cigarette packages contain a warning, are supplied by a "license- or permit-holding" tobacco manufacturer or distributor, and are not altered in a way that obscures the warnings. *Id.* at 15,708. FDA can enforce the Rule through "warning letters, civil money penalties, no-tobacco-sale orders, seizures, injunction, or criminal prosecution." *Id.* at 15,692.

1. FDA's Failure to Disclose Information About or Adequately Explain Key Aspects of Its Decision-Making

72. FDA failed to disclose key decisions and data that determined the outcome of its graphic-warning selection process. FDA's decision about which health risks its graphic warnings should feature was central to the underlying rulemaking. The TCA presumptively requires FDA to use the TCA's 9 textual warning statements, covering cancer, heart disease and strokes, smoker lung disease, addiction, death, fetal harm, quitting, nonsmoker lung disease, and harm to children, when issuing graphic warnings. *See* 15 U.S.C. § 1333(a)(1). FDA may adjust these warnings' text only if FDA finds, after rulemaking, that doing so would "promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2].

73. FDA says it set out to determine whether and how to revise the TCA's textual warning statements to better serve its asserted consumer-education interest. To do so, FDA explained that it "undertook a rigorous science-based, iterative research process," which involved "carefully reviewing the scientific literature on the health risks associated with cigarette smoking," including a 2014 report by the Surgeon General, as well as "evaluating the public's general awareness and knowledge of those health risks." 85 Fed. Reg. at 15,658. FDA then "determined there was sufficient support to propose adjusting the text of the TCA statements." *Id.*

74. In previous litigation, FDA similarly emphasized that it followed an elaborate decision-making process to determine which health risks the warnings would cover. FDA's affidavit from Mitchell Zeller, Director of FDA's Center for Tobacco Products, states that an expert-laden "working group" engaged in "in-depth consideration of the interplay among textual warnings, graphic depictions, public health objectives, scientific approaches and study models for testing the warning statements and images, the statutory mandate, and Constitutional considerations." Zeller Decl. ¶¶ 11-12. This working group apparently prompted FDA's

"determin[ation] that it would modify the text of the warning statements in the TCA," and FDA's "science staff" accordingly developed initial warning statements. *Id.* ¶ 13.

75. FDA has not provided meaningful information regarding these processes or decisions for selecting which health risks to cover. FDA has only indicated that, before its first internal study in July 2015, FDA used an undisclosed process to select 13 categories of health information to feature in new warnings. Those categories comprised the 9 TCA categories—cancer, heart disease and strokes, smoker lung disease, addiction, death, fetal harm, quitting, nonsmoker lung disease, and harm to children—plus 4 new risks—blindness, amputation, diabetes, and erectile dysfunction—that the TCA never mentions. *See* July 2015 Study Rpt. app. G.

76. FDA states that it made those selections after "evaluating the public's general awareness and knowledge of" smoking-related health risks and concluding that consumers "suffer from a pervasive lack of knowledge about and understanding of many of the negative health consequences of smoking." 85 Fed. Reg. at 15,655, 15,658. FDA asserts that it aimed to "cover a range of smoking-related health effects" identified by the Surgeon General's 2014 report, with a preference for health conditions that were "newly identified" by that report. *Id.* at 15,654; 84 Fed. Reg. at 42,766. FDA also apparently ensured that its selected health conditions were "causally linked" to smoking and were "not rare." 84 Fed. Reg. at 42,767; *see* 85 Fed. Reg. at 15,669.

77. But those criteria do not shed light on FDA's selection process, because many health conditions that FDA omitted—including liver cancer, colorectal cancer, tuberculosis, rheumatoid arthritis, and impaired immune function—would satisfy them. FDA also omitted a number of health risks that were more prevalent or fatal than its selected conditions, such as trachea, bronchus, and lung cancer; pancreatic cancer; stomach cancer; acute myeloid leukemia; colorectal cancer; cervical cancer; asthma; or aortic aneurysm. *See* Atria Cmt. 29, tbl.1 & fig.8.

FDA has provided no explanation for how or why it decided to develop warnings featuring several less prevalent, less fatal conditions.

78. Indeed, many of FDA's selections make no sense when viewed against FDA's statement that it targeted "less known" health risks. *E.g.*, 85 Fed. Reg. at 15,654. FDA tested warnings covering several health consequences, such as addiction, death, and nonsmoker lung disease, which FDA acknowledged were "better-known" by consumers. 84 Fed. Reg. at 42,767 n.5; *see* Altria Cmt. 28-29. Moreover, FDA chose to develop warnings covering 4 health consequences (smoker lung disease, heart disease, benefits of quitting, and fetal harm) that the Surgeon General's warnings have long featured—even though FDA critiques the Surgeon General's warnings for "not address[ing] areas where there are significant gaps in public understanding about the negative health consequences of cigarette smoking." 85 Fed. Reg. at 15,653. FDA has not reconciled its decision to focus on those well-known health risks with its asserted "focus[] on less-known health consequences of smoking." *Id.* at 15,653; *see also id.* at 15,650, 15,654, 15,666.

79. And yet FDA's unexplained pre-selection of health risks determined the risks FDA chose to focus on for the remainder of the rulemaking. While FDA winnowed down the health risks to those it ultimately featured in its final graphic warnings, the Rule warns against only those categories of conditions that FDA selected at the outset. *Compare* July 2015 Study Rpt. app. G, *with* 85 Fed. Reg. at 15,708-09. Because the decision was made from the start, none of FDA's internal studies considered, much less evaluated, different categories of health risks.

80. Furthermore, FDA delayed disclosing other, highly relevant information, even when FDA had that information in hand during the comment periods. FDA only disclosed the results of the peer-review process for its quantitative studies, as well as FDA's response to the

peer-review comments, when FDA issued the Final Rule on March 18, 2020. *See* Versar, Inc., *Final Summary Report, External Letter Peer Review of FDA's Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act* (Nov. 19, 2019) ("Peer Review Report"), https://www.fda.gov/media/136124/download; 85 Fed. Reg. at 15,658. Yet FDA's peer-review report is dated November 19, 2019. FDA did not explain why it failed to release the report during the supplemental comment period from November 12 to November 27, 2019, when stakeholders could have assessed and commented on this information, which criticizes FDA's process and conclusions.

81. In issuing the Final Rule, FDA also disclosed, for the first time, final versions of its quantitative study reports. *See* FDA, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* (Feb. 2020), https://www.regulations.gov/document?D=FDA-2019-N-3065-0607; FDA, *Experimental Study of Cigarette Warnings: Study 2 Report* (Feb. 2020), https://www.regulations.gov/document?D=FDA-2019-N-3065-0841. These "final" study reports reflect revisions FDA made in response to the peer-review comments. Specifically, FDA "updated" both the April 2018 and the May 2019 study reports by "adding clarifying details about the studies' procedure and analysis," as well as additional citations to research that purportedly bolstered FDA's approach. 85 Fed. Reg. at 15,661. Though none of FDA's revisions addressed the significant failings with FDA's studies, FDA's failure to timely disclose final versions of its central quantitative reports exemplifies FDA's slipshod process.

82. On March 23, 2020, nearly one week after FDA published the Final Rule, FDA announced the online publication of two journal articles in *Nicotine & Tobacco Research* reporting the results of FDA's April 2018 and May 2019 quantitative studies. The title pages of the articles

indicate that the journal received those articles in July 2019—before FDA published the Proposed Rule—and accepted them on February 3, 2020. The articles contain additional discussion of the research framework, results, and limitations of FDA's quantitative studies that underpin its Final Rule. But again, FDA never made these articles, or the final versions of the underlying study reports, available for public comment.

83. FDA never disclosed other critical information prior to issuing its rule. For instance, FDA did not provide information underlying its quantitative and qualitative studies, including datasets and transcripts of the focus-group interviews, despite repeated requests that it do so. *See, e.g.*, King & Spalding, Cmt., Docket No. FDA-2019-N-3065 (Sept. 9, 2019) (citing 2-year-old FOIA request for information related to FDA's studies). Without this information, stakeholders could not check the validity of FDA's results.

2. FDA's Flawed Evidentiary Basis for the Final Graphic Warnings

a. The Faulty Internal Studies

84. FDA's process for developing its warnings primarily consisted of a series of internal qualitative and quantitative studies performed between July 2015 and May 2019.

85. Even the incomplete study information FDA has disclosed undercuts FDA's claim that its warnings will improve consumer understanding of smoking-related health risks, especially less-known risks. A step-by-step review of FDA's studies shows FDA repeatedly ignored study feedback that its chosen warnings related to well-known information, were unclear, confusing, or unhelpful, and were shocking and disturbing. Further, as several peer reviewers confirmed: FDA failed to assess consumer understanding, and it arbitrarily prioritized "new information" and "self-reported learning" instead.

1) Qualitative Studies

86. FDA's Final Rule acknowledges that FDA relied on its qualitative studies as "formative" in allowing FDA to "refine[] and reduce[]" its proposed textual warning statements and images to the final versions FDA promulgated. 85 Fed. Reg. at 15,661, 15,664.

87. But FDA's Final Rule then turns around and disavows those same qualitative studies. FDA asserts that it "did not directly rely on these studies" in the "rulemaking itself," and, similarly, that the "qualitative studies are not key data relied upon by the Agency to make final decisions about the proposed and final rules." *Id.* at 15,651, 15,667. FDA further notes that the qualitative studies "are based on small sample sizes, are not nationally representative, and do not yield data that can be generalized." *Id.* at 15,666. But those qualitative studies were the *only* studies that informed FDA's selection of the particular text and images to test in its quantitative studies. Thus, the shortcomings in FDA's qualitative studies infect FDA's quantitative studies on which FDA unquestionably relies.

88. The results of FDA's qualitative studies further impugn FDA's warning-development process. FDA's Final Rule repeatedly portrays its graphic warnings as purely factual and devoid of non-essential, emotionally charged elements. *See, e.g.*, *id.* at 15,646, 15,661, 15,670, 15,671. But the qualitative studies showed that participants found FDA's warnings gratuitously shocking, disturbing, or scary, and that FDA refined warning images to heighten their emotional appeal. The studies also belie FDA's claims that the warnings will promote consumer understanding, as participants found FDA's chosen warnings unhelpful, unclear, or confusing.

89. July 2015 Qualitative Study of Textual Warnings: FDA's initial, July 2015 qualitative study gathered focus-group reactions to proposed textual warning statements and evaluated "consumers' awareness of the negative health consequences of cigarette smoking," their

"comprehension of each statement, the believability of the content of each statement," and if the warned-against "health condition was new information to participants." 84 Fed. Reg. at 42,767.

90. FDA tested textual warning statements consisting of the 9 warning statements from the TCA, *see supra* ¶ 36, as well as 17 new, FDA-drafted warning statements. 84 Fed. Reg. at 42,767. Together, all of the statements covered the 13 health consequences that FDA zeroed in on at the outset of its rulemaking. *See supra* ¶ 75; July 2015 Study Rpt. app. G. Based on the July 2015 study results, FDA picked 24 statements (the 9 TCA statements, the 14 FDA-drafted statements FDA tested, and one statement that FDA had never tested, involving head and neck cancer) to refine and advance for further testing. *See* 84 Fed. Reg. at 42,767 & tbl.1.

91. FDA has yet to explain how it decided to advance those textual warning statements given the study findings. The July 2015 study reported that "[t]he *most prevalent finding* across groups and statements was the negative reaction to statements of the type 'X causes Y' (e.g. 'cigarettes cause' … [specific disease / health effect])." July 2015 Study Rpt. 52 (emphasis added). The report indicated that participants "reasoned that these statements are not true," because the participants identified other causal factors, and knew that smokers did not inevitably contract the warned-against conditions. *Id.* The study also concluded that respondents "were less likely to believe" warnings that provide "new information." *Id.* at 51; *see also id.* at 7 ("[P]articipants often questioned the believability of some of these novel statements.").

92. In line with these findings, most participants expressed that various FDA-drafted warnings were not believable—suggesting that these warnings would not meaningfully educate consumers. For instance, most adult participants did not believe that smoking "causes" bladder cancer because they considered the causation language too strong. *Id.* at 26. Similarly, "[m]any participants" did not believe textual warnings covering sexual dysfunction, amputation, and

diabetes. *Id.* at 42, 44. Yet FDA finalized the bladder cancer warning using the same definitive causal language, and FDA's other warnings mix up conditional language ("can harm," "can require," "can cause") with more definitive language ("causes"), without explanation. *See* 85 Fed. Reg. at 15,708-09.

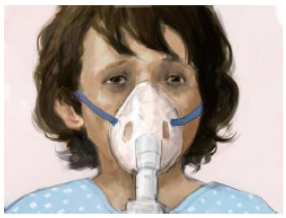
93. The July 2015 qualitative study also demonstrated that certain FDA warnings generally did *not* provide new health information to participants, and thus undercut FDA's stated consumer-education aim. For instance, *zero* percent of adults found the warning "smoking during pregnancy can stunt your baby's growth" to contain new information. July 2015 Study Rpt. 33 ("0.0%"). Only 2.6% of adults deemed the "tobacco smoke can harm your children" warning as providing new information. *Id.* at 35. Yet FDA advanced (and ultimately finalized) both of those warnings using virtually identical text. *See* 85 Fed. Reg. at 15,708. FDA's decision inexplicably contradicts its asserted focus on less-known risks of smoking, as well as its conclusion that certain TCA warning statements—involving addiction, quitting, death, and nonsmoker lung disease—"describe[] … better-known health consequences of smoking," and thus "revised statements on these conditions likely would not promote greater public understanding of the negative health consequences of smoking." 84 Fed. Reg. at 42,767 n.5.

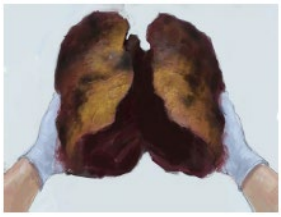
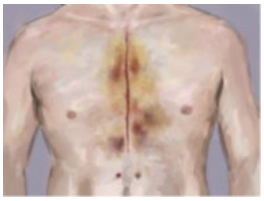
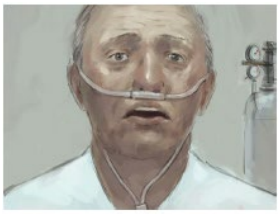
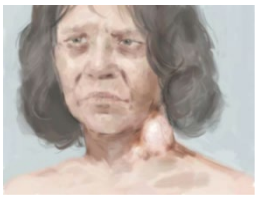
94. March 2016 Qualitative Study of Spanish-Language Textual Warnings: FDA next conducted a qualitative evaluation of Spanish-language cigarette warning text. In this study, 9 native Spanish speakers provided their thoughts regarding Spanish-language versions of 15 proposed textual warnings covering cancer (specifically, mouth and throat cancer, head and neck cancer, and bladder cancer); fetal harm; harm to children; heart disease and strokes; smoker lung disease; erectile dysfunction; amputation; diabetes; and blindness. March 2016 Study Rpt. 1-10.

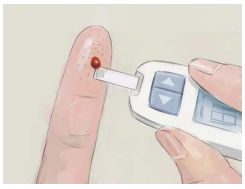
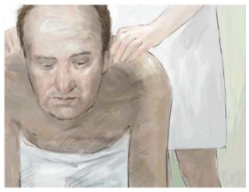
This study, too, concluded: "When the warning statements contained new information, participants were less likely to find them believable." *Id.* at 3. FDA never discusses this study.

95. June 2016 Qualitative Study of Proposed Images: FDA's June 2016 qualitative study examined proposed "image concepts," i.e., 24 proposed images to illustrate 10 of the 13 health conditions that FDA had decided to consider as candidates for its ultimate graphic warnings: 5 for cancer; 4 for heart disease and strokes; 2 for smoker lung disease; 2 for erectile dysfunction; 1 for amputation; 2 for diabetes; 2 for blindness; 1 for death; 3 for fetal harm; and 2 for harm to children. *See* June 2016 Study Rpt. 20 (reproducing tested images). Focus-group participants viewed the 24 images and indicated whether they found the images "clear …, attention-grabbing, worth remembering, credible, and relevant," plus whether the images "provided any new information" about smoking-related health risks. 84 Fed. Reg. at 42,770.

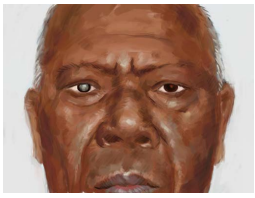
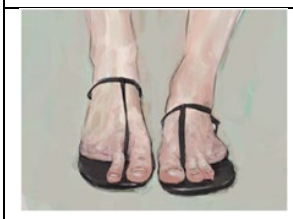
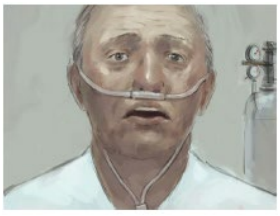
96. The June 2016 study indicated that FDA's proposed images were shocking, disgusting, or fear-provoking, and gave FDA recommendations aimed at increasing the attention-grabbing nature of the warnings by "elicit[ing] a visceral reaction," June 2016 Study Rpt. 17:

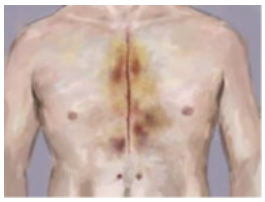
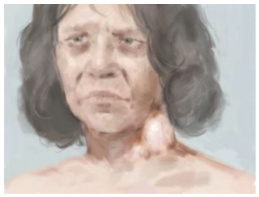
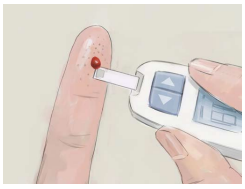
	• ***Harm to children image*** – "The sadness expressed in the subject's eyes and the oxygen mask grabbed participants' attention." *Id.* at 22. Participants described the image as "scary," "cruel[]," and provoking "despair." *Id.* at 23-24, 26. The study recommended that FDA's image "[m]aintain the look of dismay (e.g., sadness in the eyes)" to grab attention. *Id.* at 158.
	• ***Fetal growth image*** – Participants described the image as "heartbreaking" and "very emotional," with one stating that the image "would really creep me out." *Id.* at 97. The study recommended refining this image because "[p]articipants clearly demonstrated an emotional connection." *Id.* at 164.

	• ***Amputation image*** – Subjects found the image "very attention-grabbing … due to the startling image of a subject with missing toes and the implication of that as a result of smoking." *Id.* at 126. Respondents repeatedly reacted to the image because it was "gross," "powerfully disturbing," provoked "disgust," and had "shock value." *Id.* at 130.
	• ***Nonsmoker lung disease image*** – "Participants were particularly affected by the image's harsh depiction of a body organ in the palms of a surgeon," *id.* at 33, and found the image "attention-grabbing because of its gruesome depiction and implication of death," *id.* at 37. In a suggestion FDA adopted, the study recommended: "[m]ak[ing] the blood on the gloves more discernible" and "[k]eep[ing] the surgeon/coroner's hands in the picture, as they convey the realism of the resulting death rather than a 'medical textbook' image" and "reinforce the undesirable state of the lungs." *Id.* at 159. Although the study tested this image to depict smoker lung disease, FDA determined to use a similar image to represent nonsmoker harm.
	• ***Heart disease and strokes image*** – "The cut down the middle of the subject's chest was the most attention-grabbing part" of the image. *Id.* at 81. The study recommended emphasizing the incision even more as the "focal point of the image," and FDA did so. *Id.* at 162.
	• ***Chronic Obstructive Pulmonary Disease (COPD) image*** – The study reported that the image "was especially attention-grabbing due to the sadness and pain depicted in the man's expression." *Id.* at 38. The study accordingly advised FDA to "[r]etain the look of misery/sadness/resignation on the man's face." *Id.* at 159.
	• ***Head and neck cancer image*** – The "woman's facial expression" of sadness was attention-grabbing. *Id.* at 61. The study recommended that FDA "[m]aintain the look of sadness/despair" on the woman's face. *Id.* at 161.

	• ***Diabetes image*** – FDA followed study recommendations to make the "blood … more discernible" and "[m]ake the finger appear somewhat less 'healthy.'" *Id.* at 166.
	• ***Erectile dysfunction image*** – After study participants found that this image and FDA's other erectile dysfunction image were incomprehensible, FDA implemented study recommendations to "[m]ake it clear that the man's emotion is shame." *Id.* at 165.

97. The June 2016 study also reported that several images were unclear or confusing:

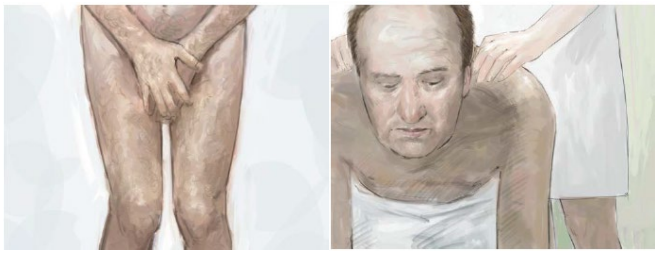
	• ***Cataracts image*** – "[M]ost participants" found the image "unclear upon initial exposure; many had to be shown the larger image for clarity," and "[a] large number could not glean any health consequences from the image." *Id.* at 143. FDA's study thus classified this image as a "[h]igh confusion image[]" that "received 'low' scores on both subject and message clarity." *Id.* at 156.
	• ***Amputation image*** – Participants observed missing toes, "but the reason why or how was unclear." *Id.* at 126. The study concluded "many will not associate [the image] with circulatory complications … without the text warning." *Id.* at 166.
	• ***Chronic Obstructive Pulmonary Disease (COPD) image*** – Participants identified that the depicted man "has a breathing problem," without knowing the condition. *Id.* at 39.

	• ***Heart disease and strokes image*** – The image struck participants as "unclear," for instance, because "[s]ome thought the subject might have lung cancer, while others thought the subject needed heart surgery." *Id.* at 77. FDA's study thus classified this image as a "[h]igh confusion image[]" that "received 'low' scores on both subject and message clarity." *Id.* at 156.
	• ***Head and neck cancer image*** – When shown this image, participants had "some confusion about what the protrusion was." *Id.* at 61. The study recommended that FDA delete the image since "[i]t wasn't clear what the message was even when the tumor was identified." *Id.* at 161.
	• ***Diabetes image*** – Participants characterized the image as "unclear" and "confusing," with one noting that the image depicts "[u]nhealthiness," but "I have no idea why" or "how." *Id.* at 123.

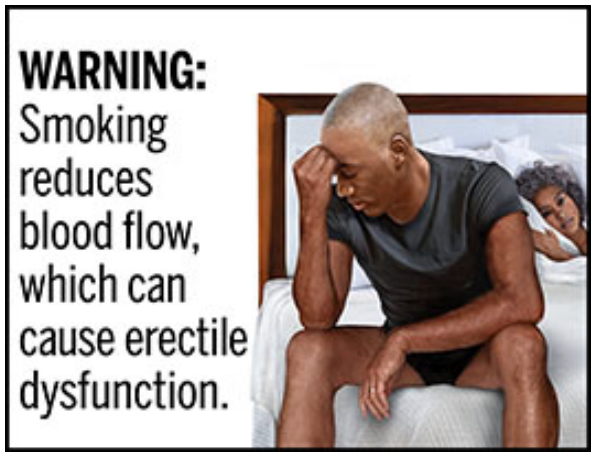
98. The June 2016 study again confirmed that several of FDA's images (the harm to children image, the blackened-lung image depicting smoker lung disease, the image of the man with the nasal cannula depicting chronic obstructive pulmonary disease, and the image of the baby on a scale to represent fetal harm) did not provide participants with "any new information," contrary to FDA's consumer-education aim. *See id.* at 25, 33, 38, 94.

99. Study participants deemed other images unbelievable or unrealistic. *See, e.g.*, *id.* at 121 ("[M]any questioned the credibility of [the] message" conveyed by the diabetes image.). In line with other study findings, the June 2016 study identified the presentation of "new information" and "alternative" causal "explanation[s]" as factors that "appeared to lessen image credibility." *Id.* at 17; *see id.* (reporting that those factors applied to erectile dysfunction, diabetes, harm to children, and bladder cancer images, among others).

100. FDA nonetheless retained all of these concepts for further testing. FDA selected and refined the tested images or generated new images to illustrate the same conditions it had already picked. *Compare* June 2016 Study Rpt. 20, *with* April 2018 Qualitative Study Rpt. app. I tbl.2. For example, FDA abandoned both of its proposed erectile dysfunction images.



Study recommendations suggested FDA instead depict a "man and a woman who have an intimate relationship in a bedroom" and "[m]ake it clear that the man's emotion is shame, not fatigue or body aches." June 2016 Study Rpt. 165. FDA did just that: it replaced those images with the final erectile dysfunction image, which depicts a man sitting on the edge of a bed with a hand on his forehead with a woman's head on a pillow behind him.

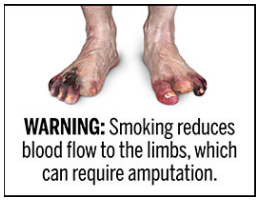


101. April 2018 Qualitative Study of Text-Image Pairings: FDA's April 2018 qualitative study tested proposed warnings pairing text and images for the first time. FDA paired 24 textual warning statements—9 generic TCA statements and 15 FDA-drafted statements—with 1, 2, or 3 potential corresponding images. The proposed graphic warnings all pertained to the 13

smoking-related health risks FDA selected at the outset. *See* April 2018 Qualitative Study Rpt. 11. This qualitative study also included new graphics for addiction and quitting.

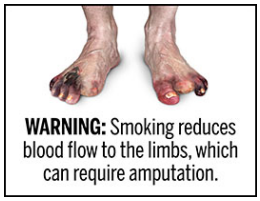
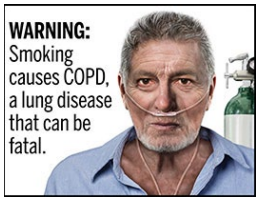
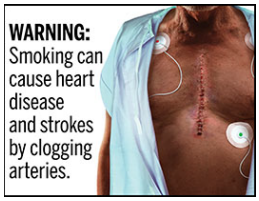
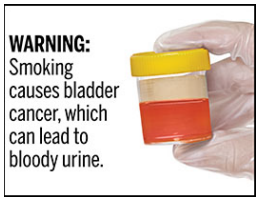
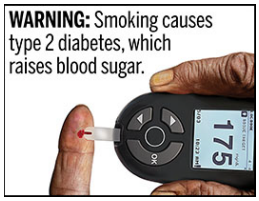
102. Participants viewed proposed warning images alone, as well as paired with textual statements, and evaluated the images and pairings for clarity, accuracy, believability, and whether they provided new information. *See id.* at 3. Several warnings scored very low on those metrics.

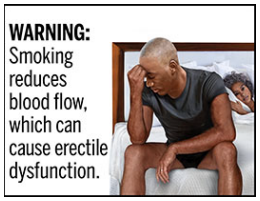
103. The April 2018 qualitative study again confirmed that many of FDA's chosen images provoked emotional reactions, such as shock, disgust, or fear:

	• ***Harm to children image*** – The image "conveys the severity" of harm to the child with "the mask, dark circles under his eyes and pale skin." *Id.* at 16.
	• ***Amputation image*** – "The idea of losing limbs scares some participants and grabs their attention." *Id.* at 68.
	• ***Diabetes image*** – Participants generally "discussed the fingernails being yellow, crusty, discolored or dirty," suggesting visceral reactions. *Id.* at 64. The study recommended reducing the amount of blood ("too much blood"), but FDA apparently did not accept that recommendation. *Id.*

104. Participants also deemed FDA's warnings confusing, unclear, or unhelpful:

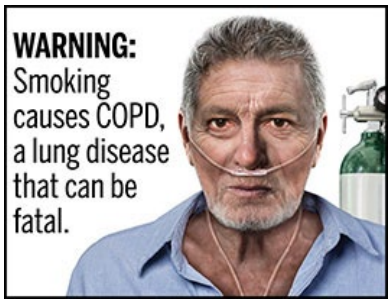
	• ***Harm to children image*** – "Some participants stated that it was unclear what was wrong with the child. Without additional information, participants would not know that the image is associated with smoking." *Id.* at 14.

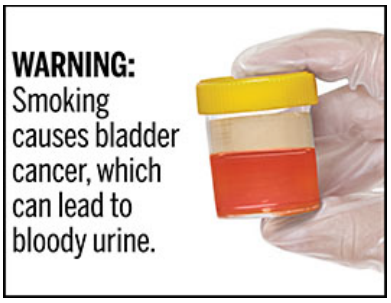
	• ***Amputation image*** – The study reported that "[t]he cause of the foot problem is unclear," the "image is confusing on its own," and "[t]he connection to smoking is not clear." *Id.* at 67.
	• ***Chronic Obstructive Pulmonary Disease (COPD) image*** – Participants expressed "some confusion about the oxygen tubes." *Id.* at 40.
	• ***Nonsmoker lung disease image*** – "It is not clear why the person is holding the lungs or whether they had just been removed or were going to be put in someone's body." *Id.* at 41.
	• ***Heart disease and strokes image*** – "Many participants were confused about the scar and the tubes" and the "type of surgery" involved. *Id.* at 59.
	• ***Bladder cancer image*** – Only "[s]ome participants said that there was blood in the urine," and then, only after seeing an image of "blood in a toilet, which may have influenced responses." *Id.* at 34-35.
	• ***Diabetes image*** – "Some participants didn't know what the rating ('175') meant (whether it was high or low)"; others questioned whether the number was representative or age-related. *Id.* at 64.

	• ***Erectile dysfunction image*** – "Many participants agreed that without the words, it was difficult to know what the image was depicting," and gave a "wide variety of interpretations for this image," such as "[t]he couple could have a strained relationship," or "[t]he woman is in 'la land,'" or "[s]tress/depression." *Id.* at 70.

105. FDA tested 2 images illustrating fetal harm. FDA paired each image with 3 different textual statements, for a total of 6 discrete text-image pairings. *See id.* at 26. The study reported that these proposed warnings imparted new information to only a "few" participants. *Id.* at 23. And study participants overwhelmingly responded that, out of FDA's proposed graphic warnings, FDA's image of a baby on a scale with a message that smoking stunts fetal growth was the *least* informative pairing (with only 0.6% favoring it). *Id.* at 26.

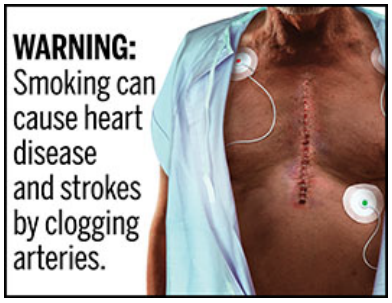
FDA finalized that graphic warning anyway. So too, few participants preferred FDA's proposed graphic warnings for nonsmoker lung disease (9.4%), chronic obstructive pulmonary disease (5.9%), head and neck cancer (5.9%), and bladder cancer (1.8%). *Id.* at 37, 47.





FDA nonetheless finalized those graphic warnings as well.

106. Participants deemed other warnings unbelievable or unrealistic. Some participants noted that the harm to children image "is not a realistic outcome of secondhand smoke." *Id.* at 16. Participants viewing the head and neck cancer warning image "thought the lump was too large to be realistic," with one noting "a person would have a tumor removed before it became that large." *Id.* at 30. Participants similarly questioned the realism of the photo in the heart disease and strokes image, noting that "the man would unlikely be able to stand immediately after surgery." *Id.* at 59.



Again, FDA finalized these warnings.

107. Indeed, FDA advanced all of these graphic warnings, unchanged, for further study, and did not reassess its selection of which 13 categories of health conditions to feature. FDA thus moved forward to quantitative testing with warnings targeting the same 13 categories of health information it inexplicably pre-selected: cancer; heart disease and strokes; smoker lung disease; erectile dysfunction; amputation; diabetes; blindness; addiction; death; fetal harm; quitting; nonsmoker lung disease; and harm to children.

2) Quantitative Studies

108. The Final Rule relies almost entirely on two FDA quantitative studies that are replete with methodological flaws and that fail to support FDA's graphic-warnings requirements.

109. April 2018 Quantitative Study of Warning Text: FDA's first quantitative study examined 15 FDA-drafted textual warning statements. *See* RTI Int'l, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* (Apr. 2018) ("April 2018 Quantitative Study Rpt."), https://www.regulations.gov/document/FDA-2019-N-3065-0131. Study participants compared the FDA-drafted statements with the TCA's 9 textual warnings so that FDA could evaluate which of its statements would "promote greater public understanding" of smoking-related health risks. 85 Fed. Reg. at 15,658.

110. Together, the 9 TCA warnings and 15 FDA-drafted warnings spanned the same 13 health-information categories that FDA identified before conducting any studies.

111. The study tested the FDA-drafted statements as well as the TCA mandated statements. According to FDA, participants were generally more likely to report that they "had not previously heard of" the specific health effects in the FDA-drafted statements and they had "learned something from the" FDA-drafted statements. 84 Fed. Reg. at 42,768.

112. Moreover, FDA's unexplained selection of study criteria, and FDA's arbitrary choice to preference some outcomes over others, significantly undermine the study's value:

113. *First*, FDA provided scant justification for its selection of what it chose to measure:

- ***New information*** – "Whether the warning statement was new information to participants";
- ***Self-reported learning*** – "Whether participants learned something from the warning statement";
- ***Thinking about risks*** – "Whether the warning statement made participants think about the health risks of smoking";

- ***Believability*** – "Whether the warning statement was believable";
- ***Informativeness*** – "Whether the warning statement was informative";
- ***Factualness*** – "Whether the warning statement was perceived to be a fact or an opinion";
- ***Health beliefs*** – "Whether participants reported beliefs linking smoking and the health consequences in the warning statement."

Id. As the list indicates, though FDA's study purported to measure consumer understanding, the study did not attempt to assess actual comprehension or understanding (e.g., questions asking participants to correctly identify health information as true or false). Without such objective measures, FDA could not and did not evaluate whether participants accurately understood the relevant health information, or instead came away with misimpressions regarding the warned-against risks. *See* Altria Cmt. 34-35.

114. *Second*, FDA inexplicably prioritized two study measures—"new information" and "self-reported learning"—over all of the others. FDA advanced those warnings that showed significant increases in both of those measures, no matter how the warnings fared on the other study outcomes. 84 Fed. Reg. at 42,769. FDA apparently "determined that the scientific literature demonstrates" that those outcomes are "most predictive" of greater public understanding because "[m]easuring whether information is new helps identify opportunities to improve understanding through increased awareness." *Id.*; 85 Fed. Reg. at 15,643. FDA has not explained or adequately supported its conclusion that "new information" and "self-reported learning" are the outcomes "most predictive" of understanding. *See infra* ¶ 129. To the contrary, the record shows that many of FDA's other measures are just as probative, if not more so, of understanding and the efficacy of warnings. *See infra* ¶ 122. And FDA's assertion that "people are more likely to pay attention to information that is new," 84 Fed. Reg. at 42,769, runs contrary to significant evidence that

consumers are more likely to *reject* new information as unbelievable or lacking credibility. *See, e.g.*, *supra* ¶ 94; *infra* ¶ 129.

115. *Third*, FDA's final warning statements did not perform well on the measures FDA chose to minimize:

- ***Thinking about risks*** – 6 of FDA's 11 final warning statements—covering head and neck cancer, bladder cancer, fetal growth, heart disease and strokes, diabetes, and cataracts—did not demonstrate statistically significant improvements in "thinking about health risks" as compared to the TCA warnings. Another—the erectile dysfunction warning statement—prompted participants to indicate that they were significantly *less* likely to think about the relevant health risk. April 2018 Quantitative Study Rpt. 3-8-3-9 (69-70)[3] & tbl.3-5; *see* Altria Cmt. 36.
- ***Informativeness*** – 8 of FDA's 11 final warning statements—covering head and neck cancer, bladder cancer, fetal growth, heart disease and strokes, erectile dysfunction, amputation, diabetes, and cataracts—failed to demonstrate statistically significant improvements in informativeness as compared to the TCA warnings. April 2018 Quantitative Study Rpt. 3-11 (72) & tbl.3-6.
- ***Factualness*** – 6 of FDA's 11 final warning statements—covering head and neck cancer, bladder cancer, erectile dysfunction, amputation, diabetes, and cataracts—were rated as significantly *less* factual than the TCA warnings. *See id.* at 3-12 (73) & tbl.3-7.

[3] Because FDA's quantitative study reports are not consecutively paginated, citations contain the PDF page number in parentheses.

- ***Believability*** – 6 of FDA's 11 final warning statements—covering head and neck cancer, bladder cancer, erectile dysfunction, amputation, diabetes, and cataracts—were ranked as significantly *less* believable than the TCA warnings. *Id.* at 3-9 (70) & tbl.3-6.

116. May 2019 Quantitative Study of Proposed Graphic Warnings: This final study was the only one that evaluated FDA's proposed graphic warnings. The study compared the 4 text-only Surgeon General's warnings as they currently appear on packaging and advertising to FDA's 16 proposed graphic warnings printed in color on 50% of a mock package or 20% of a mock advertisement. *See* RTI Int'l, *Experimental Study of Cigarette Warnings: Study 2 Report* (May 2019) ("May 2019 Study Rpt."), https://www.regulations.gov/document/FDA-2019-N-3065-0155; 84 Fed. Reg. at 42,771 tbl.2.

117. The study was web-based, and consisted of three sessions. In the first session, participants answered a series of questions about their beliefs regarding the health consequences of smoking. The phrasing of these health-belief questions was "derived directly from the text of the proposed graphic health warnings." Altria Cmt. 34. Participants next viewed their assigned warning: one of the Surgeon General's warnings for the control group participants, or one of FDA's proposed graphic warnings for treatment group participants. Participants then judged their warnings based on several criteria, *see infra* ¶ 120. Next, 1-2 days later, participants viewed the same warning as before, and answered the same health-belief questions. Fourteen days later, participants completed the third session, in which they again answered the same health-belief questions as well as a question measuring warning recall. *See* 84 Fed. Reg. at 42,771-72.

118. Like FDA's first quantitative study, serious flaws plagued this study.

119. *First*, FDA again used a non-representative sample, which means the study's results cannot be reliably applied to the general population. The study sample comprised 9,760

participants, including adolescents, younger adult (aged 18 to 24) current smokers and nonsmokers, and older adult (aged 25 years and older) current smokers and nonsmokers. *Id.* at 42,771. Study participants volunteered primarily through online and social media platforms. FDA's study sample thus was not "nationally representative," and its results are not generalizable. 85 Fed. Reg. at 15,660.

120. *Second*, FDA chose and prioritized study outcomes in a manner even more arbitrary than in its qualitative studies. FDA measured the following outcomes:

- ***New information*** – "Whether the warning was new information to participants";
- ***Self-reported learning*** – "Whether participants learned something from the warning";
- ***Thinking about risks*** – "Whether the warning made participants think about the health risks of smoking";
- ***Perceived informativeness*** – "Whether the warning was perceived to be informative";
- ***Perceived understandability*** – "Whether the warning was perceived to be understandable";
- ***Perceived factualness*** – "Whether the warning was perceived to be a fact or an opinion";
- ***Health beliefs*** – "Whether participants reported beliefs linking smoking and each of the health consequences presented in the warning";
- ***Perceived helpfulness*** – "Whether the warning was perceived to help participants understand the negative health effects of smoking";
- ***Attention*** – "Whether the warning grabbed their attention";
- ***Recall*** – "Whether the warning was recalled."

85 Fed. Reg. at 15,658-59.

121. *Third*, FDA omitted measures that are highly relevant to its asserted inquiry into consumer understanding:

- ***Actual comprehension*** – FDA again failed to test actual comprehension or understanding of the warnings. That failure makes it impossible to assess what information participants took from the graphic warnings, much less whether participants came away with an "accurate" understanding of the relevant health risks. *Id.* at 15,648.
- ***Believability*** – FDA inexplicably declined to assess believability, even though it measured that factor as part of its first quantitative study. FDA's omission of believability is notable in light of significant literature indicating that warning believability and credibility are closely linked to whether consumers will accept warnings. *See infra* ¶ 129.
- ***Emotional impact*** – FDA did not assess the emotional impact of its graphic warnings, despite research indicating that consumers—and especially current smokers—tend to reject or avoid warnings that evoke emotions like fear or disgust. *See* Altria Cmt. 41-42.

122. *Fourth*, FDA again inexplicably prioritized "new information" and "self-reported learning" as the measures most predictive for "the task of identifying which of the cigarette health warnings increase understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,772; *see* 85 Fed. Reg. at 15,658. As before, FDA's prioritization of these two measures lacks support in the scientific literature. *See infra* ¶ 129. It also overlooks other measures directly undercutting its decision:

- ***Factualness*** – Participants considered 7 of FDA's 11 final graphic warnings—covering nonsmoker lung disease, head and neck cancer, bladder cancer, erectile dysfunction, amputation, diabetes, and cataracts—significantly *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102) & tbl.3-3; *see* Altria Cmt. 37.
- ***Health beliefs*** – 5 of FDA's 11 final graphic warnings—covering heart disease and strokes, smoker lung disease, erectile dysfunction, harm to children, and fetal harm—*did not*

meaningfully affect participants' health beliefs after repeated exposure. May 2019 Study Rpt. 3-14-3-15 (110-11), tbl.3-7 & 3-16 (112) tbl.3-8; *see* Altria Cmt. 37. Five more warnings—covering diabetes, head and neck cancer, cataracts, bladder cancer, and amputation—had small effects that diminished, rather than grew, over time. *See* May 2019 Study Rpt. 3-10-3-11 (106-07), 3-13-3-15 (110-11). That result contradicts FDA's claims that the warnings' efficacy will increase over time as individuals "integrate new information into their existing belief system." 85 Fed. Reg. at 15,663.

123. FDA used the quantitative study—in particular, its preferred outcomes of "self-reported learning" and "new information"—to winnow down the 16 tested graphic warnings to the 13 graphic warnings FDA proposed finalizing. FDA eliminated only the 3 warnings related to addiction, death, and the benefits of quitting, *compare* 84 Fed. Reg. at 42,767 tbl.1, *with id.* at 42,771 tbl.2.

124. The evolution of each of FDA's warnings highlights irrational and unexplained choices throughout FDA's "science-based" approach. For convenience, Plaintiffs attach a chart as Exhibit 2 to this Complaint detailing each individual warning's shortcomings, including their potential to mislead, which Plaintiffs incorporate and allege as though set forth fully herein.

125. Peer-Review Report of Quantitative Studies: The peer-review report of FDA's April 2018 and May 2019 quantitative studies (referred to in the report as "Study 1" and "Study 2," respectively), which is dated during the reopened comment period but FDA released only after issuing the Final Rule, confirms that FDA's quantitative studies are unsound.

126. FDA's Final Rule claims that the peer reviewers "concluded that the studies were strong and that 'both studies are very well done in terms of design and data analysis' and 'appropriate to address the study's [sic] purpose.'" 85 Fed. Reg. at 15,661.

127. In fact, the peer reviewers harshly criticized the design of FDA's quantitative studies, as well as FDA's decision-making process more broadly, along many of the same lines discussed above.

128. *First*, reviewers criticized the way in which FDA purported to assess consumer understanding in both studies. FDA's approach and chosen measures of understanding appeared to lack support in both existing research and theory. *See, e.g.*, Peer Review Report at 5 (Reviewer 1) (noting "the lack of an appropriate theoretical framework" for research and absence of a "rationale for including the other two primary aims and the four secondary aims"); *id.* at 23 (Reviewer 2) ("The lack of an overarching framework for and validity of the outcomes assessed makes it challenging to interpret results ….); *id.* at 43 (Reviewer 4) ("[T]he study needs greater levels of conceptual and empirical motivation …. "). Reviewers deemed FDA's approach "novel," "underdetermined," and akin to "*post-hoc rationalization*." *Id.* at 7 (Reviewer 1); *id.* at 12, 14 (Reviewer 2); *see also id.* at 25 (Reviewer 3) ("I am concerned that the measures deployed—perceived novelty and awareness—are not convincing measures of the underlying constructs that the research is targeting.").

129. *Second*, reviewers took particular issue with FDA's prioritization of certain outcomes and complete failure to test others:

- ***Arbitrary prioritization of "new information" and "self-reported learning"*** – Reviewers deemed FDA's apparent prioritization of the outcomes of "new information" and "self-reported learning" as "arbitrary," "not convincing," and "odd," among other things. *Id.* at 14 (Reviewer 2); *id.* at 25, 27 (Reviewer 3); *see also id.* at 12 (Reviewer 2) (noting "concerns about designating some measures as secondary without any theoretical or empirical justification"). Reviewers also noted the tension between FDA's focus on new

information and research regarding the believability of warnings, with one stating that "simply put, new is not necessarily acceptable; new is often less believable and that's borne out here." *Id.* at 28 (Reviewer 3); *see also id.* at 14 (Reviewer 2).

- ***Failure to assess warning credibility and factualness*** – Reviewers faulted FDA's final quantitative study for omitting consideration of whether the proposed warnings were believable or credible, noting that the issue was "crucially important" to understanding whether the warnings would be effective. *Id.* at 28 (Reviewer 3); *see also, e.g.*, *id.* at 27-30, 33; *id.* at 14 (Reviewer 2). One reviewer was confounded as to why FDA dropped the believability measure from the May 2019 quantitative study after testing it in the April 2018 quantitative study. *See id.* at 33-34 (Reviewer 3) ("What happened to believability?").
- ***Failure to assess actual measures of comprehension/recall*** – Reviewers noted that FDA's use of "self-reported" measures, as opposed to other "confirmed" measures, was another "limitation" of the studies. *Id.* at 21 (Reviewer 2); *see id.* at 28 (Reviewer 3).

130. *Third*, reviewers also did not understand how FDA incorporated the studies' results. *See id.* at 18 (Reviewer 2) ("Looking at the data for the revised statement on erectile dysfunction, for example, it generates more knowledge but lower thinking about risks and lower believability—which would recommend against its use."); *id.* at 19 ("[T]here is no justification for the selection of stimuli for Study 2."); *id.* at 33 (Reviewer 3) ("What led to the choices of the 16 given the results of the prior study? Why not stay with the original set? Why drop back to some of the previous warnings in the tested set? How do the texts developed from Study 1 play into the selections for Study 2? What did I miss?"); *id.* at 44 (Reviewer 4) ("The present study is linked to the former

study [in April 2018] but it does not appear as though the results of that former study were used to inform the stimuli choice in the present study.").

131. The peer reviewers' significant critiques came far too late for FDA to properly address them, as FDA acknowledged. FDA's Response to Peer Review Report 8 (Feb. 4, 2020), https://www.fda.gov/media/136887/download. FDA instead responded to the peer review report by adding a brief literature review, as well as other "clarifying details," to the study reports. 85 Fed. Reg. at 15,661. FDA published revised versions of the study reports along with the Final Rule. *Id.* FDA thus did not publicly disclose the final versions of its quantitative study reports, or the newly cited literature within them, during the notice-and-comment process. And FDA's surface-level revisions of the study reports could not rectify problems with the studies' design, execution, and failure to assess consumer comprehension and warning credibility.

b. Inapposite Studies of Different Graphic Warnings

132. FDA's other basis of support for its graphic warnings is scientific literature examining different graphic-health warnings, including "numerous non-U.S. studies" assessing the efficacy of graphic cigarette warnings. 84 Fed. Reg. at 42,763; *see id.* at 42,789-96. FDA cites the non-U.S. studies as supporting "the role of pictorial cigarette warnings in generally promoting understanding of the negative health consequences of smoking." 85 Fed. Reg. at 15,657. Yet only one of the four non-U.S. countries (Canada) mentioned in FDA's primary studies had pictorial warnings at the time. *See* Altria Cmt. 38-39. Further, those studies examined substantively different warnings and recognized that "[l]evels of effectiveness differ across countries, even for very similar health warnings." *Id.* at 38 (quoting Reference 39, Hammond 2011 at 334); *see* 84 Fed. Reg. at 42,762-65.

I. Fifth Circuit Litigation Involving the Final Rule

133. In April 2020, a group of plaintiffs—including cigarette manufacturer R.J. Reynolds—challenged FDA's Rule in the Eastern District of Texas on both First Amendment and Administrative Procedure Act (APA) grounds. The district court, with the FDA's initial approval, postponed the Rule's effective date nationwide while the court considered whether to vacate the Rule or grant FDA's motions to dismiss or for summary judgment.

134. In December 2022, the district court vacated FDA's Rule after concluding that FDA's graphic warnings violated the First Amendment, but did not address the plaintiffs' separate APA claims. *R.J. Reynolds Tobacco Co. v. FDA*, 2022 WL 17489170 (E.D. Tex. Dec. 7, 2022).

135. After the district court vacated FDA's Rule, FDA announced that "[p]ursuant to the [district] court order, any obligation to comply with a deadline tied to the effective date is … postponed." FDA, *Cigarette Labeling and Health Warning Requirements* (Dec. 9, 2022), https://tinyurl.com/4x22bvvm. In other words, FDA notified regulated parties that no company would be subject to the Rule while the district court's order remained in place.

136. In March 2024, the Fifth Circuit reversed the district court's decision. The Fifth Circuit held that FDA's Rule does not violate the First Amendment and remanded for the district court to consider the plaintiffs' claims that the Rule is arbitrary and capricious under the APA. *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863, 887-88 (5th Cir. 2024).

137. In August 2024, R.J. Reynolds and the other challengers filed a petition for certiorari in the Supreme Court seeking review of the Fifth Circuit's decision. *See R.J. Reynolds Tobacco Co. v. FDA*, S. Ct. No. 24-189. The Supreme Court denied the petition on November 25, 2024. *See id.* While the petition was pending, the Eastern District of Texas stayed further proceedings on the remaining APA claims pending the outcome. Order Staying Case, *R.J. Reynolds Tobacco Co. v. FDA*, No. 20-cv-00176 (E.D. Tex. June 26, 2024), ECF 116.

J. FDA's Disparate Implementation Timelines

138. FDA intends to begin enforcing the Rule in December 2025. Based on FDA's public statements in litigation, FDA remarkably appears poised to enforce the policy differently for different manufacturers, allowing some (such as R.J. Reynolds Tobacco Co.) to implement the warnings months after the rest of the industry (including PM USA) must do so. Distributors and retailers will thus also need to differentiate between cigarette brands as to whether some must include graphic warnings at one time to be lawfully distributed or sold while others will not. FDA's guidance provides the following notice:

> FDA intends to exercise enforcement discretion and generally not enforce requirements of the final rule for 15 months after the issuance of this guidance, until December 12, 2025. FDA also intends to exercise enforcement discretion and generally not enforce requirements of the final rule for an additional 30 days, until January 12, 2026, with respect to products manufactured before December 12, 2025. These time periods are consistent with section 201(b) of the Tobacco Control Act and the effective date of the final rule upon its publication. As FDA recommended at the time of publication of the final rule, FDA recommends that entities that do not already have approved cigarette plans submit such plans as soon as possible, but in any event within 5 months of the issuance of this guidance, by February 10, 2025. Early submission will facilitate timely FDA review.

Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements: Guidance for Industry at 3 (September 12, 2024), https://www.fda.gov/media/181776/download (footnote omitted). The FDA specifically identified this Guidance as "final." FDA, *Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements; Guidance for Industry; Availability*, 89 Fed. Reg. 74,831, 74,831 (Sept. 13, 2024); *see* FDA, *Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements: Guidance for Industry* (Sept. 2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-required-warnings-cigarette-packages-and-advertisements.

139. FDA, however, has separately announced that a different compliance timetable will apply to one major manufacturer, R.J. Reynolds Tobacco Co., as well as several other tobacco

manufacturers and retailers—those that sued FDA in the Eastern District of Texas. For simplicity, we refer to this entire group as "R.J. Reynolds." Specifically, FDA "agreed not to enforce the Rule" against R.J. Reynolds "during the pendency of the forthcoming proceedings before the Supreme Court" regarding R.J. Reynolds' challenge to the Final Rule "and for an additional period of fifteen months after the Supreme Court's disposition of the case in the event that the Court denies certiorari or, after granting certiorari, rules in favor of the government on the merits." Defendants' Status Report at 2-3, *R.J. Reynolds Tobacco Co. v. FDA*, No. 20-cv-00176 (E.D. Tex. June 21, 2024), ECF No. 115.

140. Based on the current litigation timetable, R.J. Reynolds will not have to comply with the Final Rule in December 2025. The Supreme Court denied R.J. Reynolds' petition on November 25, 2024. *See R.J. Reynolds Tobacco Co. v. FDA*, S. Ct. No. 24-189. The Rule will therefore not be enforced against the *R.J. Reynolds* plaintiffs until February 25, 2026.

141. FDA has declined to address the arbitrary consequences of its disparate enforcement policy, notwithstanding Altria's repeated efforts on behalf of PM USA to raise this problem to the agency.

142. On September 20, a week after the guidance was announced, Altria submitted a comment on behalf of PM USA to FDA objecting that the disparate enforcement timelines were arbitrary and risked misleading consumers. Altria Comment, Docket No. FDA-2024-D-3742 (Sept. 20, 2024), https://tinyurl.com/4zwhyfpz.

143. Despite Altria's efforts, FDA counsel did not address the arbitrariness of disparate enforcement timetables either. On September 26, Altria's Associate General Counsel emailed Mark Raza, FDA's Chief Counsel, to alert FDA to Altria's comment and the problems with FDA's

disparate timelines. Ex. 3 (Email from Kamran Khan to Mark Raza (Sept. 26, 2024)).[4] Mr. Raza acknowledged receipt but did not otherwise engage. Ex. 3 (Email from Mark Raza to Kamran Khan (Sept. 26, 2024)). On October 20, Altria's Associate General Counsel again reached out to FDA, describing the "urgency" for Altria "due to the fact that [it] is incurring significant costs based on the timelines." Ex. 3 (Email from Kamran Khan to Mark Raza (Oct. 20, 2024)). Two days later, FDA's Deputy General Counsel merely confirmed "FDA has received your letter. The agency has no further response at this time." Ex. 3 (Email from Julie Lovas to Kamran Khan (Oct. 22, 2024)).

144. Finally, on November 12, 2024, Altria's outside counsel informed FDA that Altria remained "very concerned that this disparate enforcement timetable is unlawful," and that "Altria also faces substantial immediate compliance costs." Ex. 3 (Email from Sarah Harris to Julie Lovas (Nov. 12, 2024)). Counsel for the FDA and the Department of Justice agreed to confer by phone on Monday, November 18, 2024. On the call, Altria's counsel explained the company's concerns and the urgent harms the company is facing. The government represented that FDA would continue to consider Altria's comment, and they had no further response.

CONCRETE AND PARTICULARIZED HARM

145. The Rule already has caused, and will continue to cause, several independent types of concrete and particularized harm to Plaintiffs and Plaintiff GACS' members.

146. *First*, the Rule's requirement that Plaintiffs add the required warnings to their packaging and advertising and display these images in their stores severely injures Plaintiffs because the Rule violates their rights or those of Plaintiff GACS' members under the First

[4] The relevant correspondence is reproduced as Exhibit 3 to this complaint.

Amendment and the APA. This harms Plaintiffs and Plaintiff GACS' members throughout the supply chain from manufacturers to distributors and retailers.

147. *Second*, the Rule will severely hamper Plaintiff PM USA's ability to distinguish and market its products. Plaintiff PM USA's packaging features distinctive logos, colors, and other identifying characteristics that appeal to and inform consumers. These identifying characteristics are central to Plaintiff PM USA's marketing efforts, especially in light of the significant restrictions on manufacturers' ability to market their products through other avenues. The Rule will force Plaintiff PM USA to remove these distinctive logos, colors, and other identifying characteristics from the top 50% of the front and rear panels of all packaging, which will force Plaintiff PM USA and distributors and retailers of its products, like Plaintiffs Stewart Distribution and Dhaliwal & Associates, and Plaintiff GACS' members, to remove their own speech and branded communications from that packaging to accommodate the warnings. The Rule will also prevent Plaintiffs PM USA and Dhaliwal & Associates, and Plaintiff GACS' members, from speaking: they will no longer be able to include promotional materials, including discounts and other offers, printed on the top portion of transparent plastic wraps covering the packages, because those promotional materials would obscure the warnings. In addition, the Rule will force Plaintiff retailer Dhaliwal & Associates and Plaintiff GACS' members to display the graphic warnings in their stores, which are likely to disturb and discourage customers.

148. Government regulations already significantly limit the available channels for Plaintiff PM USA to communicate its brand messaging. As a result, Plaintiff PM USA relies on its distinctive and visible packaging to market its products in retail locations, where cigarettes are required to be held in non-self-serve locations, generally behind store counters. Adult smokers of legal age thus cannot physically inspect Plaintiff PM USAs' products to make their purchasing

decision, unlike most other consumer goods. Plaintiff PM USA relies on its packaging's visible branding to market its products to adult smokers of legal age, inform potential customers that their product is available in a store or may carry discounts or other offers, and allow store clerks to easily identify which products are available and service adult smokers' requests. And the ability of Plaintiff Dhaliwal & Associates and Plaintiff GACS' members to market their own brand in their stores will be hampered as well, as it will be difficult to maintain a positive, family-friendly environment in the midst of the required graphic warnings.

149. In certain retail locations, the Rule's graphic warnings may obscure Plaintiff PM USA's distinctive branding from the view of consumers or salespeople. Cigarette fixtures in some stores have spring-loads along the bottom portion of the shelves, which automatically ensure that a new cigarette package replaces one that is removed from the shelves, but also covers part of the bottom portion of cigarette packaging. Often, the bottom portion of the cigarette packages are also covered by pricing information. The Rule will thus prevent PM USA from appealing to and informing consumers with its package design. And it will make Plaintiff Dhaliwal & Associates' stores and stores of GACS' members less customer friendly and more confusing as a result.

150. The Rule also will interfere with Plaintiff PM USA's ability to communicate with age-verified adult smokers aged 21 and over on its branded websites. Adult smokers aged 21 and over can access these websites after their age is verified by a third party and they affirm that they currently smoke cigarettes. The new graphic warnings—which will be in addition to the Department of Justice messages that already appear on Plaintiff PM USA brands' websites—may be fixed on the screen, so they will continue to cover the top portion of the screen even when a user scrolls through the websites. Those full-color, grotesque images may repel adult smokers attempting to learn more about Plaintiff PM USA's brands and products.

151. *Third*, FDA's graphic warnings would force Plaintiff PM USA to mislead consumers about the health risks associated with the cigarette products. The warnings cover less prevalent, or less fatal, conditions and outcomes while omitting many conditions and outcomes that are more prevalent, or more fatal. In so doing, the warnings give consumers a false sense of the relative risks and seriousness of smoking-related consequences. The warnings similarly mislead consumers by falsely suggesting that all of the covered health consequences, from head and neck cancer, to raised blood sugar, to erectile dysfunction, stand on equal footing. Finally, the warnings highlight health consequences that are rare or worst-case scenarios, which misleads consumers regarding the odds that they would face the covered outcomes. The warnings further hamper the ability of Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff GACS' members to create a trusted relationship with their consumers.

152. *Fourth*, Plaintiffs and Plaintiff GACS' members will suffer the loss of customer goodwill. FDA's disparate enforcement will force PM USA to include the Rule's gruesome and off-putting images, which would squander goodwill for Plaintiff PM USA's cigarette products without accurately informing consumers of the relative risks of the health-related harms that FDA has chosen to highlight. Plaintiffs Stewart Distribution and retailers like Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff GACS' members will be forced to ensure that these warnings are present on packages involving PM USA cigarettes and those of other companies not subject to the *R.J. Reynolds* plaintiffs' disparate enforcement timeline.

153. *Fifth*, the Rule will impose substantial and onerous compliance costs, which Plaintiffs and Plaintiff GACS' members already have started incurring:

- Plaintiff PM USA must overhaul its packaging and processes in order to comply with the Rule's requirements, including the random-and-equal display requirements.

- Plaintiff PM USA must spend tens of millions of dollars during the 15-month implementation period to procure and retool printing materials, as well as print compliant packaging, in time to comply with the Final Rule's enforcement date. Plaintiff PM USA has already begun incurring these costs, which will only grow during the implementation period. In order to meet the Rule's effective date, Plaintiff PM USA must complete this process, and make those expenditures beginning now so they can begin printing compliant packaging while they are also printing the current packaging.
- Plaintiff PM USA must deploy significant resources during the implementation period to redesign its websites and other advertisements to display the Final Rule's required warnings.
- Plaintiffs Stewart Distribution and Dhaliwal & Associates and Plaintiff GACS' members must prepare to cease distributing and selling, respectively, cigarettes with the old, text-based warnings and will incur unrecoverable costs for any cigarettes that do not include graphic warnings. Retailers like Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff GACS' members must alter display cases for cigarettes to avoid obscuring the graphic warnings and remove advertising that does not include the graphic warnings.

154. FDA's disparate timeline has also already has caused, and will continue to cause, several independent types of concrete and particularized harm to Plaintiffs and Plaintiff GACS' members.

155. *First,* FDA's disparate enforcement timelines destroy the Rule's asserted aim of educating consumers and exacerbate First Amendment problems by misleadingly conveying that certain cigarettes manufactured by R.J. Reynolds are somehow safer than PM USA's products.

156. *Second,* FDA's disparate enforcement timelines harm Plaintiffs PM USA and retailers like Plaintiff Dhaliwal & Associates' stores and the stores of Plaintiff GACS' members by forcing them to confuse the very customers they aim to serve. Forcing Plaintiffs and Plaintiff GACS' members to participate in consumer confusion erodes consumers' trust in Plaintiffs and Plaintiff GACS' members and harms their relationship with their customers.

157. *Third,* Plaintiff PM USA anticipates they will have to spend significant resources to correct these consumer misapprehensions. Educating consumers about why they are witnessing the disparate warnings will likely be a substantial burden. And Plaintiff PM USA anticipates devoting significant resources to minimize the damage to their brands and consumer relationships caused by the inevitable confusion.

158. *Fourth,* Plaintiff PM USA anticipates the disparate enforcement timelines will harm sales. Sales of PM USA brands will be harmed because PM USA will be forced to bear the graphic warnings while other brands do not. Many consumers are likely to view cigarettes that bear the graphic warnings as more harmful to their health, and switch to brands that do not bear the warnings.

COUNT ONE

The Rule Violates the Tobacco Control Act and 5 U.S.C. § 706(2)(C)

159. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-158 of this Complaint, as though fully set forth herein.

160. In promulgating the Rule, FDA exceeded its statutory authority by mandating 11 warnings when the text of the TCA only specifies 9 warnings and does not vest FDA with the discretion to promulgate an additional number of warnings.

161. FDA exceeded its statutory authority to only "adjust the … text of" the TCA mandated warning statements, and even that only if the agency "finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2].

162. Far from merely adjusting the TCA statements, FDA engaged in wholesale rewrites, jettisoning some warnings entirely, establishing new ones, and transforming others. For example, the TCA warnings about addictiveness and the benefits of quitting disappeared. The Rule's warnings about amputation, blindness, diabetes, and erectile dysfunction sprung out of thin air. And the TCA's "Cigarettes cause cancer" warning morphed into two different warnings in the Rule: "Smoking causes bladder cancer, which can lead to bloody urine" and "Smoking causes head and neck cancer."

163. Moreover, FDA made those changes without making the statutorily required finding that each change improves consumer understanding. In fact, FDA's studies failed to assess had to test whether its warnings better helped the public comprehend the risks of tobacco than the TCA's warnings. Instead, FDA tested whether information was new to consumers and whether they had learned something new by viewing the warnings.

164. FDA also independently violated the TCA by failing to ever engage in a head-to-head comparison between each of its new warnings and the three TCA warnings it discarded.

165. Plaintiffs seek the entry of a judgment declaring the Rule unlawful and vacating the Rule and remanding to FDA, as well as a preliminary delay of the Rule's effective date or a preliminary injunction enjoining the current effective date of FDA's Rule allowing Plaintiffs and Plaintiff GACS' members to continue using, selling, and distributing cigarettes in current

packaging and using current advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT TWO

The Rule Violates 5 U.S.C. § 706(2)(A)

166. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-165 of this Complaint, as though fully set forth herein.

167. In promulgating the Rule, FDA acted arbitrarily and capriciously by attempting to justify the Rule (and its rejection of alternatives to the Rule) on grounds that were not adequately explained, or were illogical, contradictory, and without support in the regulatory record, and by failing to demonstrate adequate consideration of important aspects of the graphic-warnings issue.

168. FDA irrationally chose to showcase "less-known health consequences of smoking" in its chosen warnings. *See* 85 Fed. Reg. at 15,640. Moreover, FDA failed to explain how it chose the particular health consequences to feature over others, isolating four new risks with the health consequences Congress singled out in the TCA.

169. FDA arbitrarily assessed consumer understanding, including failing to assess comprehension and relying on irrational "new information" and "self-learning" metrics. FDA did so only after its studies revealed that its warnings performed poorly on other important aspects of understanding.

170. FDA's actions in advancing and finalizing its chosen warnings was irrational considered against the results of FDA's studies, which indicated that the warnings were not new information, were not credible, or were incomprehensible to consumers. The quantitative studies were themselves methodologically unsound, and FDA itself has disavowed the utility of its qualitative studies. Methodological flaws aside, FDA's internal studies do not support its

conclusions about the efficacy of the warnings, but instead demonstrate that many of the warnings do not alter consumers' beliefs regarding the health consequences of smoking.

171. FDA failed to adequately address evidence that graphic warnings backfire by prompting consumers generally, and smokers in particular, to avoid the warnings out of fear or disgust. FDA acknowledges that its images may "concern[]" "some viewers," *id.* at 15,670, but claims it "did not design the required warnings to evoke negative emotions," *id.* at 15,663. Yet FDA's internal studies repeatedly indicated that participants found the warning images to be frightening, disgusting, or disturbing, and FDA adopted study recommendations aimed at heightening the images' emotional appeal.

172. Plaintiffs seek the entry of a judgment declaring the Rule unlawful and vacating the Rule and remanding to FDA, as well as a preliminary delay of the Rule's effective date or a preliminary injunction enjoining the current effective date of FDA's Rule allowing Plaintiffs and Plaintiff GACS' members to continue using, selling, and distributing cigarettes in current packaging and using current advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT THREE

The Rule Violates 5 U.S.C. §§ 553(b)(3) and (c) and § 706(2)(D)

173. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-172 of this Complaint, as though fully set forth herein.

174. In promulgating the Rule, FDA failed to provide Plaintiffs with meaningful notice and opportunity to comment as required under 5 U.S.C. §§ 553(b)(3) and (c), by failing to disclose key technical data, methodologies, and assumptions underlying the Rule. *See supra* Factual Allegations Sections D–J (¶¶ 49-144).

175. Plaintiffs seek the entry of a judgment declaring the Rule unlawful and vacating the Rule and remanding to FDA, as well as a preliminary delay of the Rule's effective date or a preliminary injunction enjoining the current effective date of FDA's Rule allowing Plaintiffs and Plaintiff GACS' members to continue using, selling, and distributing cigarettes in current packaging and using current advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT FOUR

The Rule Violates the First Amendment

176. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-175 of this Complaint, as though fully set forth herein.

177. The Rule's size-and-placement regulations—requiring that the government's messages occupy 50% of the front and rear panels of packages and 20% of advertisements—alone violate the First Amendment.

178. Government-compelled disclosures cannot be "unjustified or unduly burdensome," a standard that requires that a disclosure extend "no broader than reasonably necessary." *NIFLA*, 585 U.S. at 776 (citations omitted); *accord NetChoice*, 34 F.4th at 1230.

179. By commandeering 50% of cigarette packaging and 20% of cigarette advertising, the Rule "drowns out" Plaintiffs' "own message[s]" and the messages of Plaintiff GACS' members about their lawful products or lawful products they sell and distribute. *NIFLA*, 585 U.S. at 776. Circuit courts have held that even government-compelled warnings that occupied some 10% of product packaging and 20% of advertisements, respectively, were unduly burdensome. *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 & n.13 (7th Cir. 2006); *Am. Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749, 753-54, 757 (9th Cir. 2019) (en banc).

180. FDA has failed to show that the Rule's size-and-placement requirements are "no broader than reasonably necessary." *NIFLA*, 585 U.S. at 776 (citation omitted). For that reason, the Rule's regulation of speech is unduly burdensome and thus unlawful under *Zauderer*.

181. A fortiori, the Rule's size-and-placement requirements are "more extensive than necessary" to further FDA's stated consumer-education interest, and thus fail intermediate scrutiny too. *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 142 (1994).

182. Contrary to FDA's assertion, the Rule also falls outside the *Zauderer* framework because the Rule's warnings are not "purely factual and uncontroversial" commercial disclosures. *NIFLA*, 585 U.S. at 768 (citation omitted). The Rule's warnings are not "purely factual" because they are misleading; they convey information regarding the relative risks, prevalence, and severity of the warned-against health consequences that is subject to misinterpretation by consumers. Speech that could mislead the public is neither purely factual nor uncontroversial under *Zauderer*. *See Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1280-81 (9th Cir. 2023); *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 847 (9th Cir. 2019); *R.J. Reynolds*, 696 F.3d at 1213-17.

183. Further, the warnings are not pure attempts to convey information to consumers; they are intended to evoke an emotional response or shock consumers into retaining any information conveyed, all in furtherance of the government's anti-smoking message. *See R.J. Reynolds*, 696 F.3d at 1216.

184. And the Rule's sensationalist warnings are not "uncontroversial" because they feature disturbing, shocking, and gory images that are far from non-ideological.

185. The Rule falls outside the *Zauderer* framework for the additional reason that *Zauderer* is limited to disclosures "related to the State's interest in preventing deception of

consumers." *NetChoice*, 34 F.4th at 1230 (citation omitted); *see also Dwyer v. Cappell*, 762 F.3d 275, 282-83 (3d Cir. 2014); *Allstate Ins. Co. v. Abbott*, 495 F.3d 151, 166 (5th Cir. 2007); *Ent. Software Ass'n*, 469 F.3d at 652; *United States v. Wenger*, 427 F.3d 840, 849-50 (10th Cir. 2005); *cf. Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996) (explaining *Zauderer* identified disclosure requirements "reasonably related to the State's interest in preventing deception of consumers"); *but see Am. Meat Inst.*, 760 F.3d at 23. But the current Surgeon General's warnings do not deceive consumers. And FDA "has not shown that the graphic warnings were designed to correct any false or misleading claims made by cigarette manufacturers," *R.J. Reynolds*, 696 F.3d at 1216.

186. The Rule's warnings are also fall outside the *Zauderer* framework because they are "unduly burdensome." *NIFLA*, 585 U.S. at 768 (citation omitted). The warnings are not "reasonably necessary" to advance the government's asserted consumer-education goal, let alone operate "no broader than reasonably necessary," *id.* at 776 (citations omitted), given the warnings' unnecessary size and the fact that the inflammatory graphic images convey no meaningful health information beyond the text of the warnings.

187. Because the Rule falls outside the *Zauderer* framework, the Rule must satisfy a higher level of scrutiny.

188. The Rule's disturbing, gratuitous graphic warnings are subject to strict scrutiny because the Rule discriminates based on the content of the speech and the speaker. Accordingly, the Rule is "presumptively unconstitutional," and may be justified "only if the government proves [it] is narrowly tailored to serve compelling state interests." *NIFLA*, 585 U.S. at 776 (citation omitted). FDA has not attempted, and cannot make, such a showing.

189. At a minimum, FDA must satisfy intermediate scrutiny and show that the Rule "is narrowly drawn to further a substantial governmental interest … unrelated to the suppression of free speech," meaning that the Rule must be "no greater than is essential to the furtherance of [FDA's] interest." *NetChoice*, 34 F.4th at 1227 (citation omitted). It cannot do so for multiple reasons.

190. *First*, FDA's informational interest is circular. FDA disavows that its Rule will affect consumer behavior or health outcomes. Rather, FDA supports the Rule by asserting an interest in "more effective[ly]" educating consumers. *E.g.*, 85 Fed. Reg. at 15,654. But that interest, without more, is far too unconnected to public health outcomes and circular to qualify as substantial. The Eleventh Circuit has rejected out of hand the government's attempt to commandeer even a five-second portion of a thirty-second television advertisement "for its general education message." *Tillman v. Miller*, 133 F.3d 1402, 1403-04 & n.4 (11th Cir. 1998). FDA's consumer-education interest impermissibly reflects distrust of consumers' ability to make choices without the government's sensationalized messages.

191. *Second*, FDA's Rule does not directly and materially advance its asserted consumer-education interest. Here, FDA did not even purport to assess whether consumers better comprehend risks after viewing FDA's graphic warnings. Moreover, several of FDA's graphic warnings relate to health conditions about which the public is well aware, and many did not meaningfully alter health beliefs after repeated exposure. FDA's own studies also indicate that FDA's chosen images were unhelpful, confusing, off-putting, or unclear to viewers.

192. *Third*, FDA cannot show that the Rule's speech restrictions are no more extensive than necessary to further its asserted consumer-education interest. Requiring enormous, shocking images is not a narrowly tailored restriction, and the size of the warnings further drowns out

Plaintiffs' own speech and the speech of Plaintiff GACS' members. FDA cannot significantly burden Plaintiffs' speech and the speech of Plaintiff GACS' members when other less-speech-restrictive alternatives—such as smaller warnings, text-only warnings, and public-education campaigns—abound.

193. Plaintiffs have no adequate remedy at law.

194. Plaintiffs seek the entry of a judgment declaring the Rule unconstitutional as applied to Plaintiffs and vacating the Rule and remanding to FDA, as well as a preliminary delay of the Rule's effective date or a preliminary injunction enjoining the current effective date of FDA's Rule allowing Plaintiffs and Plaintiff GACS' members to continue using, selling, and distributing cigarettes in current packaging and using current advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT FIVE

The Tobacco Control Act's Graphic-Warnings Requirement Violates the First Amendment

195. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-194 of this Complaint, as though fully set forth herein.

196. The Tobacco Control Act directs FDA to issue a graphic-warnings rule that purports to require that graphic warnings occupy "the top 50 percent of the front and rear panels" of cigarette packages and "at least 20 percent" of the top of advertisements. 15 U.S.C. § 1333(a)(2), (b)(2).

197. Congress set forth no findings of fact or justification regarding the need to burden that much speech.

198. The TCA's requirements as to the size and placement of the graphic warnings violate the First Amendment by unduly burdening Plaintiffs' speech about their lawful products,

and the speech of Plaintiffs and Plaintiff GACS' members about lawful products they sell and distribute.

199. Plaintiffs have no adequate remedy at law.

200. Plaintiffs seek entry of a judgment declaring the TCA's size-and-placement requirements unconstitutional, and permanently enjoining Defendants from enforcing them.

COUNT SIX

The Rule Violates 5 U.S.C. § 706(2)(B)

201. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-200 of this Complaint, as though fully set forth herein.

202. In promulgating the Rule, FDA acted contrary to constitutional right, power, privilege, or immunity because the Rule violates Plaintiffs' rights and those of the Plaintiff GACS' members under the First Amendment.

203. Plaintiffs therefore seek an order vacating the Rule under 5 U.S.C. § 706(2)(B), and remanding to FDA, as well as a preliminary delay of the Rule's effective date or a preliminary injunction enjoining the current effective date of FDA's Rule and allowing Plaintiffs and Plaintiff GACS' members to continue using, selling, and distributing cigarettes in current packaging and using current advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT SEVEN

Declaratory Judgment That the Effective Dates in the Tobacco Control Act Do Not Come Into Effect Until FDA Issues a Legally Valid Rule

204. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-203 of this Complaint, as though fully set forth herein.

205. Under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, this Court has the power to declare the rights and legal relations of Plaintiffs and Defendants with respect to Plaintiffs' obligations under the Rule.

206. The TCA mandates that the new textual and graphic warnings become effective "15 months after the issuance of the regulations" establishing the graphic-warnings requirements. TCA § 201(b), 15 U.S.C. § 1333 note.

207. The Tobacco Control Act thus contemplates a single implementation date for the new textual and graphic warnings, which prevents manufacturers like Plaintiff PM USA from having to completely revamp their packaging and advertisements multiple times, and Plaintiffs and Plaintiff GACS' members from having to discard products they sell and distribute, reorganize their stores, etc. The effective date then is conditioned on FDA's "issuance" of a graphic-warnings rule that does not offend the First Amendment and that adheres to the procedural requirements of the APA. Forcing Plaintiffs and Plaintiff GACS' members to comply with an invalid Rule would have substantial and detrimental legal effect.

208. An actual controversy of sufficient immediacy exists between the Parties as to whether FDA has promulgated a valid rule under the TCA and whether Plaintiffs and Plaintiff GACS' members are obligated to comply with the Rule's mandates. Indeed, the Rule already threatens Plaintiffs' constitutional and statutory rights, and those of Plaintiff GACS' members, and imposes mounting implementation costs on Plaintiffs and Plaintiff GACS' members.

209. Plaintiffs accordingly seek a declaration that the new textual and graphic warnings for cigarette packaging and advertising required in section 201(a) of the TCA, and the related requirements of the TCA, shall become effective as to Plaintiffs and Plaintiff GACS' members 15

months after the issuance by FDA of regulations (as required by section 201(a) of the TCA) that are permissible under the United States Constitution and federal law.

210. Plaintiffs seek an order enjoining Defendants from enforcing against Plaintiffs and Plaintiff GACS' members in this case the new textual and graphic warnings for cigarette packaging and advertising required in section 201(a) of the TCA until 15 months after the issuance by FDA of regulations (as required by section 201(a) of the TCA) that are permissible under the Constitution and federal law.

COUNT EIGHT

FDA's Disparate Implementation Timeline for Different Manufacturers Violates 5 U.S.C. § 706(2)(A)-(B)

211. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-210 of this Complaint, as though fully set forth herein.

212. In creating disparate enforcement timelines for different manufacturers and retailers, FDA acted arbitrarily and capriciously on grounds that were not adequately explained, or were illogical, contradictory, and without support in the regulatory record, and by failing to demonstrate adequate consideration of the effects of the disparate enforcement timelines.

213. There is no logical reason for having different compliance periods for different manufacturers and retailers, particularly when litigation related to these requirements is unresolved. Especially so when the Rule treats everyone's cigarettes as equally likely to cause the identified health risks. FDA never provided any explanation for why it is treating similarly situated parties differently.

214. As of December 2025, cigarettes manufactured by R.J. Reynolds—about 45% of all cigarettes—would continue to display the old, text only warnings on their packaging and advertisements. But for the remaining 55% of the market, manufacturers' cigarettes would have

to display the new graphic warnings in packaging and advertisements. The same pattern would repeat for retailers, with those who were parties to the Eastern District of Texas litigation displaying the old text-only warnings while others must display the new graphic ones.

215. This arbitrary disparity in warnings would exacerbate the Rule's First Amendment problems and make a mockery of FDA's sole asserted interest in educating consumers. Many consumers would logically (and wrongly) assume that cigarette brands without graphic warnings were in some way better or safer. Those disparities would plainly confuse consumers, who would be perplexed as to why only some cigarette brands had new, graphic warnings but others did not. Concerningly, many consumers would logically (and wrongly) assume that cigarette brands without graphic warnings were in some way better or safer. And Plaintiffs and Plaintiff GACS' members would be forced to communicate this misleading message.

216. Pending final judgment, Plaintiffs seek a preliminary order delaying the Rule's enforcement against Plaintiffs and Plaintiff GACS' members or a preliminary injunction against the rule preventing Defendants from enforcing the Rule against Plaintiffs and Plaintiff GACS' members until the Rule is enforceable against R.J. Reynolds and the other parties to the Eastern District of Texas litigation. Plaintiffs also seek vacatur or a permanent injunction of FDA's enforcement guidance.

PRAYER FOR RELIEF

An actual controversy exists between the parties that entitles Plaintiffs and Plaintiff GACS' members to prospective relief.

WHEREFORE, Plaintiffs pray that this Court:

(A) Enter a judgment declaring that the Rule violates the TCA and APA and vacating the Rule and remanding to FDA;

(B) Enter a judgment declaring the Rule to be an unconstitutional abridgement of the First Amendment and vacating the Rule and remanding to FDA;

(C) Enter a judgment declaring the TCA's size-and-placement requirements to be an unconstitutional abridgement of the First Amendment and permanently enjoining Defendants from enforcing the requirements;

(D) Enter a judgment declaring that the new textual and graphic warnings for cigarette packaging and advertising shall not become effective until 15 months after FDA issues regulations that are constitutionally permissible and that are promulgated in compliance with federal law;

(E) Enter an order postponing the Rule's effective date and allowing Plaintiffs and Plaintiff GACS' members to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on their claims;

(F) Enter a preliminary injunction enjoining the Rule's effective date and allowing Plaintiffs and Plaintiff GACS' members to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on their claims;

(G) Enter an order enjoining enforcement of the Rule or postponing the Rule's effective date or such that the rule will not be enforced on a disparate timeline;

(H) Enter an order vacating or enjoining FDA's enforcement guidance.

(I) Grant Plaintiffs such additional or other relief as it deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

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Respectfully submitted,

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