IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA INC.,
6601 West Broad Street
Richmond, VA 23230

SHERMAN GROUP HOLDINGS, LLC,
10 Sterling Boulevard
Englewood, NJ 07631

Plaintiffs,

v. Case No.: _____

UNITED STATES FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue S.W.
Washington, D.C., 20201

STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration,
10903 New Hampshire Avenue
Silver Spring, MD 20993

ALEX AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services,
200 Independence Avenue S.W.
Washington, D.C., 20201

Defendants.

COMPLAINT

INTRODUCTION

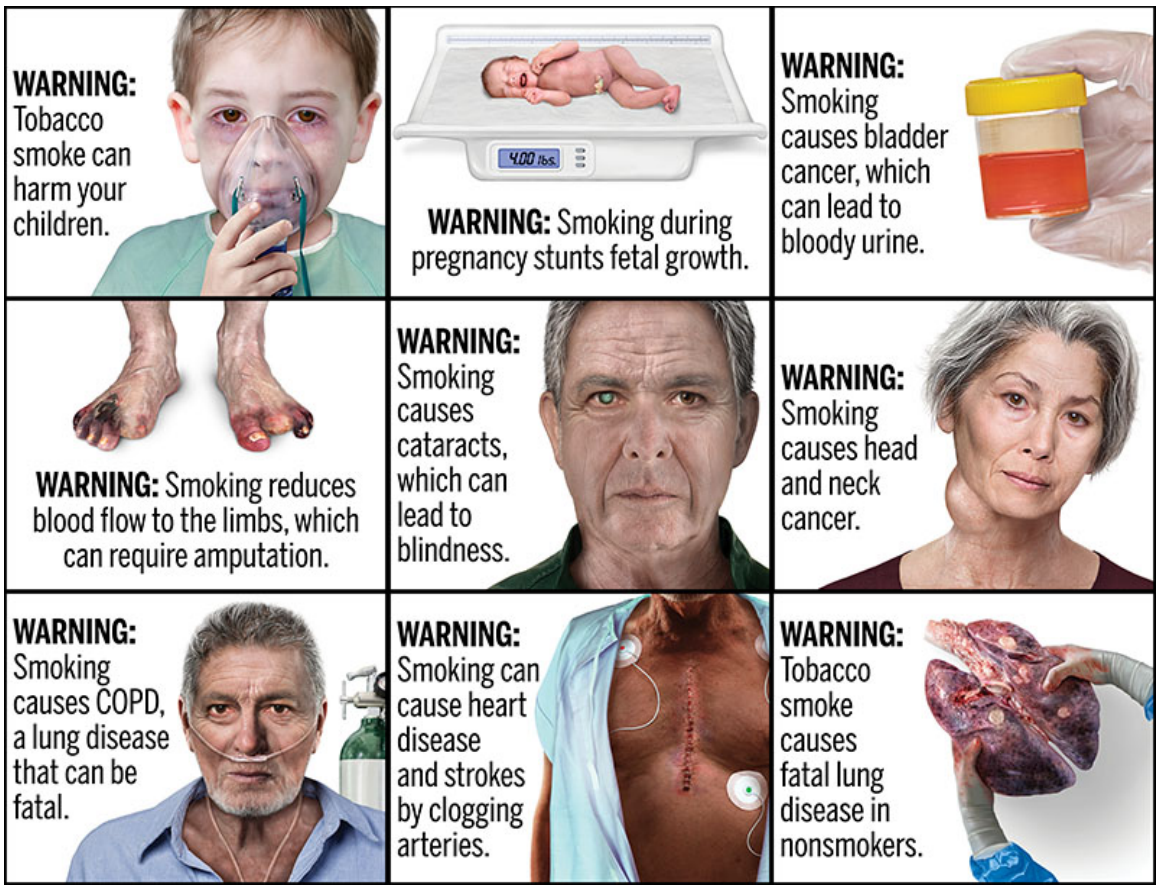
1. In 2011, the United States Food and Drug Administration ("FDA") issued an unprecedented rule compelling cigarette manufacturers to feature massive graphic warnings on their packaging and advertisements. Cigarette packaging and advertisements have long featured text-only Surgeon General's warnings about the health consequences of smoking. But FDA's 2011 rule represented a sea change in FDA's regulatory approach. FDA promulgated that 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. The TCA grants FDA some discretion to modify the text of proposed warning statements and to pick its own accompanying color images. But FDA chose to implement that statutory mandate by requiring manufacturers to display provocative images—such as a wailing baby in an incubator and bloodied organs taken out of a body—in an attempt to scare or disgust consumers and deter them from buying cigarettes.

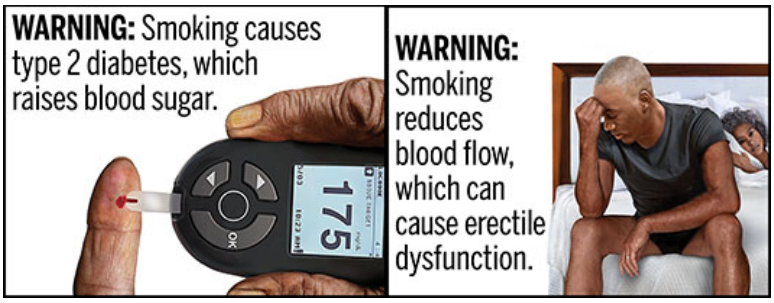
2. A court in this district enjoined FDA's novel graphic-warnings rule before it could take effect, and the D.C. Circuit struck down the rule as an unlawful regulation of manufacturer speech. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). The D.C. Circuit held that the First Amendment barred FDA from requiring manufacturers to disparage their own products with shocking and inflammatory graphic images that did not directly and materially advance FDA's asserted interest in reducing smoking rates. Any graphic-warnings regime FDA imposes, the court explained, must comply with the First Amendment's restrictions on compelled government speech.

3. In the ensuing years, FDA acknowledged that developing a new graphic-warnings rule presented significant legal and conceptual challenges given the novelty of the undertaking. A

federal district court in the District of Massachusetts, however, issued an injunction requiring FDA to promulgate a new rule on an expedited, court-ordered schedule that FDA opposed. The court's prescribed schedule required FDA to issue a final rule by March 15, 2020, 20 months less than the minimum time FDA considered necessary. The extraordinarily rushed process that followed compromised the rulemaking process, as well as FDA's reasoning and results.

4. On March 18, 2020, FDA issued its second attempt at a graphic-warnings rule. *See Rule on Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (to be codified at 21 C.F.R. pt. 1141) (the "Rule"). FDA's Rule would revolutionize cigarette packaging and advertising by forcing manufacturers to prominently emblazon the following 11 graphic warnings on all packaging and advertisements:





5. FDA's graphic warnings would occupy an unprecedented amount of premium real estate on packaging and advertising. Manufacturers must dedicate at least the top 50% of the front and back of all cigarette packaging and the top 20% of all cigarette advertising to the warnings. Plaintiffs know of no other government-mandated disclosure regime that has ever attempted to seize so much speech, let alone to seize the most prominent and visible locations on packaging and advertising for the government's messages.

6. Satisfying the Rule will require manufacturers to overhaul their packaging, advertising, and printing processes. Further, the Rule compels manufacturers to rotate the warnings to ensure "random" and "equal" distribution on their packaging, and rotate the warnings quarterly across all advertising. FDA also requires manufacturers to submit implementation plans for pre-approval. The Rule gives manufacturers only until June 18, 2021, to accomplish these major changes; after that, manufacturers cannot introduce or advertise any cigarette products that do not comply with an FDA-approved implementation plan for featuring FDA's graphic warnings to FDA's specifications. Plaintiffs already had to submit an implementation plan and begin work—at significant expense—to avoid the risk that FDA will bar their products from the market.

7. FDA's new Rule is profoundly unlawful. To start, the Rule violates the First Amendment under any standard of scrutiny. Even apart from the warnings' content, the Rule's (and the TCA's) size and placement requirements place an unwarranted burden on manufacturer speech that FDA has come nowhere close to justifying. The provocative, inflammatory content of

FDA's warnings aggravates the First Amendment problems. The Rule operates as a content-, speaker-, and viewpoint-based restriction by forcing manufacturers to promote the government's anti-smoking messages, which bear no resemblance to purely factual or uncontroversial information. FDA's marginal interest in more effectively educating consumers about less-known health risks of smoking is insufficient to justify a regime that forces manufacturers to carry messages aimed at pushing away their own customers. The Rule independently violates the First Amendment because FDA's warnings would mislead consumers about the relative risks of smoking-related health consequences, and the government has no interest in such misinformation. And by prohibiting manufacturers from selling or advertising their products without FDA pre-approval of manufacturers' plans for implementing the warnings regime, the Rule operates as an unlawful prior restraint.

8. FDA's rulemaking is also replete with Administrative Procedure Act ("APA") violations. *See* 5 U.S.C. §§ 551-559, 701-706. FDA has thwarted meaningful notice and comment by refusing to adequately explain or disclose critical decisions and underlying data, leaving stakeholders and the public in the dark as to the validity of FDA's choices. The TCA prescribes 9 textual warnings as the default and requires FDA to justify departures from those formulations. FDA's new Rule diverges from those warnings and features a hodgepodge of 11 health consequences, including several the TCA does not mention, such as erectile dysfunction and amputation. 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. FDA apparently pre-selected all of those health consequences at the outset of its rulemaking and never considered featuring different consequences no matter how badly its proposed warnings performed in ensuing studies. Yet FDA has never explained why

or how it picked these health consequences, as opposed to other smoking-related conditions that are more prevalent or more fatal. Further, FDA failed to timely disclose the internal studies it relied on to craft its graphic warnings, has yet 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 rulemaking violates the APA in other respects as well. FDA's only evidence about the effectiveness of its specific warnings comes from the qualitative and quantitative studies FDA undertook as part of the rulemaking. But even the incomplete data FDA has disclosed about those studies indicts FDA's conclusion that its chosen warnings would advance FDA's asserted aim of improving consumer education. As the highly critical peer review of FDA's studies underscores, FDA repeatedly ignored study feedback that the graphic warnings were not new information, were not believable, or were unclear or confusing. Several of FDA's chosen warnings performed dismally in FDA's quantitative studies, even after the flawed design of those studies stacked the deck in FDA's favor. FDA's only other evidentiary support for the Rule relates to different warning regimes in foreign countries—the very type of inapposite, non-U.S. data FDA has questioned in other contexts. FDA also failed to adequately consider important aspects of the graphic-warnings issue, including why less-burdensome text-only or smaller graphic warnings would not equally advance FDA's consumer-education aims and the significant implementation problems the Rule creates. Finally, FDA unlawfully promulgated 11 warnings when the TCA authorizes only 9.

10. Plaintiffs thus respectfully request that this Court: (1) declare that the Rule and the TCA violate the First Amendment, (2) declare that the Rule violates the APA and the TCA, (3) preliminarily enjoin Defendants from enforcing the Rule's new textual and graphic warnings

for cigarette packaging and advertising until 15 months after a decision on the merits, (4) enjoin the TCA's size and placement requirements, and (5) vacate the Rule in its entirety.

PARTIES

11. Plaintiff Philip Morris USA Inc. ("PM USA") 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. PM USA is a signatory to the 1998 Master Settlement Agreement ("MSA") between various tobacco companies and 46 states, the District of Columbia, and five U.S. territories, and which applies to the other 4 states through separate agreements. *See* MSA (Nov. 23, 1998), https://tinyurl.com/yx63uks6.

12. Plaintiff Sherman Group Holdings, LLC ("Nat Sherman") is a Delaware corporation with corporate offices in Englewood, New Jersey. Founded in New York City in 1930, Nat Sherman sells super-premium cigarettes and cigars under brand names including Classic, MCD, and Originals (cigarettes), as well as Timeless, Metropolitan, and Epoca (cigars). Nat Sherman's super-premium cigarette products are manufactured in Greensboro, North Carolina. Nat Sherman is also a signatory to the MSA.

13. 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 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.

14. Defendant HHS is a federal agency of the United States. Under the TCA and the 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.

15. Defendant Dr. Stephen M. Hahn is the Commissioner of FDA. Commissioner Hahn oversees the implementation and day-to-day enforcement of the Rule. Plaintiffs sue Commissioner Hahn in his official capacity.

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

JURISDICTION AND VENUE

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

18. Venue is proper in this district under 28 U.S.C. § 1391(e) because at least one defendant resides in this district and a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred here.

19. An actual controversy currently exists between the parties concerning the constitutionality and legality of the Rule. That controversy is justiciable: Plaintiffs already are suffering injury, and speedy relief is necessary to preserve Plaintiffs' rights.

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

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

FACTUAL ALLEGATIONS

A. Federal Warnings Requirements for Cigarettes

22. Federal law recognizes the lawfulness of selling cigarettes, but has long required manufacturers to relay factual, text-only warnings developed by the Surgeon General concerning smoking-related health risks. The 1965 Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965), required cigarette packaging and advertising to state: "Caution: Cigarette Smoking May Be Hazardous to Your Health." A few years later, Congress amended the warning statement to read: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87.

23. 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."

24. 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 explains, 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.

25. 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 regime that seizes significant portions of manufacturers' packaging and advertising for the display of government-generated graphic health warnings.

26. The TCA first mandates 9 new textual warning statements covering 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).

27. 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 that rulemaking authority to FDA.

28. The TCA vests FDA with authority to alter certain aspects of the graphic-warnings requirements. Section 202(b) permits FDA, acting 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." 15 U.S.C. § 1333(d)[2].

29. 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 consider the First Amendment implications of that mandate, nor include any findings regarding the need for those size and placement requirements in the statute.

30. The TCA also requires manufacturers to "randomly display[]" the graphic warnings on their 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 manufacturers' advertisements. *Id.* § 1333(c)(2). Before manufacturers may sell or advertise cigarettes, FDA must pre-approve manufacturers' plans for implementing the TCA's random-and-equal and quarterly rotation requirements. *Id.* § 1333(c)(1)-(2).

[1] There are two subsections designated (d) in the statute. 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.

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

B. Further Restrictions on Tobacco Advertising and Sales

32. Federal warnings requirements are just one of many types of restrictions on how cigarette manufacturers may market their products. Since 1971, federal law has severely limited the channels by which cigarette manufacturers may advertise their products. For instance, federal law criminalizes advertising cigarettes on television or the radio. *See id.* § 1335. Federal law also bans manufacturers from engaging in other promotional efforts, such as distributing or selling promotional items bearing their brand names or other product identification. *See* 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34.

33. In addition, since November 1998, many cigarette manufacturers, including Plaintiffs, have been parties to the MSA 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* MSA § III.

34. The 2009 TCA imposed many additional advertising restrictions. For example, it prevents cigarette manufacturers 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 from marketing cigarettes with any other product regulated by FDA. 21 U.S.C. § 321(rr)(4). The TCA further allows federal agencies, states, and Indian tribes to adopt 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)).

35. Together, the restrictions significantly limit the manner and means by which Plaintiffs and other cigarette manufacturers may market their products to consumers.

C. FDA's Vacated 2011 Graphic-Warnings Rule

36. 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) (the "2011 Rule"). 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.

37. 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. *See supra* ¶ 26. FDA set out to create "attention-grabbing" graphic warnings that would make viewers feel "depressed, discouraged, and afraid" to buy cigarettes. 76 Fed. Reg. at 36,638, 36,654. The 2011 graphic 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*, 696 F.3d at 1212 (citation omitted).

38. R.J. Reynolds Tobacco Company and other manufacturers challenged the 2011 Rule on First Amendment and APA grounds. This Court preliminarily enjoined the rule in November 2011, *R.J. Reynolds Tobacco Co. v. FDA*, 823 F. Supp. 2d 36 (D.D.C. 2011), and set aside the rule on First Amendment grounds in February 2012, 845 F. Supp. 2d 266 (D.D.C. 2012). The D.C. Circuit affirmed that decision, concluding that the 2011 Rule violated the First Amendment. *R.J. Reynolds*, 696 F.3d at 1205, *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).

39. The D.C. Circuit first held that the compelled-speech framework in *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626 (1985), did not govern the First Amendment inquiry. That framework applies only to purely factual and uncontroversial disclosures. But the D.C. Circuit held that FDA's warnings were not aimed at imparting factual information—indeed many did "not convey *any* warning information at all, much less make an 'accurate statement' about cigarettes." *R.J. Reynolds*, 696 F.3d at 1216. Rather, FDA's warnings were "primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning." *Id.* The warnings, the D.C. Circuit further noted, could be "misinterpreted by consumers" by "suggesting" that certain unlikely outcomes were in fact "common consequence[s] of smoking." *Id.* The D.C. Circuit also held that the government can justify compelled disclosures under the *Zauderer* framework, as opposed to intermediate

scrutiny, only if the disclosures aim at preventing consumer deception—something the 2011 Rule did not do. *Id.* at 1214-15.

40. The D.C. Circuit thus concluded that the warnings were subject to and failed intermediate scrutiny. FDA did not offer "a shred of evidence" showing that the warnings would "directly advance" its asserted interest in reducing the number of Americans who smoke. *Id.* at 1219. Indeed, the D.C. Circuit was skeptical even "that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product" in the first place. *Id.* at 1218 n.13. The D.C. Circuit also rejected FDA's backup interest in "'effectively communicating health information' regarding the negative effects of cigarettes" because "'effective' communication is too vague to stand on its own." *Id.* at 1221.

41. The D.C. Circuit vacated the 2011 Rule and remanded the matter to FDA for further consideration. The D.C. Circuit declined to rehear the case en banc, and, in early 2013, the government decided not to seek Supreme Court review.

42. The en banc D.C. Circuit later overruled *R.J. Reynolds* in part, rejecting the holding that *Zauderer* applied only to disclosures aimed at preventing consumer deception. *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The *American Meat* decision did not disturb the *R.J. Reynolds* court's holding that FDA's warnings were not "purely factual and uncontroversial." *Id.* at 27.

D. FDA Rushes to Issue the New Proposed Rule

43. 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., *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 rulemaking is "a time-consuming process that requires extensive resources," and that developing a new graphic-warnings rule involved particular "complexities"

and challenges, including that such 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 identified at least 20 additional steps it would need to take to promulgate a rule, and estimated that, to perform the necessary steps properly, FDA would need until November 2021 at the earliest to finalize a rule. *See id.* ¶¶ 9-14; 1st Suppl. to Def.'s Stmt. of Undisp. Mat. Facts 2, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. Jan. 22, 2018), ECF No. 42. FDA cautioned that a "rushed rulemaking process only increases the risk of a successful litigation challenge, which would even further delay the eventual implementation of a final rule." FDA's Mem. in Supp. of Mot. for Summ. J. and in Opp. to Pls.' Mot. for Summ. J. 14, *Am. Acad. of Pediatrics v. FDA*, No. 16-cv-11985 (D. Mass. May 26, 2017).

44. 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. Though FDA requested 13 months to review and respond to comments, *id.* at *3, the court gave FDA only 5 months, ordering FDA to issue a final rule by March 15, 2020—i.e., 20 months sooner than FDA had represented was feasible, *id.* at *4.

E. FDA's Proposed Rule

45. 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) (to be codified at 21 C.F.R. pt. 1141) (the "Proposed Rule").

46. As with FDA's 2011 Rule, FDA's Proposed Rule would 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 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 would have to submit plans for implementing those requirements to FDA for pre-approval before manufacturers could sell or advertise their products once the Final Rule took effect. *Id.* at 42,787.

47. 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 42,767.

48. Also unlike the 2011 Rule, FDA's proposed graphic warnings did not track the 9 TCA warning statements. Rather, FDA proposed to mandate the following 13 graphic health warnings:

49. 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.

50. The Proposed Rule justified FDA's new graphic warnings by relying heavily 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.

51. FDA's Proposed Rule also relied upon quantitative studies—studies that focus on gathering numerical or statistical data, as opposed to textual or narrative data, from study participants—from April 2018 and May 2019. 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 study methodologies and results but did not release the underlying data. FDA promised to subject the quantitative studies to peer review, but it issued the Proposed Rule before peer review was complete.

F. Initial Comments to FDA

52. FDA provided a 60-day comment period, through October 15, 2019, for the Proposed Rule. On October 15, 2019, Plaintiffs submitted to FDA extensive comments 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. Other commenters, ranging from cigarette manufacturers to pro-graphic-warnings health groups, echoed many of these concerns.[2]

53. Plaintiffs' comments explained why the Proposed Rule's warning requirements would violate the First Amendment. *See* Altria Cmt. 45-66. Plaintiffs noted that the massive size and prominent placement requirements of the Proposed Rule would unconstitutionally burden speech, irrespective of the warnings' content. Plaintiffs explained that FDA had failed to show that its speech restrictions were "no broader than reasonably necessary," as required to support a compelled disclosure under the Supreme Court's decision in *Nat'l Inst. of Fam. & Life Adv. v. Becerra*, 138 S. Ct. 2361, 2377 (2018) ("*NIFLA*"), and that courts have invalidated less-burdensome speech restrictions on that ground.

54. Further, Plaintiffs detailed why the proposed warnings would be impermissible speaker-, content-, and viewpoint-based regulations of speech that would fail under any standard of review. Altria Cmt. 49-54. Plaintiffs explained that, like FDA's invalid 2011 warnings, FDA's new warnings would force manufacturers to convey the government's anti-smoking viewpoint through shocking and inflammatory warnings aimed at eliciting negative emotional responses rather than informing consumers. The warnings were thus not the type of "purely factual and

[2] All referenced comments were filed on FDA Docket No. FDA-2019-N-3065, https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=FDA-2019-N-3065.

uncontroversial" disclosures the government might compel under *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626 (1985). Altria Cmt. 50-51. Plaintiffs further noted that the warnings did not survive intermediate scrutiny because FDA's asserted interest in more effective consumer education did not support its massive speech intrusion, and the warnings were more extensive than necessary. *Id.* at 53.

55. Plaintiffs also pointed out that the proposed graphic and textual warnings violate the First Amendment because they risk misleading consumers about the relative risks associated with various smoking-related health consequences, as they treat conditions with varying prevalence and severity as if they were equal and emphasize extreme and unlikely outcomes. The misleading nature of the warnings rendered them unlawful under any standard, because the government has no legitimate interest in misinforming consumers. *Id.* at 54-55.

56. Plaintiffs also noted multiple ways in which FDA's Proposed Rule, if finalized, would run afoul of the APA. *See id.* at 26-45. Plaintiffs explained that FDA had failed to disclose information underlying its threshold decision to highlight certain health consequences over others, as well as how it selected the graphics, and how it determined the proposed warnings were comprehensible to consumers. Plaintiffs stressed that FDA's failure to disclose important information regarding its cited internal studies had prejudiced Plaintiffs' ability to assess the validity of FDA's methodology or verify FDA's conclusions. Plaintiffs further argued that FDA's internal quantitative studies were methodologically flawed and, in any event, did not meaningfully support FDA's claim that its massive graphic warnings would enhance consumer understanding of smoking-related health risks. Further, Plaintiffs observed that FDA had ignored significant scientific studies and other evidence that rebutted FDA's conclusions, and that FDA failed to assess alternatives to its proposed warnings.

57. Compounding the APA problems, Plaintiffs noted that the proposed graphic-warnings requirements—including FDA's requirement that manufacturers display an odd, prime number of warnings and reproduce those warnings in the correct size and placement on digital advertising in various formats—would be more difficult and costly to timely satisfy than FDA had acknowledged. Plaintiffs pointed out that FDA had failed to consider these significant implementation challenges when crafting the warning requirements and setting the 15-month effective date—a failure that, if not addressed, would render FDA's action arbitrary and capricious. *Id.* at 23-26.

58. Other manufacturers raised similar objections. R.J. Reynolds, Liggett Group, and ITG Brands all submitted comments contending that the Proposed Rule violated the First Amendment and the APA and, if finalized, would present significant implementation challenges. *See* Liggett Group, Cmt., Docket No. FDA-2019-N-3065 (Oct. 15, 2019) ("Liggett Cmt."), https://tinyurl.com/y7xllukq; RAI Servs. Co., Cmt., Docket No. FDA-2019-N-3065 (Oct. 11, 2019) ("RAI Cmt."), https://tinyurl.com/u85jd4f; ITG Brands, Cmt., Docket No. FDA-2019-N-3065 (Oct. 15, 2019), https://tinyurl.com/y82mocru.

59. 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 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.

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

60. On November 12, 2019, nearly a month after the initial comment period closed, FDA announced that it had published 600 additional pages of material to the public docket. *See* FDA, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966 (Nov. 12, 2019). Those 600 pages comprised 4 reports 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.

61. The 4 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. of 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* (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* (April 27, 2018) ("April 2018 Qualitative Study Rpt."), https://www.regulations.gov/document?D=FDA-2019-N-3065-0488. FDA relied on the results of this qualitative evaluation to select the text-image pairings that FDA tested in its final quantitative study.

62. FDA acknowledged that it "used" these studies to "inform" the development of its Proposed Rule. 84 Fed. Reg. at 60,967. At the same time, however, 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. FDA re-opened the comment period for a mere 15 days. FDA claimed that period would provide interested parties with "adequate time" to review, analyze, and respond to the newly disclosed information "without significantly delaying rulemaking." *Id.* at 60,967-68.

65. Plaintiffs filed a supplemental comment 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."). Plaintiffs 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. Plaintiffs 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. R.J. Reynolds likewise commented that the qualitative study materials showed FDA designed the warnings to evoke negative emotion, rather than convey useful health information. *See* RAI Servs. Co., Suppl. Cmt. Letter 1-2, Docket No. FDA-2019-N-3065 (Nov. 25, 2019), https://tinyurl.com/wvzxg3q.

H. The Final Rule

66. FDA published the final graphic-warnings rule on March 18, 2020. *See* FDA, *Rule on 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. 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 further stressed that "increased smoking cessation and decreased initiation are not the purpose" of the Final Rule, *id.* at 15,650. FDA's sole justification for the Rule 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.

68. The Rule would impose significant speech restrictions in service of FDA's aim to more effectively educate consumers. The Final Rule takes effect 15 months after it issued, on June 18, 2021. In response to a suit from a group of cigarette manufacturers and retailers challenging the Final Rule in the Eastern District of Texas, FDA, citing the "disruptive effects of the global outbreak of COVID-19," has proposed to postpone the Rule's effective date by 120 days. Joint Mot. for Entry of Stipulated Order to Postpone Rule's Effective Date and Set Briefing Schedule, *R.J. Reynolds Tobacco Co. v. FDA*, 20-cv-176 (E.D. Tex. May 6, 2020), ECF No. 30. That proposal remains pending decision by the district court. Once the Rule takes effect, it will be unlawful for manufacturers to distribute cigarettes packages or advertisements that do not bear FDA's required graphic-health warnings. *See* 85 Fed. Reg. at 15,694. FDA can enforce the Final Rule through "warning letters, civil money penalties, no-tobacco-sale orders, seizures, injunction, or criminal prosecution," among other mechanisms. *Id.* at 15,692.

69. FDA's Final Rule reduced the number of required graphic warnings from 13 to 11. *See id.* at 15,688. The Final Rule thus eliminated two of the graphic warnings from the Proposed Rule: the warning for age-related macular degeneration, which featured an image of a needle jabbing an eyeball, and one of the two COPD warnings—the version paired with an image of bloody, disembodied lungs. *Id.* at 15,685. 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 manufacturers' packaging and advertising display the remaining 11 graphic warnings, with the same text and image pairings as in the Proposed Rule. *See supra* ¶ 4.

70. As applied to cigarette packages, the Final Rule requires manufacturers to display the graphic warnings on "at least the top 50 percent" of both the front and back of the packages. 85 Fed. Reg. at 15,709.

71. 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.*

72. FDA estimated the cost of the Proposed Rule to be 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.

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

73. 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 the text of those statutory warnings if FDA finds, after notice-and-comment rulemaking, that doing so would "promote greater public understanding of the risks associated with cigarette smoking." 85 Fed. Reg. at 15,658 (citing 15 U.S.C. § 1333(d)[2]).

74. 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." *Id.* FDA then "determined there was sufficient support to propose adjusting the text of the TCA statements." *Id.*

75. In the District of Massachusetts 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.

76. FDA has not provided any meaningful information regarding these processes or decisions for selecting which health risks to cover. FDA has only indicated that, prior to its very first internal study in July 2015, FDA used an undisclosed process to select 13 categories of health information to feature in its 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—as well as 4 new risks—blindness, amputation, diabetes, and erectile dysfunction—that the TCA never mentions. *See* July 2015 Study Rpt. Appx. G.

77. FDA generically 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 also 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.

78. 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. FDA's failure to provide key information about its selection process leaves the public with no way to scrutinize whether FDA's choice of health conditions was rational in light of the facts before the agency and its asserted consumer-education goal.

79. 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, 15,656, 15,666.

80. And yet FDA's unexplained, and seemingly arbitrary, 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. Appx. G, *with* 85 Fed. Reg. at 15,708-09. Because the decision was made from the start, none of FDA's internal studies even considered, much less evaluated, different categories of health risks. As such, the problems with FDA's threshold selection of health conditions carried forward and tainted FDA's rulemaking in its entirety.

81. Furthermore, FDA delayed disclosing other, highly relevant information, even when FDA had that information in hand during the comment periods. For example, 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.

82. 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 on Warning Statements for Cigarette Graphic Health 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.

83. 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.

84. FDA has yet to disclose other critical information. For instance, FDA has not provided 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 cannot check the validity of FDA's results.

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

a. The Faulty Internal Studies

85. 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.

86. 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.

1) Qualitative Studies

87. FDA's Final Rule acknowledges that FDA relied on its qualitative studies as part of its warning-development process. According to FDA, the studies were "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. That makes sense: FDA's qualitative studies are the only studies that examined the actual warning text and images that FDA tested in its final quantitative studies, and ultimately selected.

88. 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 again, 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.

89. The results of FDA's qualitative studies further impugn FDA's warning-development process. FDA's Final Rule repeatedly asserts that its graphic warnings are 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 to be 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 indicated that FDA's chosen warnings were unhelpful, unclear, or confusing.

90. 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.

91. FDA tested textual warning statements consisting of the 9 warning statements from the TCA, *see supra* ¶ 26, 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: cancer, heart disease and strokes, smoker lung disease, erectile dysfunction, amputation, diabetes, blindness, addiction, death, fetal harm, benefits of quitting, nonsmoker lung disease, and harm to children. *See supra* ¶ 76; July 2015 Study Rpt. Appx. 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.

92. 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.").

93. 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

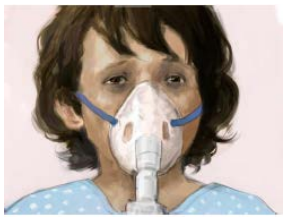
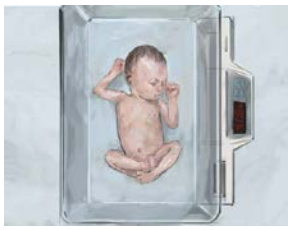
require," "can cause") with more definitive language ("causes"), without explanation. *See* 85 Fed. Reg. at 15,708-09.

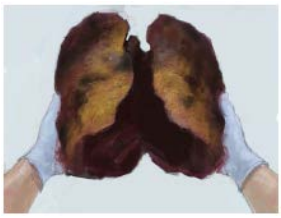
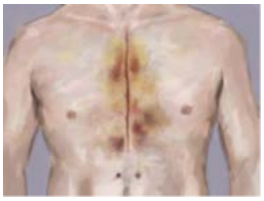
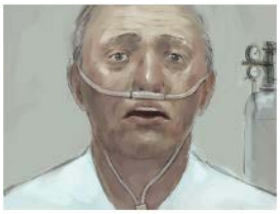
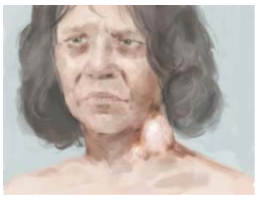
94. The July 2015 qualitative study also demonstrated that certain FDA warnings generally did *not* provide new health information to participants, and thus undercut FDA's stated consumer-education aim. For instance, *zero* percent of adults found the warning "smoking during pregnancy can stunt your baby's growth" to contain new information. July 2015 Study Rpt. 33. 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.

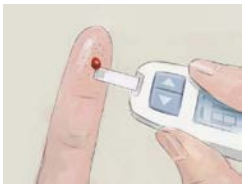
95. March 2016 Qualitative Study of Spanish-Language Textual Warnings: FDA next conducted a qualitative evaluation of Spanish-language cigarette warning text. In this study, 9 native Spanish speakers provided their thoughts regarding Spanish-language versions of 15 proposed textual warnings covering 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. 1-9. This study, too, concluded: "When the warning statements contained new information, participants were less likely to find them believable." *Id.* at 3. FDA does not discuss this study in the Proposed Rule or the Final Rule.

96. 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.

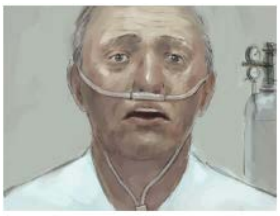
97. The June 2016 study indicated that FDA's proposed images were shocking, disgusting, or fear-provoking, and gave FDA recommendations aimed at increasing the attention-grabbing nature of the warnings by "elicit[ing] a visceral reaction," June 2016 Study Rpt. 17:

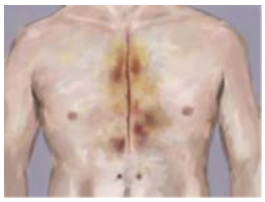
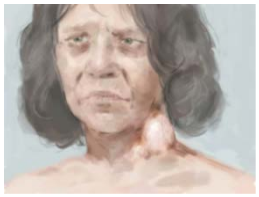
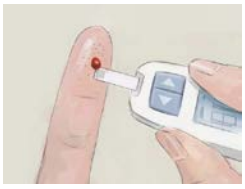
	• ***Harm to children image*** – "The sadness expressed in the subject's eyes and the oxygen mask grabbed participants' attention." *Id.* at 22. Participants described the image as "scary," "cruel[]," and provoking "despair." *Id.* at 23-24, 26. The study recommended that FDA's image "[m]aintain the 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.

98. The June 2016 study also reported that several of FDA's images were unclear or confusing to participants:

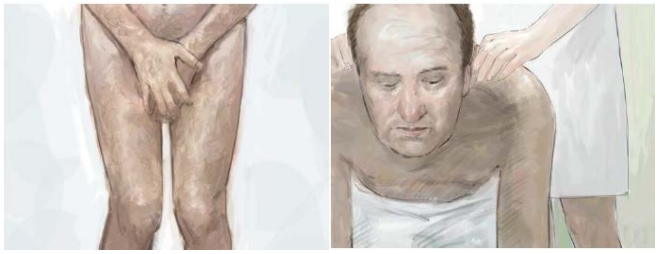
	• ***Cataracts image*** – "[M]ost participants" found the image "unclear upon initial exposure; many had to be shown the larger image for clarity," and "[a] large number could not glean any health consequences from the image." *Id.* at 143. FDA's study thus classified this image as a "[h]igh confusion 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.

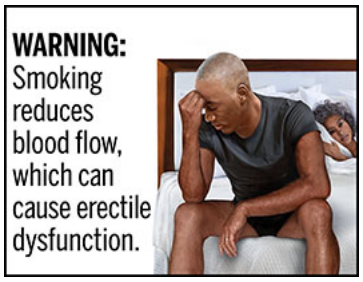
99. The June 2016 study again confirmed that several of FDA's images (the harm to children image, the blackened-lung image depicting smoker lung disease, the image of the man with the nasal cannula depicting chronic obstructive pulmonary disease, and the image of the baby on a scale to represent fetal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

100. Finally, 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).

101. FDA nonetheless retained all of these concepts for further testing. FDA either 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. Appx. I tbl.2. For example, FDA abandoned both of its proposed erectile dysfunction images (i.e., the groin area of a headless body crouched in pain, and a scene of a man being comforted by a nurse).



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.

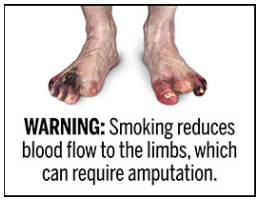
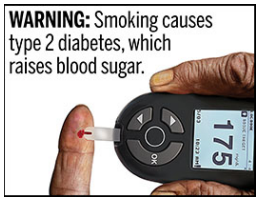


102. April 2018 Qualitative Study of Text-Image Pairings: FDA's April 2018 qualitative study tested proposed warnings pairing text and images for the first time. FDA paired 24 textual warning statements—9 generic TCA statements and 15 FDA-drafted statements—with either 1, 2, or 3 potential corresponding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

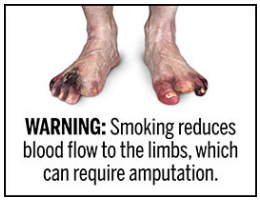
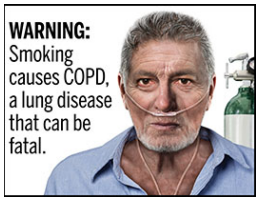
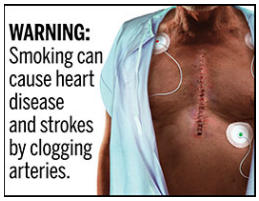
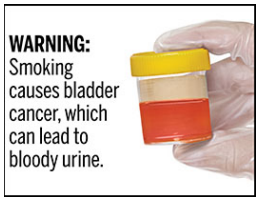
to the 13 smoking-related health risks FDA had selected at the outset. *See* April 2018 Qualitative Study Rpt. 11. This qualitative study also included new graphics for addiction and quitting that FDA had not tested before.

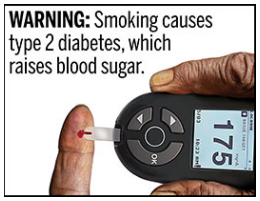
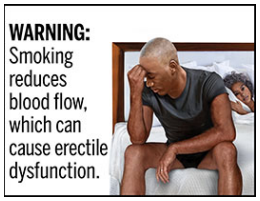
103. Participants viewed proposed warning images alone, as well as paired with textual statements, and evaluated the images and pairings for clarity, accuracy, believability, and whether they provided new information. *See id.* at 3. Several warnings scored very low on those metrics.

104. 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.*

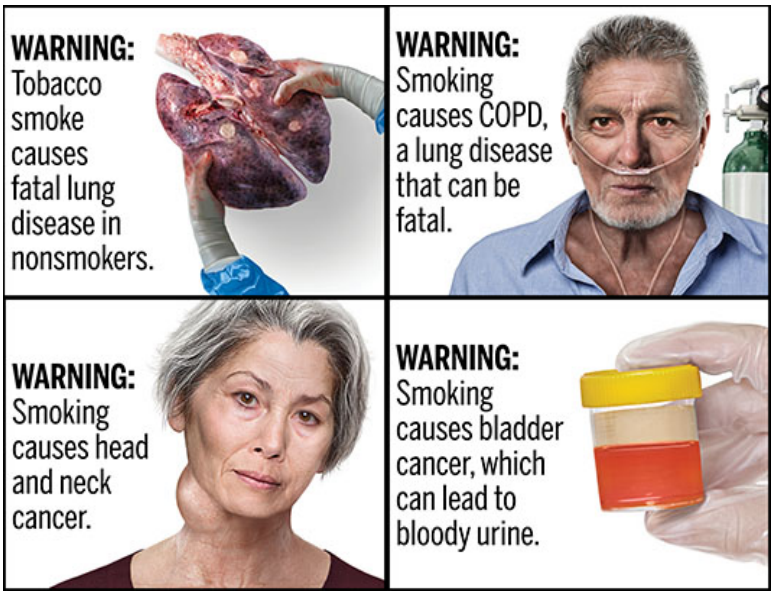
105. Participants also deemed FDA's warnings confusing, unclear, or unhelpful for myriad reasons:

	• ***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 la land,'" or "[s]tress/depression." *Id.* at 70.

106. 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.

107. 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.

108. 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. *Id.* at 26. 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

109. 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.

110. 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."). 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.

111. Together, the 9 TCA warnings and 15 FDA-drafted warnings spanned the same 13 health-information categories that FDA identified prior to its initial study in 2015, *see* 84 Fed. Reg. at 42,767 tbl.1:

- ***Cancer*** – FDA tested 4 warnings relating to cancer, comprising the TCA's generic cancer warning ("Cigarettes cause cancer"), as well as 3 FDA-drafted warnings ("Smoking causes mouth and throat cancer," "Smoking causes head and neck cancer," and "Smoking causes bladder cancer, which can lead to bloody urine").
- ***Heart disease and strokes*** – FDA tested 2 warnings related to heart disease and strokes, comprising the TCA's generic heart disease and strokes warning ("Cigarettes cause strokes and heart disease"), as well as 1 FDA-drafted warning ("Smoking can cause heart disease and strokes by clogging arteries").

- ***Smoker lung disease –*** FDA tested 3 warnings relating to smoker lung disease, comprising the TCA's generic smoker lung disease warning ("Cigarettes cause fatal lung disease"), as well as 2 FDA-drafted warnings ("Smoking causes COPD, a lung disease that can be fatal," and "Smoking causes serious lung diseases like emphysema and chronic bronchitis").
- ***Fetal harm –*** FDA tested 4 warnings relating to fetal harm, comprising the TCA's generic fetal harm warning ("Smoking during pregnancy can harm your baby"), as well as 3 FDA-drafted warnings ("Smoking during pregnancy causes premature birth," "Smoking during pregnancy stunts fetal growth," and "Smoking during pregnancy causes premature birth and low birth weight").
- ***Harm to children –*** FDA tested 2 warnings relating to harm to children from secondhand smoke, comprising the TCA's generic harm to children warning ("Tobacco smoke can harm your children"), as well as 1 FDA-drafted warning ("Secondhand smoke causes respiratory illnesses in children, like pneumonia").
- ***Erectile dysfunction*** – The TCA does not contain a warning relating to erectile dysfunction. FDA tested 1 FDA-drafted statement for this condition ("Smoking reduces blood flow, which can cause erectile dysfunction").
- ***Amputation*** – The TCA does not contain a warning relating to amputation. FDA tested 1 FDA-drafted statement for this condition ("Smoking reduces blood flow to the limbs, which can require amputation").
- ***Diabetes*** – The TCA does not contain a warning relating to diabetes. FDA tested 1 FDA-drafted statement for this condition ("Smoking causes type 2 diabetes, which raises blood sugar").

- ***Blindness –*** The TCA does not contain a warning relating to blindness. FDA tested 2 FDA-drafted statements for this condition ("Smoking causes age-related macular degeneration, which can lead to blindness," and "Smoking causes cataracts, which can lead to blindness").
- ***Addiction –*** FDA tested the TCA's generic warning relating to addiction ("Cigarettes are addictive").
- ***Death*** – FDA tested the TCA's generic warning relating to death ("Smoking can kill you").
- ***Quitting*** – FDA tested the TCA's generic warning relating to quitting ("Quitting smoking now greatly reduces serious risks to your health").
- ***Nonsmoker lung disease –*** FDA tested the TCA's generic warning relating to nonsmoker lung disease ("Tobacco smoke causes fatal lung disease in nonsmokers").

112. The study tested the FDA-drafted statements against their TCA counterparts—e.g., it compared FDA's bladder cancer warning to the TCA's generic cancer warning, FDA's "stunts fetal growth" warning to the TCA's generic warning that smoking "can harm your baby," and so forth. The study tested the 5 FDA-drafted statements that do not have a TCA counterpart (amputation, erectile dysfunction, diabetes, and 2 for blindness) against randomly selected TCA statements. *See id.* at 42,768.

113. FDA's study suffered from at least two serious design flaws that undercut its utility. *See* Altria Cmt. 34-36.

114. *First*, the study's non-representative sample limits the applicability of its findings. 85 Fed. Reg. at 15,663. The sample comprised 2,505 participants, including adolescents (half of whom had never smoked), younger adult (aged 18 to 24) current smokers, and older adult (aged 25 years and older) current smokers. 84 Fed. Reg. at 42,767. Study organizers recruited all of the

participants via email. The study was not "nationally representative," and its results cannot be generalized to the population beyond the study sample. *See* 85 Fed. Reg. at 15,663.

115. *Second*, FDA's study failed to employ meaningful controls. FDA did not control for the difference in length or specificity between the TCA's generic statements and the FDA-drafted statements. FDA thus failed to account for the fact that "survey respondents may artificially inflate self-reported measures of 'learning' or 'new information' by conflating specificity and length of the new statements with new knowledge." Altria Cmt. 34. In addition, 5 of FDA's new warnings (covering erectile dysfunction, amputation, and diabetes, and 2 warnings about conditions causing blindness), had no TCA counterparts, which made the study likely to overstate FDA's desired results. FDA acknowledged as much, noting that randomly comparing these new statements to unrelated TCA statements "may have resulted in larger effects for these 'new content' statements." 84 Fed. Reg. at 42,769 n.8. Yet FDA never controlled for that distortion. *See* Altria Cmt. 34.

116. 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 for a number of reasons.

117. *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."

84 Fed. Reg. at 42,768. 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.

118. *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.* at 42,769; 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* ¶ 136. 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* ¶ 128. 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* ¶ 95; *infra* ¶ 136.

119. *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.

FDA's choice to minimize the importance of those measures, rather than justify its decision to advance warnings that flunked them, smacks of post-hoc rationalization.

120. 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."); 84 Fed. Reg. at 42,771 tbl.2.

121. 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* ¶ 126. In the second session, 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.

122. Like FDA's first quantitative study, serious design and methodological flaws plagued this study.

123. *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.

124. *Second*, the study did not assess differences between the various demographic groups comprising the sample. That failure makes it impossible to know, for example, whether adult smokers reacted differently to the proposed warnings than did adult nonsmokers.

125. *Third*, FDA did not control for key variables. For example, FDA did not control for the prospect that participants would view the graphic warnings as relaying new information solely because they are bigger, colorful, and in a different format than existing warnings. *See* Altria Cmt. 34. Nor did FDA test the new text and images separately, or evaluate the effect of smaller-sized graphic warnings. *See id.*; 85 Fed. Reg. at 15,650, 15,664.

126. In addition, 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.

127. *First*, 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* ¶ 136.
- ***Emotional impact*** – FDA also did not assess the emotional impact of its graphic warnings. That is so 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.

128. *Second*, 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* ¶ 136. 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.

129. FDA used the quantitative study—in particular, its two preferred outcomes of "self-reported learning" and "new information"—to winnow down the 16 tested graphic warnings

to the 13 graphic warnings FDA proposed to finalize. FDA eliminated only the 3 warnings related to addiction, death, and the health benefits of quitting, *compare* 84 Fed. Reg. at 42,767 tbl.1, *with id.* at 42,771 tbl.2. FDA concedes that those 3 warnings all contain well-known information. *Id.* at 42,767 n.5.

130. 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 at the end of this Complaint detailing each individual warning's shortcomings, including their potential to mislead, which Plaintiffs incorporate and allege as though set forth fully herein.

131. 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.

132. 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.

133. 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.

134. *First*, the peer reviewers pointed out numerous methodological and design flaws that call into question the studies' reliability and probative value:

- ***Non-representative samples*** – Reviewers critiqued the studies' non-representative sample composition, and the resulting "potential biases and limits to generalizability," with one noting that the studies' "sampling frame is a significant weakness for this research." Peer

Review Report 40, 44 (Reviewer 4); *see also, e.g.*, *id.* at 21 (Reviewer 2) (noting "[c]oncerns about generalizability); *id.* at 28 (Reviewer 3) ("The justification for this distribution" of study sample "is not clear . . . ."). Reviewers expressed particular concern with the May 2019 quantitative study's inclusion of adult nonsmokers, which prevented FDA from assessing whether the warnings had a differential effect on smokers, who are their "intended audience." *Id.* at 57 (Reviewer 6); *see id.* at 21 (Reviewer 2) ("[I]t is not clear why adult nonsmokers were included."); *id.* at 52 (Reviewer 5) ("I am puzzled why non-smoking adults were studied. Why would you want to ask a 60- or 70-year-old non-smoker what they think about these warning labels? There is almost no chance that they will become a smoker."). Reviewers also highlighted the May 2019 study's differential "attrition" rate for smokers—i.e., the fact that smokers dropped out of the latter phases of the study at higher rates than did nonsmokers—which risks skewing the sample towards individuals who already possess strong beliefs regarding the "negative health consequences" of smoking and thus "overstat[ing]" the warnings' effectiveness. *Id.* at 35 (Reviewer 3); *see also, e.g.*, *id.* at 22 (Reviewer 2) (noting "meaningful attrition" by "smoking status over time"); *id.* at 43 (Reviewer 4) ("the attrition rate" is "very problematic").

- ***Participant priming*** – Several reviewers noted their concern that the studies, by exposing participants to "pretest measures of negative health consequences," were likely to have primed participants to reach FDA's preferred results. *Id.* at 33 (Reviewer 3); *see also, e.g.*, *id.* at 32 ("[W]e never ask the key outcome measures at baseline BEFORE the messages to be processed as we believe that that distorts how content is handled—priming, focusing,

differential attention, etc."); *id.* at 60 (Reviewer 6) ("[T]here might be a priming effect of the health belief assessment for those participants in the treatment condition.").

- ***Lack of meaningful controls*** – Reviewers pointed out the weaknesses in the way in which FDA's studies compared the control-group warnings (the TCA textual statements in the April 2018 study and the Surgeon General's warnings in the May 2019 study) against the new FDA-drafted textual statements and graphic warnings. One reviewer, for example, critiqued the May 2019 study for analyzing all of the control-group participants who viewed Surgeon General's warnings together, rather than "test[ing] differences between specific [Surgeon General's] warnings and [graphic-health warnings] that are most comparable." *Id.* at 21 (Reviewer 2). Another pointed out that FDA's choice to test the longer, more specific textual warnings and graphic warnings against the generic TCA or text-only Surgeon General's warnings "could easily overstate the effectiveness of the new" warnings, especially in those instances where FDA's new warnings did not have content "comparable" to the old warnings. *Id.* at 27 (Reviewer 3).

135. *Second*, reviewers criticized the way in which FDA purported to assess consumer understanding in both studies. Several reviewers noted that FDA's approach and chosen measures of understanding appeared to lack support in both existing research and theory. *See, e.g., id.* 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 . . . . The current explanation is neither based in empirical evidence nor theory."); *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.").

136. *Third*, 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 criticized FDA's apparent prioritization of the outcomes of "new information" and "self-reported learning." Reviewers deemed FDA's focus on those two measures "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 also 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) (questioning why FDA did not treat "credibility" measures, including "factuality," as "primary, especially given that the messages are mostly about less well-known smoking-related outcomes"). 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 34 (Reviewer 3) ("What happened to believability?"); *id.* at 33 ("The believability criterion was not included in [the May 2019] study and that is problematic.").

- ***Failure to assess actual measures of comprehension or recall*** – Reviewers also noted that FDA's use of "self-reported" measures, as opposed to other "confirmed" measures, was an additional "limitation" of the studies. *Id.* at 21 (Reviewer 2); *see id.* at 28 (Reviewer 3) ("I am also not a fan of self-reported learning nor of novelty—that is awareness—as a criterion.").

137. *Fourth*, FDA's decision-making and use of the study results perplexed reviewers. Multiple peer reviewers expressed confusion about FDA's process for generating its tested warnings. *See id.* at 26 (Reviewer 3) ("[T]his reviewer was a bit perplexed about the sources and topics that generated the new warnings."); *id.* at 44 (Reviewer 4) ("[T]he development process for the graphic images needs to be more clearly described. What was the formative testing process that went into designing and then finally choosing those images? What was the charge given to the designer that developed those images?"). 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.").

138. The peer reviewers' significant critiques of FDA's methodology and chosen outcomes came far too late for FDA to properly address them. FDA admitted as much in its response to the peer reviewers' comments, also released with the Final Rule, stating that its studies were "complete," and thus that it was "unable to include new measures." 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. In any event, FDA's surface-level revisions of the study reports could not rectify the many issues with the studies' design, execution, and failure to assess important measures of consumer comprehension and warning credibility.

b. Inapposite Studies of Different Graphic Warnings

139. 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.

140. 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. Only one of the four non-U.S. countries (Canada) evaluated in the studies FDA primarily cites for that proposition 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. Yet FDA simply assumes that the effects of proposed warnings in other countries would be similar in the United States. *See* Altria Cmt. 38.

141. In other areas of tobacco regulation, FDA has expressed skepticism about the applicability of non-U.S. data to a U.S. context. In a rule setting forth requirements for applications under the Premarket Tobacco Product pathway, *see* 21 U.S.C. § 387j, FDA stated that, in order to rely on foreign studies, applications "should provide a scientific rationale for why the results of the study can be generalized to other demographic groups that are representative of the U.S. population as [a] whole." Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566, 50,600 (Sept. 25, 2019) (to be codified at 21 C.F.R. pts. 1100, 1107, and 1114). FDA has not reconciled its reliance on foreign studies with that directive.

3. FDA's Uncertain Implementation Process

142. Despite receiving multiple comments flagging significant implementation problems, FDA's Final Rule ignores major difficulties in implementing the Final Rule's graphic-warnings regime.

143. *First*, the Final Rule's requirements for distributing the graphic warnings on packaging and advertising will necessitate significant changes in manufacturers' printing processes for which FDA has not adequately accounted. The Final Rule requires manufacturers to rotate the 11 graphic warnings "randomly" and "equally" throughout the year on cigarette packaging, and in "alternating sequence" every 3 months for advertisements. 85 Fed. Reg. at 15,686. Further, manufacturers must submit implementation plans to FDA for pre-approval, or manufacturers cannot sell or advertise their products when the Rule's requirements take effect. *Id.* at 15,690, 15,694. Those plans must describe how manufacturers intend to satisfy the Rule's

random-and-equal requirements for packaging and the quarterly rotation requirement for advertising. *Id.* at 15,690.

144. Plaintiffs and other manufacturers described the "extremely difficult" and expensive changes they would need to make in order to implement the warning-distribution requirements, and explained how requiring an odd, prime number of warnings would make those changes and associated costs even greater. Altria Cmt. 13; *see id.* at 13-26; Liggett Cmt. 5-10. The Final Rule states that FDA "recognize[d] and underst[ood] the difficulties" manufacturers face when implementing the warning-distribution requirements with an odd, prime number of warnings. 85 Fed. Reg. at 15,691. Yet FDA promulgated 11 warnings, another odd, prime number, anyway.

145. FDA signaled that it would help account for the resulting difficulties by allowing manufacturers "some flexibility" when implementing the random-and-equal requirements. *Id.* But FDA's Final Rule did not address what level of deviation would be permitted, instead stating that FDA would "discuss these concerns" with manufacturers when reviewing their implementation plans. *Id.* Nor did FDA account for the manufacturers' implementation challenges when setting the Final Rule's effective date. Rather, FDA simply asserted that a "15-month period" would be sufficient for manufacturers to "adjust any printing processes that may require updating," and that it "intends to assist manufacturers . . . with specific questions and concerns." *Id.* at 15,652, 15,695.

146. *Second*, the Final Rule's requirements for displaying the warnings on digital advertisements generate "unnecessary complications" that FDA has failed to address. Altria Cmt. 24. The Final Rule applies to advertisements on "internet web pages, digital platforms, mobile applications, and email correspondence." 85 Fed. Reg. at 15,709 (21 CFR § 1141.10(d)(1)). Manufacturers therefore must display the warnings "in a conspicuous and prominent format and

location" at the top of advertisements on those digital platforms. *Id.* (21 CFR § 1141.10(d)(2)). But digital platforms come in all shapes, sizes, and formats, and electronic devices may display the same advertisement differently depending upon the device or software. Those challenges render compliance with FDA's requirements for digital advertisements "an exercise in guesswork." Altria Cmt. 24. FDA's Final Rule does not address those implementation challenges or clearly instruct manufacturers on how to satisfy the advertising requirements on digital platforms. FDA instead punted the issue to the implementation phase, "invit[ing] manufacturers to raise the specific implementation issue they have as part of the submission" of their implementation plans. 85 Fed. Reg. at 15,694.

147. FDA's implementation process compounds the compliance difficulties. The Final Rule states that FDA "strongly encourage[s] entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within 5 months after the publication of this final rule," or August 18, 2020. *Id.* FDA's "best estimate is that it will take up to 6 months" to review manufacturers' initial implementation plans. *Id.* at 15,695. Under this "estimate," it could take until February 18, 2021, for FDA to review an implementation plan submitted 5 months after publication of the Final Rule, on August 18, 2020. That would leave manufacturers with a grossly inadequate time period to procure the supplies and make the extensive changes necessary to comply with the Rule by the effective date. *See* Altria Cmt. 25.

148. FDA acknowledges, moreover, that it may need more than six months to review and approve manufacturers' implementation plans. *See* 85 Fed. Reg. at 15,695. Manufacturers without approved implementation plans may have their advertising and products banned from the market when the Final Rule takes effect.

149. FDA "intends to ensure" its delay in reviewing plans will not lead to that result, so long as manufacturers "submit an adequate plan within 5 months of publication of this final rule," or August 18, 2020, and "work in good faith with FDA to complete its review." *Id.* FDA repeated that statement in the non-binding guidance document it issued in connection with the Final Rule. *See* FDA, *Submission of Plans for Cigarette Packages and Cigarette Advertisements, Guidance for Industry*, at 7 (Mar. 2020), https://www.fda.gov/media/133839/download.

150. FDA's solution creates more problems than it solves. *First*, FDA does not define what it means by "good faith," other than to say that manufacturers should work "diligently with FDA" and "be responsive by submitting any requested information in a timely manner." 85 Fed. Reg. at 15,695. FDA does not further indicate what it means by "diligently" or "timely." *See id.* FDA also does not explain what an "adequate" plan contains, or how FDA will be able to say whether a plan is "adequate" if it has not reviewed that plan. *See id.* FDA thus has failed to provide meaningful explanation of requirements that could make or break manufacturers' ability to sell and advertise their products after the Rule's effective date.

151. *Second*, by instructing parties to submit implementation plans as soon as possible, and no later than 5 months after the Final Rule's publication, while deferring clear guidance on several key implementation challenges, FDA has forced manufacturers to scramble to submit plans that can only guess at how FDA would resolve significant implementation issues. This dynamic further hampers manufacturers' ability to timely implement the Rule's requirements.

CONCRETE AND PARTICULARIZED HARM

152. The Rule already has caused, and will continue to cause, several independent types of concrete and particularized harm to Plaintiffs.

153. *First*, the Rule's requirement that Plaintiffs add the required warnings to their packaging and advertising severely injures Plaintiffs because the Rule violates their rights under the First Amendment and the APA.

154. *Second*, the Rule will severely hamper Plaintiffs' ability to distinguish and market their products. Plaintiffs' packaging features distinctive logos, colors, and other identifying characteristics that appeal to and inform consumers. These identifying characteristics are central to Plaintiffs' marketing efforts, especially in light of the significant restrictions on manufacturers' ability to market their products through other avenues. The Rule will force Plaintiffs 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 Plaintiffs to remove their own speech and branded communications from that packaging to accommodate the warnings. The Rule will also prevent Plaintiffs from speaking: they will no longer be able to include their website URL on those products' packaging, and 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.

155. Government regulations significantly limit the available channels for Plaintiffs to communicate their brand messaging. As a result, Plaintiffs rely significantly on their distinctive and visible packaging to market their 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 Plaintiffs' products to make their purchasing decision, unlike most other consumer goods. Plaintiffs rely on their packaging's visible branding to market their 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.

156. In certain retail locations, the Rule's graphic warnings may obscure Plaintiffs' 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 Plaintiffs from appealing to and informing consumers with their package design.

157. The Rule also will interfere with Plaintiffs' ability to communicate with age-verified adult smokers aged 21 and over on Plaintiffs' 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 Plaintiffs' websites—may be fixed, 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 Plaintiffs' brands and products.

158. *Third*, FDA's graphic warnings would force Plaintiffs to mislead consumers about the health risks associated with their 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.

159. *Fourth*, Plaintiffs will suffer the loss of customer goodwill. The Rule's gruesome and off-putting images would squander goodwill for Plaintiffs' cigarette products without accurately informing consumers of the relative risks of the health-related harms that FDA has chosen to highlight.

160. *Fifth*, the Rule will also impose substantial and onerous compliance costs, which Plaintiffs already have started incurring:

- Manufacturers must make significant changes to their packaging and processes in order to comply with the Rule's requirements, including the random-and-equal display requirements. In light of those changes, Plaintiffs already have rushed to submit an implementation plan and will need the entire 15-month transition period to complete all necessary steps to comply with the Rule. Plaintiffs cannot wait until their implementation plan is approved to begin their implementation efforts—those efforts have already begun.
- Plaintiffs must spend tens of millions of dollars during the 15-month implementation period to redesign packaging, procure and retool printing materials, and print compliant packaging in time to comply with the Final Rule's effective date. Plaintiffs have already begun incurring these costs, which will only grow during the implementation period. In order to meet the Rule's effective date, Plaintiffs 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.

- Plaintiffs must also deploy significant resources during the implementation period to redesign their websites and other advertisements to display the Final Rule's required warnings.

COUNT ONE

The Rule Violates the First Amendment

161. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-160 of this Complaint, as though fully set forth herein.

162. The Rule violates the First Amendment for four independent reasons.

163. *First*, 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—violate the First Amendment.

164. Government-compelled disclosures cannot be "unjustified or unduly burdensome," a standard that requires that a disclosure extend "no broader than reasonably necessary." *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) ("*NIFLA*") (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626, 651 (1985)).

165. By commandeering 50% of cigarette packaging and 20% of cigarette advertising, the Rule "drowns out" Plaintiffs' "own message" about their lawful products. *NIFLA*, 138 S. Ct. at 2378.

166. Where, as here, manufacturers have limited means to speak, commandeering the content of their speech also constitutes a ban on speech.

167. FDA has failed to show that the Rule's size-and-placement requirements are "no broader than reasonably necessary." *Id.* at 2377. For that reason, the Rule's regulation of speech is unduly burdensome and thus unlawful under *Zauderer*.

168. 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. *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 142 (1994).

169. *Second*, the Rule compels manufacturers to display grotesque images designed to shock and repulse consumers, even though this speech restriction is a poor fit for FDA's consumer-education interest. The Rule's warnings are unconstitutional under any standard of review.

170. The disturbing, gratuitous graphic warnings are subject to strict scrutiny because they require Plaintiffs to "speak a particular message." *NIFLA*, 138 S. Ct. at 2371. Accordingly, the Rule is "presumptively unconstitutional," and may be justified "only if the government proves [it] is narrowly tailored to serve compelling state interests." *Id.* FDA has not attempted, and cannot make, such a showing.

171. Contrary to FDA's assertion, the Rule falls outside the *Zauderer* framework because the Rule's warnings are not "purely factual and uncontroversial" commercial disclosures. *NIFLA*, 138 S. Ct. at 2372. 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 Tobacco Co. v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012).

172. The Rule's warnings also 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.

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

174. The Rule falls outside the *Zauderer* framework for the additional reason, recognized by some courts, that *Zauderer* is limited to compelled disclosures correcting misinformation. *See 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); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006); *United States v. Wenger*, 427 F.3d 840, 849-50 (10th Cir. 2005); *Am. Beverage Ass'n v. City & Cty. of S.F.*, 916 F.3d 749, 768 (9th Cir. 2019) (op. of Nguyen, J.); *but see Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 23 (D.C. Cir. 2014) (en banc).

175. Even applying the *Zauderer* framework, the Rule is unconstitutional. The Rule's warnings are not "reasonably necessary" to advance the government's asserted consumer-education goal, let alone are "no broader than reasonably necessary," *NIFLA*, 138 S. Ct. at 2377, because the inflammatory graphic images convey no meaningful health information beyond the text of the warnings.

176. Because the Rule falls outside the *Zauderer* framework, FDA must show that the Rule "directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142. It cannot do so.

177. 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. But that interest, without more, is far too unconnected to public health outcomes and circular to qualify as substantial. FDA's consumer-education interest impermissibly reflects distrust of consumers' ability to make choices without the government's sensationalized messages.

178. In addition, FDA's Rule does not directly and materially advance its asserted consumer-education interest. 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, moreover, indicate that FDA's chosen images were unhelpful, confusing, off-putting, or unclear to viewers. FDA's non-U.S. studies of different warning regimes in different countries do not provide meaningful support for the Rule's graphic warnings.

179. Further, FDA cannot show that the Rule's speech restrictions are no more extensive than necessary to further its asserted consumer-education interest. Cigarette manufacturers already face drastic limitations on how they can promote their products, but FDA's Rule significantly burdens speech when other less-speech-restrictive alternatives—such as smaller warnings, text-only warnings, and public-education campaigns—abound.

180. *Third*, because the Rule emphasizes extreme and unlikely conditions and treats conditions of differing severity as if they were equal, the Rule's graphic warnings are misleading and cannot be justified as speech restrictions under any standard of review.

181. Misleading information, by definition, is not "purely factual and uncontroversial."

182. Further, FDA lacks a legitimate interest in disseminating misleading information.

183. *Fourth*, the Rule's requirement that Plaintiffs seek FDA pre-approval of their packaging and advertising implementation plans before they can sell or advertise products in compliance with the Rule is an unconstitutional prior restraint.

184. Plaintiffs have no adequate remedy at law.

185. Plaintiffs seek the entry of a judgment declaring the Rule unconstitutional as applied to Plaintiffs, vacating the Rule, and remanding to FDA, and a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to

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

COUNT TWO

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

186. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-185 of this Complaint, as though fully set forth herein.

187. 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).

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

189. 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.

190. Plaintiffs have no adequate remedy at law.

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

COUNT THREE

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

192. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-191 of this Complaint, as though fully set forth herein.

193. In promulgating the Rule, FDA acted contrary to constitutional right, power, privilege, or immunity because the Rule violates Plaintiffs' rights under the First Amendment.

194. Plaintiffs therefore seek an order vacating the Rule under 5 U.S.C. § 706(2)(B), and remanding to FDA, and a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT FOUR

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

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

196. In promulgating the Rule, FDA failed to provide Plaintiffs with meaningful notice as required under 5 U.S.C. § 553(b)(3), by failing to disclose key technical data, methodologies, and assumptions underlying the Rule.

197. FDA failed to disclose key information and data regarding its decision-making process, including why the Rule departs from Congress' recommended warnings in the TCA (15 U.S.C. § 1333(a)(1)), how FDA determined that its chosen warnings would promote greater consumer understanding (*id*. § 1333(d)[2]), and why FDA initially chose to focus on particular health risks but not others.

198. FDA failed to disclose any of the reports underlying its cited qualitative studies in connection with the Proposed Rule until November 12, 2019, nearly a month after the close of the comment period. FDA's allowance of a mere 15 days to review the reports and provide supplemental comments was inadequate to provide the required notice of and opportunity to comment on the cited studies.

199. FDA failed to disclose the Peer Review Report on its cited quantitative studies, as well as final versions of the quantitative studies, prior to the issuance of the Final Rule. That is so

even though the Peer Review Report is dated November 19, 2019, a date that falls within the 15-day supplemental comment period.

200. FDA has failed to disclose the raw data underlying its quantitative studies, as well as any transcripts, notes, or participant worksheets from its qualitative studies.

201. FDA's disclosure failings have prejudiced Plaintiffs by depriving Plaintiffs of an opportunity to verify FDA's study conclusions or analyze the data to identify trends that may undermine FDA's stated reasoning.

202. Plaintiffs seek an order vacating the Rule under 5 U.S.C. § 706(2)(D), and remanding to FDA, and a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT FIVE

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

203. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-202 of this Complaint, as though fully set forth herein.

204. 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 several important aspects of the graphic-warnings issue.

205. FDA's actions in advancing and finalizing its chosen warnings was irrational considered against the results of its internal 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.

206. The other evidence FDA proffers to support the Rule is inapposite. FDA's reliance on non-U.S. data involving the effectiveness of different graphic warnings in different countries arbitrarily contravenes FDA's own scientific standards regarding studies of non-U.S. populations.

207. FDA fails to adequately address several key problems with the graphic warnings. FDA did not assess whether it could achieve its consumer-education objective through measures, such as text-only warnings or smaller graphic warnings, less burdensome of manufacturer speech. Despite its burden to show that the Rule's speech restrictions are no broader than reasonably necessary, FDA "disagree[d]" that it needed to examine smaller warnings, or whether the images added any informational value beyond the textual warning statements. 85 Fed. Reg. 15,650, 15,664.

208. FDA failed to adequately address contrary evidence that undermines the notion that FDA's graphic warnings will enhance consumer understanding.

209. FDA downplays evidence indicating that graphic warnings do *not* meaningfully influence consumers' understanding of smoking-related risks, including highly relevant findings from U.S.-based studies showing that graphic warnings are ineffective in improving comprehension regarding the health consequences of smoking. FDA dismissed these findings as "partly or fully attributable" to the fact that the tested warnings "focus[ed] on better-known health consequences of smoking." 85 Fed. Reg. at 15,657. But that critique is also true of many of FDA's graphic warnings, as well as non-U.S.-based studies on which FDA relied.

210. 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.

211. FDA claims that its images depict "common visual presentations of the health conditions." *Id.* at 15,646. But many depict unusual outcomes.

212. FDA also failed to resolve significant implementation problems with the Rule, such as the significant retooling of printing technology required to attempt compliance with the random-and-equal display requirements, or the inability of manufacturers to apply warnings to products of varying shapes and sizes or digital advertisements without distorting or obstructing some part of the required text and images. While FDA promised to relax requirements about not distorting images, FDA concedes that displaying properly sized warnings on certain packaging, and in digital and other formats, presents challenges. *Id.* at 15,692-94.

213. Plaintiffs therefore seek an order vacating the Rule under 5 U.S.C. § 706(2)(A), and remanding to FDA, and a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on Plaintiffs' claims.

COUNT SIX

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

214. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-213 of this Complaint, as though fully set forth herein.

215. 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.

216. Plaintiffs therefore seek an order vacating the Rule under the TCA and 5 U.S.C. § 706(2)(C), and remanding to FDA, and a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to continue using their current packaging and 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

217. Plaintiffs incorporate and re-allege each allegation contained in paragraphs 1-216 of this Complaint, as though fully set forth herein.

218. 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.

219. 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.

220. The Tobacco Control Act thus contemplates a single implementation date for the new textual and graphic warnings, which prevents manufacturers like Plaintiffs from having to completely revamp their packaging and advertisements multiple times. 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 to comply with an invalid Rule would have substantial and detrimental legal effect.

221. 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 are obligated to comply with the Rule's mandates. Indeed, the Rule already threatens Plaintiffs' constitutional and statutory rights and imposes mounting implementation costs on Plaintiffs.

222. 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 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.

223. Plaintiffs seek an order enjoining Defendants from enforcing against Plaintiffs 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 United States Constitution and federal law.

PRAYER FOR RELIEF

An actual controversy exists between the parties that entitles Plaintiffs to a declaration and injunctive relief.

WHEREFORE, Plaintiffs pray that this Court:

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

(B) 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;

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

(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 a preliminary injunction enjoining the current effective date of June 18, 2021 of FDA's Rule and allowing Plaintiffs to continue using their current packaging and advertising until 15 months after this Court issues a Final Judgment on their claims; and

(F) 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.

DATED: May 6, 2020

Respectfully submitted,

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FDA Description: "The image shows the head and shoulders of a young boy (aged 8-10 years) wearing a hospital gown and receiving a nebulizer treatment for chronic asthma resulting from secondhand smoke exposure." 85 Fed. Reg. at 15,671.

The warning is not "purely factual and uncontroversial."

- The image of a sickly looking child in a hospital gown in need of oxygen is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. Adults viewing the image would be horrified at the thought of inflicting such harm on their children. Contrary to FDA's assertion, the image includes "unnecessary details" and "elements" that "evoke a negative emotional response." 85 Fed. Reg. at 15,671. FDA's studies confirm this:
  - Participants in FDA's April 2018 qualitative study (p. 16) said the image "conveys the severity" of harm based on "the mask, dark circles under his eyes, and pale skin."
  - FDA's June 2016 Study (pp. 22-24, 158) reported, with respect to an earlier, similar version of the image, that "[t]he sadness expressed in the subject's eyes and the oxygen mask grabbed participants' attention" and that participants described the image as "scary," "cruel[]," and provoking "despair," and recommended that FDA "[m]aintain the look of dismay (e.g., sadness in the eyes)" to grab attention.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- Harm to children is not a "less-known" health consequence of smoking. Rather, it was not new information to over 97% of adults. *See* July 2015 Study Rpt. 35; *see also* June 2016 Study Rpt. 22 (reporting that earlier, similar image "did not provide participants with new information").
- The image does not effectively convey the health information FDA asserts. No reasonable consumer would be able to determine from the image that the child depicted has "chronic asthma resulting from secondhand smoke exposure" or is "receiving a nebulizer treatment." Rather, the image suggests only that the child is experiencing a medical emergency that requires receipt of oxygen. *See* April 2018 Qualitative Study Rpt. 14 ("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."). Indeed, less than one-fifth of study respondents selected this graphic warning as the best representation of how smoking harms children. *See id.* at 18.
- The warning did not meaningfully affect participants' health beliefs about smoking after repeated exposure. *See* 85 Fed. Reg. at 15,672.

The warning is misleading.

- Contrary to FDA's assertion, the selected image does not depict a "common visual presentation of the health condition [or] show[] the disease state as it is typically experienced," *id.*, but instead depicts the "worst case" scenario. Ex. G to RAI Servs. Cmt., Brooks Decl. ¶ 4.

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FDA Description: "The image shows gloved hands holding a pair of diseased lungs containing cancerous lesions from chronic secondhand smoke exposure." 85 Fed. Reg. at 15,673.

The warning is not "purely factual and uncontroversial."

- The image of blood-covered hands holding bloody, diseased lungs from a deceased individual is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image is clearly aimed at shocking or disturbing viewers with its goriness, which is "unnecessary" to convey the relevant health risk. 85 Fed. Reg. at 15,673. FDA's June 2016 study confirmed this:
  - The study reported (pp. 33, 37), with respect to a materially similar image, that "[p]articipants were particularly affected by the image's harsh depiction of a body organ in the palms of a surgeon," and found the image "attention-grabbing because of its gruesome depiction and implication of death."

  FDA heightened the emotional appeal of the image, adopting the study's recommendation to "[m]ake the blood on the gloves more discernible" and "[k]eep the surgeon/coroner's hands in the picture, as they convey the realism of the resulting death rather than a 'medical textbook' image." *Id.* at 159.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- FDA acknowledged that nonsmoker lung disease is not a "less-known" smoking-related health condition, but instead is a "better-known health consequence[] of smoking." 84 Fed. Reg. at 42,767 n.5.
- The image does not effectively convey the health information FDA asserts. As FDA's April 2018 study illustrates, the image does not provide any information not already contained in the text:
  - The study (pp. 41, 43) reported "[i]t 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," noting that participants relied on the textual warning to "help[] them to understand what was happening in the image." Some participants, moreover, thought the lungs were healthy.
- The warning states that smoking "causes" fatal lung disease, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52. Less than 10% of study participants selected this warning as best illustrating the relevant health condition. April 2018 Qualitative Study Rpt. 47.
- Participants found the warning *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. tbl.3-3.

The warning is misleading.

- The warning misleadingly emphasizes a condition that is less prevalent than other smoking-attributable health conditions. *See* Altria Cmt. tbl.1.
- The image does not accurately depict the warned-against risk. Environmental tobacco smoke would not result in the depicted pigmentation or legions. *See* Ex. I to RAI Sevs. Cmt., Farber Decl. ¶¶ 4-6.

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FDA Description:
"The image shows the head and neck of a woman (aged 50-60 years) who has neck cancer caused by cigarette smoking. The woman has a visible tumor protruding from the right side of her neck just below her jawline." 85 Fed. Reg. at 15,674.

The warning is not "purely factual and uncontroversial."

- The image of a woman with a large tumor protruding from her neck is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The disturbing and unsightly image is clearly aimed at provoking disgust or discomfort at the sight of the image or fear at the prospect of experiencing the uncomfortable medical condition. FDA's June 2016 study confirms this:
  - The study (p. 61) reported that the "woman's facial expression" of sadness in an earlier, similar image was attention grabbing. The study recommended that FDA "maintain look of sadness/despair" on the woman's face. *Id.* at 161.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. FDA's own studies illustrate this:
  - Fewer than 6% of participants in FDA's April 2018 qualitative study (p. 37) selected this warning as the text/image pairing that best represents how smoking causes cancer. The June 2016 study (pp. 61, 161) reported, with respect to a similar earlier image, that participants had "some confusion about what the protrusion was," and recommended that FDA delete the image since "[i]t wasn't clear what the message was even when the tumor was identified."
- The warning states that smoking "causes" head and neck cancer, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52.
- Participants deemed the textual statement significantly *less* believable and factual than the generic TCA cancer statement, and the statement did not demonstrate a statistically significant improvement in the "thinking about health risks" measure. April 2018 Quantitative Study Rpt. 3-8-3-9 (69-70) & tbls.3-5, 3-6.
- Participants deemed the graphic warning *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. tbl.3-3.

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that their relative risk of exposure to head and neck cancer is the same as or greater than their relative risk of exposure to other, more-prevalent smoking-related conditions, *see* Altria Cmt. tbl.1; and 2) emphasizes head and neck cancer while FDA omits other conditions with worse survival rates, *id.* fig.8.
- The warning does not accurately portray the warned-against risk. The image is "misleading" to the extent is suggests "that a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." Ex. J to RAI Servs. Cmt., Jones Decl. ¶¶ 4-5. Participants in FDA's April 2018 qualitative study (p. 30) likewise reported that the "lump was too large to be realistic."

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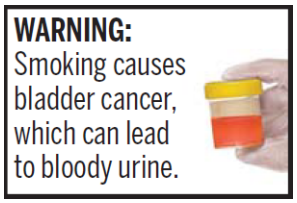


FDA Description:
"The image shows a gloved hand holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking." 85 Fed. Reg. at 15,675.

The warning is not "purely factual and uncontroversial."

- The image of a red-orange colored liquid in a specimen cup is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image is clearly aimed at provoking an emotional reaction of fear or disgust.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. No reasonable consumer would be able to determine from the image alone that the liquid depicted is "bloody urine," let alone "bloody urine resulting from bladder cancer." All the image conveys is that an unknown person with a gloved hand is holding an unspecified red-orange liquid in a sample cup. FDA's own studies show this:
  - FDA's April 2018 qualitative study (p. 35) reports that "[t]he most common interpretation of the image was that it was a urine sample," but 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."
  - Participants deemed this graphic warning the *least* effective warning for demonstrating how smoking causes cancer, with only 1.8% of study participants selecting it. *Id.* at 37.
- The warning states that smoking "causes" bladder cancer, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52. FDA's July 2015 study reports that "[m]ost adult participants did not believe" the statement that smoking causes bladder cancer. *Id.* at 26.
- Participants ranked the text of the warning as significantly *less* believable and factual than the generic TCA cancer warning statement. April 2018 Quantitative Study Rpt. 3-9 (70), 3-12 (73). The textual statement did not demonstrative statistically improvements in measures of informativeness or "thinking about risks." *Id.* at 3-8-3-9 (69-70).
- The warning ranked as significantly *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102).

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests that bloody urine is a more serious health concern than bladder cancer, a fatal disease; 2) suggests to consumers that bladder cancer is just as or more prevalent than other, more-prevalent smoking-related conditions that the warnings depict, such as COPD, peripheral vascular disease, stroke, or coronary heart disease; 3) suggests to consumers that their relative risk of bladder cancer is the same as their relative risk of exposure to other smoking-related conditions with smaller relative risk rates, such as cataracts, erectile dysfunction, or type 2 diabetes; and 4) emphasizes bladder cancer while FDA omits numerous other conditions with worse survival rates. *See* Altria Cmt. fig.8.

ATTACHMENT

FDA Description: The image depicts "[a]n infant with low birth weight resulting from stunted fetal growth. The image shows a newborn infant on a medical scale, and the digital display on the scale reads four pounds." 85 Fed. Reg. at 15,676.

The warning is not "purely factual and uncontroversial."

- The image of a small, crying, newborn infant is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image is clearly aimed at triggering an instinctive, emotional need in adult viewers to comfort the child and alleviate its distress—distress that is "unnecessary" to convey the relevant health risk. 85 Fed. Reg. at 15,677. FDA's June 2016 Study (p. 97) confirms this reaction:
  - Study participants described an earlier similar image as "heartbreaking" and "very emotional," with one stating that the image "would really creep me out."

  Indeed, the moderators of FDA's June 2016 study recommended that FDA keep the warning due to the "clear[]" emotional response it evoked in participants. *See id.* at 164.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- Contrary to FDA's asserted interest, the warned-against harm is not a "less-known" health consequence of smoking. The Surgeon General's warnings, which FDA concedes cover well-known health risks, have long warned against fetal harm. FDA's studies also report that "few," if any, participants found the warning to contain new information. April 2018 Qualitative Study Rpt. 23. *Accord* July 2015 Study Rpt. 33 (earlier similar warning statement provided new information to 0.0% of study participants); June 2016 Study Rpt. 94 (earlier similar image "did not provide new information to participants").
- The textual warning statement did not demonstrative statistically improvements in measures of informativeness or "thinking about risks." April 2018 Quantitative Study Rpt. 3-8-3-9 (69-70), 3-11 (72).
- The graphic warning does not effectively convey the health information FDA asserts. FDA's April 2018 qualitative study (p. 26) reports that 0.6% of participants selected the warning as the text/image pairing that best illustrated fetal harm. The warning also did not meaningfully affect participants' health beliefs about smoking after repeated exposure. *See* May 2019 Study Rpt. 3-15 (111) tbl.3-7 & 3-16 (112) tbl.3-8.

The warning is misleading.

- Although FDA has provided scientific support for the link between maternal smoking and lower birth weight, the scale's depiction of "4.00 lbs." conveys a very low birth weight commonly associated with premature birth. FDA has not claimed, let alone demonstrated, that a birth weight of four pounds is a likely outcome of maternal smoking. Yet the image would mislead consumers into believing that maternal smoking will commonly cause low birth weight to this degree.

ATTACHMENT

FDA Description: The image "depict[s] a patient who recently underwent heart surgery to treat heart disease caused by smoking. The image shows the chest of a man (aged 60-70 years) wearing an open hosptial gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring." 85 Fed. Reg. at 15,677.

The warning is not "purely factual and uncontroversial."

- The image of a man with a large, recently sutured incision is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image is clearly intended to disgust or shock consumers by depicting a graphic wound, or to make consumers fearful of the prospect of needing to undergo major heart surgery and medical monitoring. FDA's June 2016 Study (p. 81) underscores this:
  - "The cut down the middle of the subject's test was the most attention-grabbing part" of an earlier similar image, the study reported, with many respondents stressing the harm from the incision.

  FDA's study (p. 162) recommended that FDA emphasize the incision even more as the "focal point of the image"—a recommendation FDA implemented in the final image.

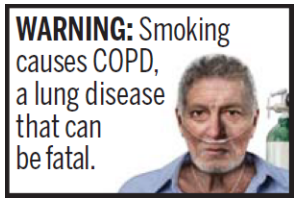
The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- Contrary to FDA's asserted interest, the warned-against harm is not a "less-known" health consequence of smoking. The Surgeon General's warnings, which FDA concedes cover well-known health risks, have long warned against heart disease.
- The selected image does not effectively convey the health information FDA asserts. The image, on its own, does not convey that the individual depicted either suffered from heart disease or a stroke. FDA's studies bear this out:
  - According to FDA's June 2016 study (p. 77), participants deemed an earlier version of the image "unclear" because "[s]ome thought the subject might have lung cancer, while others thought the subject needed heart surgery." The study classified this image as a "[h]igh confusion image[]" that "received 'low' scores on both subject and message clarity." *Id.* at 156.
  - FDA's April 2018 qualitative study (p. 59) likewise reports that "[m]any participants were confused about the scar and the tubes" and the "type of surgery" depicted by the image.
- The textual warning statement did not demonstrative significant improvements in measures of informativeness or "thinking about risks." April 2018 Quantitative Study Rpt. 3-8-3-9 (69-70), 3-11 (72). Participants in FDA's April 2018 qualitative study (p. 59) deemed the image unrealistic. The graphic warning did not meaningfully affect participants' health beliefs about smoking after repeated exposure. *See* May 2019 Study Rpt. 3-15 (111) tbl.3-7 & 3-16 (112) tbl.3-8.

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that their risk of exposure to heart disease and strokes is the same as their risk of exposure to other warned-against conditions with smaller relative risk rates, such as cataracts, erectile dysfunction, or type 2 diabetes, *see* Altria Cmt. tbl.1; 2) emphasizes heart disease and strokes while FDA omits several other conditions with worse survival rates, *see id.* fig.8.

ATTACHMENT



FDA Description: The "image depict[s] a man receiving oxygen support because he has COPD caused by cigarette smoking. The image shows the head and neck of a man (aged 50-60 years) who has a nasal cannula under his nose supplying oxygen; the oxygen tank can be seen behind his left shoulder." 85 Fed. Reg. at 15,678.

The warning is not "purely factual and uncontroversial."

- The image of a man receiving oxygen through an oxygen tank and nasal cannula is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image appears designed to make consumers fearful of the prospect of needing to rely upon an oxygen tank to survive. FDA's internal studies illustrate this:
  - FDA's April 2018 qualitative study (p. 40) reports that participants stated "the man has been smoking/sick for a long time," that "he can't get enough oxygen," and "that he'd have to take the tank with him everywhere."
  - Participants in FDA's June 2016 study (p. 42) reported that an earlier, similar image was "especially attention-grabbing" because of "the man's miserable expression and external oxygen aids."

Indeed, FDA's June 2016 study recommended that FDA "[r]etain the look of misery/sadness/resignation on the man's face," and FDA apparently agreed to do so. *Id.* at 159.

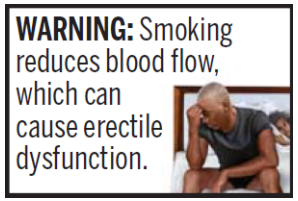
The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- Contrary to FDA's asserted interest, the warned-against harm is not a "less-known" health consequence of smoking. The Surgeon General's warnings, which FDA concedes cover well-known health risks, have long warned against smoker lung disease. FDA's own studies confirm this. *See* June 2016 Study Rpt. 38; July 2015 Study Rpt. 16, 20.
- The selected image does not effectively convey the health information FDA asserts, as FDA's studies demonstrate:
  - Participants in FDA's April Qualitative 2018 Study (p. 40) expressed "some confusion about the oxygen tubes." FDA's June 2016 Study (p. 39) reports that participants knew the man "has a breathing problem," without knowing the condition.
- The warning states that smoking "causes" COPD, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52; *see also id.* at 19.
- Only 5.9% of study participants selected this graphic warning as the text/image pairing that best illustrates smoker lung disease. April 2018 Qualitative Study Rpt. 47. The warning did not meaningfully affect participants' health beliefs about smoking after repeated exposure. *See* May 2019 Study Rpt. 3-15 (111) tbl.3-7 & 3-16 (112) tbl.3-8.

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that their relative risk of exposure to COPD is the same as their relative risk of exposure to other smoking-related conditions with smaller relative risk rates, such as bladder cancer, peripheral vascular disease, stroke, coronary heart disease, cataracts, erectile dysfunction, or type 2 diabetes, *see* Altria Cmt. tbl.1; and 2) emphasizes COPD while FDA omits several other conditions with worse survival rates, such as stomach, liver, or pancreatic cancer, *see id.* fig.8.

ATTACHMENT



FDA Description: The "image depict[s] a man who is experiencing erectile dysfunction caused by smoking. The image shows a man (aged 50-60 years) sitting on the edge of a bed and leaning forward, with one elbow resting on each knee. The man's head is tilted down, with his forehead pressed into the knuckles of his right hand. Behind him on the bed, his female partner looks off in another direction." 85 Fed. Reg. at 15,680.

The warning is not "purely factual and uncontroversial."

- The selected bedroom scene of a despondent man and a woman "look[ing] off in another direction" is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image is clearly designed to generate embarrassment and shame in viewers regarding the sensitive topic of sexual intimacy. FDA's June 2016 Study (p. 165) underscores this:
  - After study participants deemed prior, very different images incomprehensible, the study recommended (and FDA apparently implemented): "Make it clear that the man's emotion is shame."

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. The man on the bed may be experiencing erectile dysfunction. Or he may be distressed for unrelated reasons. The image on its own in no way illuminates how smoking could cause erectile dysfunction. FDA's April 2018 qualitative study (p. 70) shows this:
  - "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 la land,'" or "[s]tress/depression."
- Participants ranked the warning's text as significantly *less* believable and factual than the generic TCA warning statements. *See* April 2018 Quantitative Study Rpt. 3-9 (70), 3-12 (73). The text did not show a statistically significant improvement in informativeness, and prompted participants to indicate that they were significantly *less* likely to think about the warned-against health risk. *Id.* at 3-9 (70) & tbl.3-5, 3-11 (72) & tbl.3-6.
- Participants ranked the graphic warning as significantly *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102). The warning did not meaningfully affect participants' health beliefs about smoking after repeated exposure. *See id.* at 3-15 (111) tbl.3-7 & 3-16 (112) tbl.3-8.

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that their risk of exposure to smoking-attributable erectile dysfunction is the same as or greater than their risk of exposure to other, more-prevalent smoking-related conditions, *see* Altria Cmt. tbl.1; 2) emphasizes a chronic, non-fatal condition, while FDA omits other conditions with high mortality rates, such as trachea, bronchus, and lung cancer, pancreatic cancer, stomach cancer, liver cancer, and acute myeloid leukemia, *see id.* fig.8; and 3) focuses on erectile dysfunction while omitting mention of more common side effects of low blood flow, such as numbness or weakness in the legs.

ATTACHMENT

FDA Description: The "image depict[s] the feet of a person who had several toes amputated due to tissue damage resulting from peripheral vascular disease (PVD) caused by cigarette smoking." 85 Fed. Reg. at 15,681.

The warning is not "purely factual and uncontroversial."

- The image of a pair of discolored and disfigured feet with several toes amputated is not "purely factual and uncontroversial," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The unsightly image is clearly designed to provoke either disgust at the sight of the image, fear at the prospect of undergoing an amputation, or both. FDA's internal studies highlight this:
  - FDA's April 2018 qualitative study (p. 68) reports: "The idea of losing limbs scares some participants and grabs their attention." Participants in FDA's June 2016 study (pp. 126, 130) found a similar earlier image "very attention-grabbing . . . due to the startling image of a subject with missing toes," and repeatedly reacted to the image because it was "gross," "powerfully disturbing," provoked "disgust," and had "shock value."

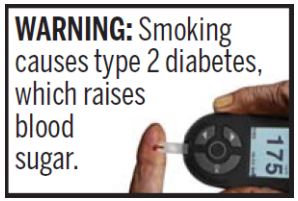
The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. No reasonable consumer would be able to determine from the image alone that the individual whose feet are depicted had an amputation due to "tissue damage from peripheral vascular disease." The only thing discernible from the image is that the depicted feet are blackened and missing several toes. FDA's studies confirm this:
  - FDA's April 2018 qualitative study (p. 67) indicates that participants said "[t]he cause of the foot problem is unclear" and found the image "confusing on its own." The study thus reported that "[t]he connection to smoking is not clear." *Id.* Participants in FDA's June 2016 study (p. 126) observed missing toes, "but the reason why or how was unclear." The study concluded "many will not associate [the image] with circulatory complications . . . without the text warning." *Id.* at 166.
- Participants deemed the text of the warning significantly *less* believable and factual than the generic TCA warning statements. *See* April 2018 Quantitative Study Rpt. 3-9 (70), 3-12 (73). The text did not demonstrate a significant improvement in informativeness. *Id.* at 3-11 (72) & tbl.3-6.
- Participants deemed the graphic warning significantly *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102).

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that peripheral vascular disease is just as or more prevalent than other, more-prevalent smoking-related conditions that other warnings depict; 2) suggests that consumers' risk of exposure to peripheral vascular disease is the same as their risk of exposure to other conditions with smaller relative risk rates, *see* Altria Cmt. tbl.1; 3) emphasizes peripheral vascular disease, while FDA omits other conditions with worse survival rates, *see id.* fig.8; and 4) depicts a complication that is a "rare" effect of reduced blood flow, *see* Ex. K to RAI Servs. Cmt., Wagmeister Decl. ¶ 5.

ATTACHMENT



FDA Description: The "image depict[s] a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking. The digital display reading of 175 mg/dL and a notation on the glucometer indicate a high blood sugar level." 85 Fed. Reg. at 15,682.

The warning is not "purely factual and uncontroversial."

- The image of a needle drawing blood and discolored fingernails is not "purely factual and uncontroversial," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The image aims to provoke the emotional reaction of fear many experience when faced with the prospect of a medical procedure involving needles, or to stigmatize smokers as dirty. FDA's internal studies highlight this:
  - FDA apparently followed recommendations from its June 2016 study (p. 166) to heighten emotional aspects of the image by making the "blood . . . more discernible" and "the finger appear somewhat less 'healthy'" than an earlier, similar image. FDA's April 2018 qualitative study (p. 64) reports that all groups of participants "discussed the fingernails being yellow, crusty, discolored, or dirty."

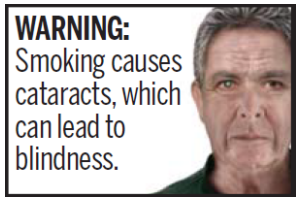
The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. The average consumer is unlikely to be aware of the meaning of the image generally or the "175" figure. FDA's studies show this:
  - Respondents in FDA's June 2016 study (p. 123) characterized the image as "unclear" and "confusing," with one noting that the image depicts "[u]nhealthiness," but "I have no idea why" or "how." FDA's April 2018 qualitative study (p. 64) similarly reports that "[s]ome participants didn't know what the rating ('175') meant . . ."
- The warning states that smoking "causes" diabetes, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52.
- Participants ranked the warning's text as significantly *less* believable and factual than the generic TCA warning statements. *See* April 2018 Quantitative Study Rpt. 3-9 (70), 3-12 (73). The text did not show statistically significant improvements in informativeness or the "thinking about risks" measure. *Id.* at 3-9 (70) & tbl.3-5, 3-11 (72) & tbl.3-6.
- Participants deemed the graphic warning *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102).

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests that consumers' risk of exposure to type 2 diabetes is the same as or greater than their risk of exposure to other, more-prevalent smoking-related conditions, *see* Altria Cmt. tbl.1; 2) emphasizes diabetes while FDA omits several other conditions with worse survival rates, *see id.* fig.8; and 3) emphasizes "raise[d] blood sugar" while omitting other, more serious consequences of diabetes.
- The warning does not accurately depict the warned-against health risk, as "175" does not necessarily represent an unsafe blood glucose level for all individuals with diabetes. *See* Am. Diabetes Ass'n, Cmt. 2.

ATTACHMENT



FDA Description: The "image depict[s] a closeup of the face of a man (aged 65 years or older) who has a cataract caused by cigarette smoking. The man's right pupil is covered by a large cataract." 85 Fed. Reg. at 15,683.

The warning is not "purely factual and uncontroversial."

- The image of a man with one artificially enhanced, discolored eye is not a "pure attempt[] to convey information," but instead seeks to advance FDA's anti-smoking viewpoint by "evok[ing] an emotional response" in consumers. *R.J. Reynolds*, 696 F.3d at 1216-17. The discomforting image is clearly aimed at shocking the viewer or generating fear at the prospect of experiencing the condition in the image.

The warning fails to advance FDA's asserted interest in a manner no more extensive than necessary.

- The selected image does not effectively convey the health information FDA asserts. The image on its own, without the accompanying text, simply shows a man with one eye differently colored than the other. There is no reason for a consumer to know that the depicted eye-color variation represents "a large cataract." FDA's June 2016 study (p. 143) confirms this:
  - "[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." The study thus classified the image as a "[h]igh confusion image[]" that "received 'low' scores on both subject and message clarity." *Id.* at 156.
- The warning states that smoking "causes" cataracts, despite an FDA study finding that consumers react negatively to that kind of definitive phrasing. July 2015 Study Rpt. 52.
- Participants ranked the warning's text as significantly *less* believable and factual than the generic TCA warning statements. *See* April 2018 Quantitative Study Rpt. 3-9 (70), 3-12 (73). The text did not show statistically significant improvements in informativeness or the "thinking about risks" measure. *Id.* at 3-9 (70) & tbl.3-5, 3-11 (72) & tbl.3-6.
- Participants deemed the graphic warning significantly *less* factual than the Surgeon General's warnings. May 2019 Study Rpt. 3-6 (102).

The warning is misleading.

- The warning misleads consumers about the relative, smoking-attributable risks because it: 1) suggests to consumers that their risk of exposure to smoking-attributable cataracts and blindness is the same as or greater than their risk of other, more-prevalent smoking-related conditions that other warnings depict, such as COPD, *see* Altria Cmt. tbl.1; 2) emphasizes a chronic, non-fatal condition, while FDA omits from the warnings other conditions with high mortality rates, *see id.* fig.8; and 3) emphasizes an outcome—blindness—that occurs in only a small minority of cases of cataracts.
- The warning does not accurately depict the warned-against risk. The vast majority of cataracts are undetectable by the unaided human eye. Ex. H to RAI Servs. Cmt., Davidorf Decl. ¶¶ 7-8.