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

R.J. REYNOLDS TOBACCO COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; ITG BRANDS, LLC; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES INC.; RANGILA LLC; SAHIL ISMAIL, INC.; and IS LIKE YOU INC.; *Plaintiffs*, *v.* UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration; and ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; *Defendants.*	CIVIL ACTION NO. __

COMPLAINT

INTRODUCTION

1. For nearly fifty-five years, cigarette packages have included textual warnings that convey factual, uncontroversial information about the risks of smoking. In 2009, however, Congress sought to replace these factual disclosures with government-created anti-smoking advocacy. Specifically, Congress instructed the Food and Drug Administration ("FDA" or "the Agency") to issue regulations that require massive "color graphics depicting the negative health consequences of smoking." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1845 (2009) (codified at 15 U.S.C. § 1333(d)[1]).[1] In 2011, FDA did so, but before the regulation took effect, the D.C. Circuit held that it violated the First Amendment. FDA has now issued a second graphic-warnings regulation. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) ("the Rule") (attached as Ex. 6). It too is invalid.

2. The Rule requires the use of eleven new textual warnings, accompanied by eleven graphic images—such as images of a specimen cup filled with bloody urine and a pair of diseased feet with several amputated toes—that are designed to frighten, shock, and disgust adult cigarette consumers. In addition, these "warnings" must occupy the top 50% of the front *and* back of cigarette packages and the top 20% of cigarette advertising. These requirements cross the line into governmental anti-smoking advocacy.

3. Such "warnings" are unprecedented. Never before in the United States have producers of a lawful product been required to use their own packages and advertising to convey an emotionally charged government message urging adult consumers to shun their product. These requirements force

[1] Two separate provisions of the Tobacco Control Act were codified as 15 U.S.C. § 1333(d). To avoid confusion, this Complaint will refer to those provisions as Sections 201(a) and 202(b) of the Tobacco Control Act and will cite to those provisions as § 1333(d)[1] and § 1333(d)[2], based on the order in which they appear in the statute.

Plaintiffs not to convey purely factual and uncontroversial statements about the risks of smoking, but to become a mouthpiece for the government's anti-smoking advocacy.

4. This is precisely the type of compelled speech that the First Amendment prohibits. As the Supreme Court has explained, the government may not compel Plaintiffs to "use their private property as a 'mobile billboard' for the State's ideological message." *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). Nor may the government use compelled disclosures to drown out commercial speech regarding lawful products that it does not like. "The State can express [its] view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 578–79 (2011).

5. When FDA first tried to transform cigarette packages and advertising into billboards for the government's anti-smoking message, the D.C. Circuit had no difficulty holding that the rule violated the First Amendment. *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 31 (D.C. Cir. 2014) (en banc). The court recognized that FDA's warnings were not "factual" disclosures; rather, they were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *Id.* at 1217. The court also recognized that the warnings were not "uncontroversial"; instead, "many of the images chosen by FDA could be misinterpreted by consumers." *Id.* at 1216. And the court held that "FDA has not provided a shred of evidence … showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219.

6. FDA's new rule fares no better. Once again, the Rule is an unconstitutional attempt to compel Plaintiffs to disparage their own products, frighten and shame their own customers, and proclaim the government's anti-smoking message. Once again, the warnings would mislead consumers

about the risks of smoking. And once again, FDA cannot show that the Rule would meaningfully affect consumers' smoking behaviors or beliefs.

7. FDA's back-to-back failures to develop a constitutional rule point to a larger problem: the Tobacco Control Act's graphic-warnings mandate itself is an unconstitutional attempt "to remove a popular but disfavored product from the marketplace." *Sorrell*, 564 U.S. at 577. Given the Act's directive, FDA will undoubtedly make a third attempt to develop a graphic-warnings rule after this one is invalidated, and the resulting rule will inevitably suffer from the same constitutional problems. The Court should break this cycle by striking down both the Rule and the Act's graphic-warnings requirement.

8. The Rule has yet more flaws. For example, in issuing the Rule, FDA contravened several core requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.* In addition, FDA lacked statutory authority for its revisions to the textual warnings in the Tobacco Control Act.

9. In light of these problems, Plaintiffs respectfully request that this Court (1) declare that the Rule and the Act's graphic-warnings requirement violate the First Amendment to the United States Constitution, (2) declare that the Rule violates the APA and the Tobacco Control Act, (3) preliminarily and permanently enjoin Defendants from enforcing either the Rule or the Act's graphic-warnings requirement, and (4) vacate the Rule in its entirety.

PARTIES

10. Plaintiff R.J. Reynolds Tobacco Company is a North Carolina corporation headquartered in Winston-Salem, North Carolina. Reynolds manufactures, sells, distributes, and advertises cigarettes nationwide, including in this district.

11. Plaintiff Santa Fe Natural Tobacco Company, Inc., is a New Mexico corporation headquartered in Oxford, North Carolina. Santa Fe manufactures, sells, distributes, and advertises cigarettes nationwide, including in this district.

12. Plaintiff ITG Brands, LLC is a Texas limited liability company headquartered in Greensboro, North Carolina. ITG Brands manufactures, sells, distributes, and advertises cigarettes nationwide, including in this district.

13. Plaintiff Liggett Group LLC is a Delaware limited liability company headquartered in Mebane, Alamance County, North Carolina. Liggett manufactures cigarettes and, through an affiliate, sells, distributes, and advertises them nationwide, including in this district.

14. Plaintiff Neocom, Inc., is a Texas corporation headquartered in Tyler, Texas. Neocom, Inc. operates three convenience stores in Tyler that sell cigarettes in this district.

15. Plaintiff Rangila Enterprises Inc. is a Texas corporation headquartered in Fort Worth, Texas. Rangila Enterprises Inc. operates five convenience stores in Fort Worth that sell cigarettes.

16. Plaintiff Rangila LLC is a Texas limited liability company headquartered in Fort Worth, Texas. Rangila LLC operates convenience stores in Fort Worth, Hurst, and Terrell that sell cigarettes.

17. Plaintiff Sahil Ismail, Inc. is a Texas corporation headquartered in Grapevine, Texas. Sahil Ismail, Inc. operates a convenience store in Grapevine that sells cigarettes.

18. Plaintiff Is Like You Inc. is a Texas corporation headquartered in Fort Worth, Texas. Is Like You Inc. operates a convenience store in Fort Worth that sells cigarettes.

19. Defendant United States Department of Health and Human Services ("HHS") is a federal agency of the United States. Under the Food, Drug, and Cosmetic Act and the Tobacco Control Act, HHS is responsible for regulating cigarettes marketed in the United States. 21 U.S.C. §§ 321(d), 387a(a). HHS is headquartered in Washington, D.C.

20. Defendant FDA is a federal agency of the United States within HHS. FDA regulates cigarettes marketed in the United States using authority delegated to it by HHS. *Id.* § 387a(e). FDA is headquartered in Silver Spring, Maryland.

21. Defendant Alex M. Azar II is the Secretary of HHS. Secretary Azar oversees FDA's activities and is responsible for the implementation and enforcement of the Tobacco Control Act and the Rule. Secretary Azar is sued in his official capacity.

22. Defendant Dr. Stephen M. Hahn is the Commissioner of FDA. Commissioner Hahn oversees the implementation and day-to-day enforcement of the Tobacco Control Act and the Rule. Commissioner Hahn is sued in his official capacity.

JURISDICTION AND VENUE

23. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 2201, and 5 U.S.C. § 701 *et seq*.

24. Venue is proper in this district under 28 U.S.C. § 1391(e) because it is where one of the Plaintiffs resides.

BACKGROUND

A. The Government's Historical Approach To Reducing Smoking

25. For decades, the government has used a multi-pronged approach to reducing smoking. The government has promulgated messages about the dangers of smoking; it has severely restricted the speech of tobacco manufacturers; and it has otherwise regulated the advertising, sale, and use of cigarettes.

26. *First*, the government has required that cigarette packages and advertising display factual warnings about the risks of smoking. In 1965, Congress "establish[ed] a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282,

282 (1965) (the "Labeling Act"). Specifically, the Labeling Act mandated that cigarette packages include the following warning: "CAUTION: Cigarette Smoking May Be Hazardous to Your Health." *Id.* at 283.

27. In 1984, Congress amended the Labeling Act to require that all cigarette packages and advertising include a series of rotating warnings that cover a variety of smoking risks:

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

Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201–02 (1984). These warnings have become known as the "Surgeon General's warnings," and they are in effect today.

28. *Second*, the government has systematically limited the avenues through which Plaintiffs can advertise their lawful products. For example, federal law prohibits Plaintiffs from advertising cigarettes in television and radio advertisements, *see* 15 U.S.C. § 1335, media that are well-suited to reach a large number of consumers.

29. Federal law also prohibits Plaintiffs from doing the following:

a. sponsoring "any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name … , logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes," 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(c);

b. marketing, licensing, distributing, or selling any promotional item (such as hats and t-shirts) bearing the "brand name … , symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes," 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(a); and

c. "distribut[ing] or caus[ing] to be distributed any free samples of cigarettes," 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R.§ 1140.16(d).

30. Federal law also provides that federal agencies, states and subdivisions, and Indian tribes may "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than" certain aspects of the Act, including with respect to "advertising and promotion," 21 U.S.C. § 387p, and that states or localities may enact statutes and promulgate regulations that impose "specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes," 15 U.S.C. § 1334(c).

31. Many cigarette manufacturers (including Reynolds and Santa Fe) are also subject to the Master Settlement Agreement ("MSA"), which settled litigation brought by forty-six states. Under this agreement, the participating manufacturers are subject to additional restrictions on cigarette advertising, including prohibitions on using billboard and transit advertising, paid product placement, event sponsorships, and advertising in sports stadiums and arenas. *See* MSA § III(d), https://tinyurl.com/y6te8olv.

32. Together, these advertising restrictions leave Plaintiffs with few avenues through which they can effectively communicate truthful information about their lawful products to adult cigarette consumers.

33. *Third*, the government has imposed numerous non-speech restrictions on the advertising, sale, and use of cigarettes. For example, federal law prohibits the sale of cigarettes to anyone under the age of twenty-one, *see* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, 133 Stat. 2534 (2019), and imposes taxes on cigarettes that are designed to deter cigarette use, *see, e.g.*, 27 C.F.R. § 40.1 *et seq.* *See also* Centers for Disease Control and Prevention ("CDC"), *State and Territorial Laws Prohibiting Sales of Tobacco Products to Persons Aged < 21 Years* (Feb. 21, 2020), https://tinyurl.com/socswzw (explaining that such strategies can "help prevent and reduce youth tobacco product use"). In addition, state and local governments across the country have regulated who may sell cigarettes, who may use cigarettes, and where cigarettes may be used.

34. *Fourth*, the government has run multiple public-education campaigns urging smokers to quit. For example, between 2009 and 2014, FDA spent more than $500 million on such campaigns. Comment Letter of RAI Services Co. at 32, Docket No. FDA-2019-N-3065 (Oct. 11, 2019) (the "Reynolds Comments") (citing U.S. Gov't Accountability Office, No. 14-561, *Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities* at 16–17 (June 2014), https://tinyurl.com/y93gktex) (attached as Ex. 2). And since 2014, FDA has run multiple public-education campaigns, including *The Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts*. *Id.* FDA has touted these campaigns as "highly successful" and as "yielding tremendous results." *Id.* at 33 (quoting Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa). Indeed, FDA alleged that *The Real Cost* had "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.* (quotation marks omitted).

35. Other government agencies have run similar campaigns. For example, the CDC regularly runs public-education campaigns, and the Surgeon General has issued more than thirty reports about the health risks of smoking. *Id.* at 13; *see also CDC's Successful* Tips From Former Smokers

Campaign Returns on March 23, CDC (Mar. 23, 2020), https://www.cdc.gov/media/releases/2020/p0323-smoker-tips-return.html.

36. This multi-pronged approach—factual warnings, advertising restrictions, non-speech restrictions, and public-education campaigns—coincided with effectively universal public awareness of the risks of smoking. Over the past several decades, the public has widely understood that smoking is harmful. For example, data from FDA's own Population Assessment of Tobacco and Health ("PATH") survey shows that *99.5%* of individuals believe that cigarette smoking is harmful to health, including 91% who believe that it is "very or extremely harmful," 7% who believe it is "somewhat harmful," and 1.5% who believe it is "slightly harmful." Reynolds Comments at 14.

37. It would be difficult, if not impossible, to improve these numbers. Experts generally agree that, "as a practical matter, getting to awareness levels above 80 or 90 percent is unrealistic." Reynolds Comments at 14 (brackets and quotation marks omitted). Indeed, the percentage of Americans who know that smoking is harmful to health is higher than the percentage of Americans who know that the Earth revolves around the sun (74%), or the percentage of young Americans who know where the United States is on a map (94%). *Id.*

38. At the same time, smoking prevalence and cigarette consumption have fallen dramatically. For example:

a. Between 1965 and 2017, the percentage of adults who smoked cigarettes fell from 42.4% to 14%. *Id.* at 23; *see also* CDC, *Current Cigarette Smoking Among Adults in the United States* (last updated Nov. 18, 2019), https://tinyurl.com/jdqoxrq (explaining that, in 2018, the percentage of adults who smoked cigarettes fell to 13.7%).

b. Between 1981 and 2017, the number of cigarettes purchased annually in the United States dropped from 640 billion to 249 billion—a decline of more than

60% despite an increase in the U.S. population of more than 100 million. Reynolds Comments at 23.

c. Between 1997 and 2017, the percentage of high school students who smoked fell from 36.4% to 8.1%. *Id.*; *see also* CDC, *Youth and Tobacco Use* (last updated Dec. 10, 2019), https://tinyurl.com/jvsmmen (explaining that, in 2019, the percentage of high school students who smoked fell to 5.8%).

39. Indeed, youth and adult smoking rates are at historic lows. As Mitch Zeller, the Director of FDA's Center for Tobacco Products, recently testified before Congress, "[w]e've made such progress in reducing the number of kids who smoke cigarettes. The numbers that are coming out will report historically low rates of kids smoking cigarettes." *The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy: Hearing Before the Subcomm. on Econ. and Consumer Policy of the H. Comm. on Oversight and Reform*, 116th Cong. (2019) (statement of Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration); *see also* CDC, *Cigarette Smoking Among U.S. Adults Lowest Ever Recorded* (Nov. 8, 2018), https://tinyurl.com/y5wcor58.

B. The Tobacco Control Act

40. In 2009, Congress changed the government's approach to cigarette warnings by enacting the Tobacco Control Act. Pub. L. No. 111-31, § 201 (amending section 4 of the Labeling Act, 15 U.S.C. § 1333). Specifically, Congress transformed the factual and uncontroversial warnings on cigarette packages and advertising into government-created anti-smoking advocacy.

41. The Tobacco Control Act requires that cigarette packages and advertising bear one of nine textual warnings:

- "**WARNING**: Cigarettes are addictive."
- "**WARNING**: Tobacco smoke can harm your children."

- "**WARNING**: Cigarettes cause fatal lung disease."
- "**WARNING**: Cigarettes cause cancer."
- "**WARNING**: Cigarettes cause strokes and heart disease."
- "**WARNING**: Smoking during pregnancy can harm your baby."
- "**WARNING**: Smoking can kill you."
- "**WARNING**: Tobacco smoke causes fatal lung disease in nonsmokers."
- "**WARNING**: Quitting smoking now greatly reduces serious risks to your health."

15 U.S.C. § 1333(a)(1), (b)(1).

42. The Act also directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" these textual warnings. *Id.* § 1333(d)[1].

43. Together, the textual warnings and color graphics must occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. *Id.* § 1333(a)(2), (b)(2). The Act does not explain why Congress believed such large warnings were necessary.

44. The Act gives FDA a limited ability to adjust the textual warnings as part of its rulemaking to require graphic warnings. Specifically, FDA can "adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." *Id.* § 1333(d)[1].

45. After the graphic warnings take effect, FDA has a greater ability to adjust them. Specifically, FDA may, via rulemaking, "adjust the format, type size, color graphics, and text of any of the label requirements … if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2].

46. In addition to adopting new textual warnings and directing FDA to issue a regulation adopting graphic images, the Tobacco Control Act imposes a related set of labeling requirements. These requirements (the "related requirements") require that cigarette packages display:

- "the name and place of business of the tobacco product manufacturer, packer, or distributor," 21 U.S.C. § 387c(a)(2)(A);
- "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," *id.* § 387c(a)(2)(B);
- "an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco," *id.* § 387c(a)(2)(C); and
- where applicable, "the statement 'Sale only allowed in the United States,'" *id.* § 387t(a).

47. The Act provides that the new textual and graphic warnings, and each of the related requirements, will become effective "15 months after the issuance of [a graphic-warnings rule]." Pub. L. No. 111-31, § 201(b) (setting the effective date for the amendments to 15 U.S.C. § 1333); *id.* § 103(q)(5) (using identical text to set the effective date for the related requirements in 21 U.S.C. § 387c(a)(2)); *id.* § 301 (using identical text to set the effective date for the related requirement in 21 U.S.C. § 387t(a)).

C. FDA's First Graphic-Warnings Rule

48. On June 22, 2011, FDA issued a rule implementing the Act's graphic-warnings requirement. *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,629 (June 22, 2011) (the "2011 Rule"). The 2011 Rule required that all cigarette packages and advertising bear one of nine disturbing images, such as images of a body on an autopsy table, diseased body parts, and a wailing baby.

49. FDA freely admitted that these images were designed to make consumers "depressed, discouraged, and afraid" to buy cigarettes. *Id.* at 36,638 (quotation marks omitted). FDA also admitted that these images were designed to convey the government's anti-smoking message. FDA said that

that these images were designed to "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [smoking] is cool"; and "encourage smokers to quit." Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), https://tinyurl.com/yyxc8x88. Indeed, FDA admitted that graphic warnings were designed to make "'every single pack of cigarettes in the country [a] mini billboard' for the government's anti-smoking message." *R.J. Reynolds*, 696 F.3d at 1212 (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)).

50. FDA claimed that the 2011 Rule was designed to further the government's interest in "reducing the number of Americans, particularly children and adolescents, who use cigarettes." 76 Fed. Reg. at 36,629. But FDA's own study determined that the warnings would not advance that interest. The study concluded that the warnings would reduce smoking rates by a mere 0.088%, a number that FDA conceded was statistically indistinguishable from zero. *Id.* at 36,775–76. As FDA explained: "our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate. Therefore, the appropriate lower bound on benefits is zero." *Id.* at 36,776.

D. *R.J. Reynolds Tobacco Co. v. FDA*

51. A federal district court enjoined the 2011 Rule before it went into effect and, in 2012, the D.C. Circuit held that it violated the First Amendment. *See R.J. Reynolds*, 696 F.3d 1205.

52. The court began by analyzing whether the 2011 Rule was subject to the standard of scrutiny set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), which holds that "purely factual and uncontroversial disclosures are permissible if they are reasonably related to the State's interest in preventing deception of consumers, provided the requirements are not unjustified or unduly burdensome." *R.J. Reynolds*, 696 F.3d at 1212 (quotation marks omitted). The court held that the *Zauderer* standard did not apply for three reasons.

53. *First*, the graphic warnings were not "reasonably related to the State's interest in preventing deception of consumers." The court explained that the Tobacco Control Act already prohibited misleading statements on cigarette packages and advertising. *Id.* at 1214. In addition, neither Congress nor FDA had found that graphic warnings were necessary to prevent consumers from being deceived. *Id.* at 1214–15.[2]

54. *Second*, the graphic warnings were not "purely factual." As "FDA tacitly admit[ted]," the warnings were "primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning." *Id.* at 1216. Because the warnings were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting," the court had no trouble concluding that they were not purely factual. *Id.* at 1217.

55. *Third*, the warnings were not "uncontroversial." On the contrary, "many of the images chosen by FDA could be misinterpreted by consumers." *Id.* at 1216.

56. Having held *Zauderer* inapplicable, the court then turned to analyzing whether the 2011 Rule satisfied the standard of scrutiny set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), which governs certain restrictions on commercial speech. Under the *Central Hudson* standard, the government had the burden to prove (among other things) that it had a "substantial" interest and that the 2011 Rule "directly advances" that interest. *Id.* at 1217 (quotation marks omitted). But FDA had utterly failed to meet its burden.

57. The court first held that the 2011 Rule would not advance the government's interest in reducing smoking. As the court explained, "FDA has not provided a shred of evidence—much less

[2] The D.C. Circuit later held that, under *Zauderer*, a compelled disclosure need not be reasonably related to preventing consumer deception. *Am. Meat Inst.*, 760 F.3d at 31. But this Circuit has taken the opposite view, noting that *Zauderer* applies to compelled disclosures that are "directed at deceptive or misleading commercial speech." *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015), *modified on other grounds*, No. 13-20250, 2015 WL 13768849 (5th Cir. Oct. 22, 2015).

the 'substantial evidence' required by the APA—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219.

58. The court then rejected FDA's argument that the government had a substantial interest in "effectively communicating health information regarding the negative effects of cigarettes." *Id.* at 1221 (quotation marks omitted). As "FDA concede[d], this purported 'interest' describes only the *means* by which FDA is attempting to reduce smoking rates." *Id.* at 1221. This "purely informational" interest was therefore "too vague to stand on its own" and was "not an independent interest capable of sustaining the Rule." *Id.*

59. Because the 2011 Rule failed to satisfy either *Zauderer* or *Central Hudson*, the court vacated it and remanded to FDA. *Id.* at 1222.

E. FDA's New Proposed Rule

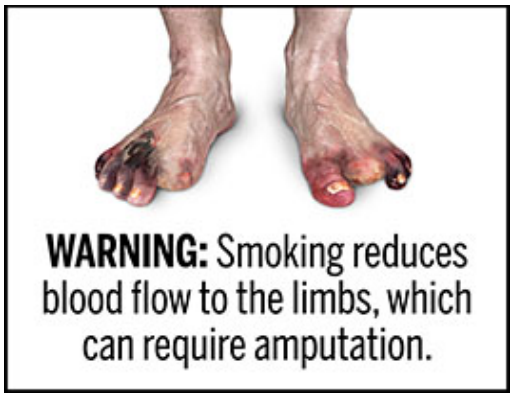
60. On August 16, 2019—almost seven years after the D.C. Circuit vacated the 2011 Rule—FDA issued a proposed rule that again implemented the Tobacco Control Act's graphic-warnings requirement. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019) (the "Proposed Rule") (attached as Ex. 1). In the Proposed Rule, FDA abandoned its previously asserted interest of "reducing the number of Americans … who use cigarettes." 76 Fed. Reg. at 36,629. Instead, FDA said that the Rule would "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. In particular, FDA said that it wanted to advance this interest by focusing on "less-known health consequences of smoking." *Id.* at 42,757.

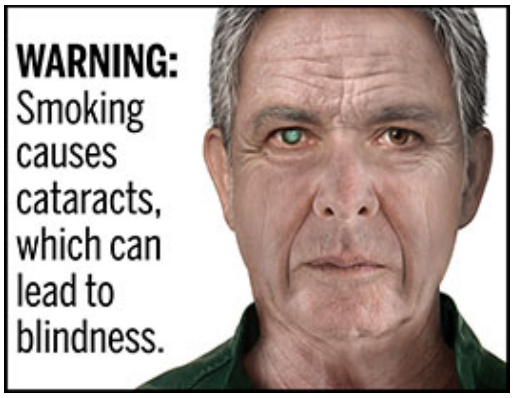
61. The Proposed Rule deleted all but two of the textual warnings prescribed by the Tobacco Control Act, and added ten FDA-created textual warnings. *Id.* at 42,772–77. Thus, the Proposed Rule required all cigarette packages and advertising to bear one of the following textual warnings:

- "**WARNING**: Tobacco smoke can harm your children."
- "**WARNING**: Tobacco smoke causes fatal lung disease in nonsmokers."
- "**WARNING**: Smoking causes age-related macular degeneration, which can lead to blindness."
- "**WARNING**: Smoking causes type 2 diabetes, which raises blood sugar."
- "**WARNING**: Smoking reduces blood flow to the limbs, which can require amputation."
- "**WARNING**: Smoking causes cataracts, which can lead to blindness."
- "**WARNING**: Smoking causes bladder cancer, which can lead to bloody urine."
- "**WARNING**: Smoking reduces blood flow, which can cause erectile dysfunction."
- "**WARNING**: Smoking causes head and neck cancer."
- "**WARNING**: Smoking can cause heart disease and strokes by clogging arteries."
- "**WARNING**: Smoking during pregnancy stunts fetal growth."
- "**WARNING**: Smoking causes COPD, a lung disease that can be fatal."

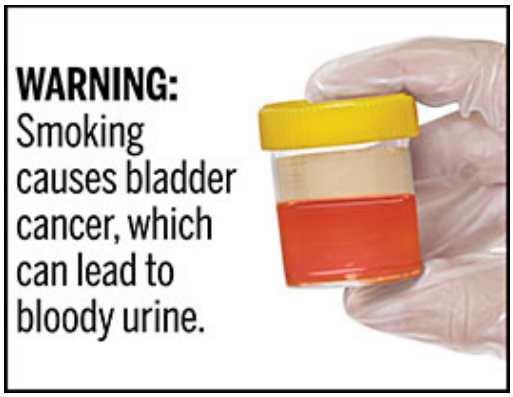
Id. at 42,797 (proposed 21 C.F.R. § 1141.10(a)).

62. The Proposed Rule also included thirteen graphic images to be paired with these textual warnings, for a total of thirteen graphic warnings. *Id.* at 42,772–77. Together, the textual warnings and graphic images must occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. *Id.* at 42,797 (proposing 21 C.F.R. § 1141.10).

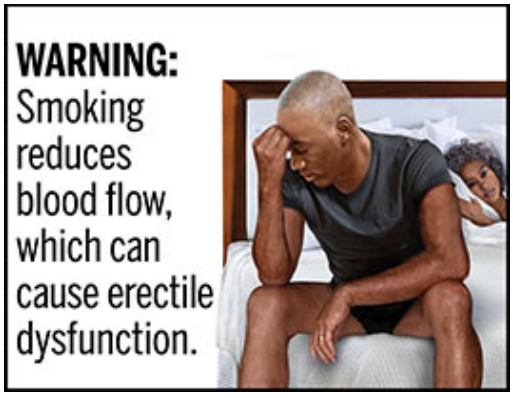

WARNING: Smoking reduces blood flow to the limbs, which can require amputation.


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

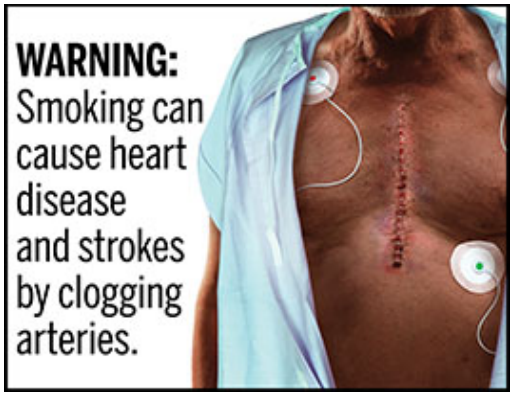

WARNING:
Tobacco smoke causes fatal lung disease in nonsmokers.

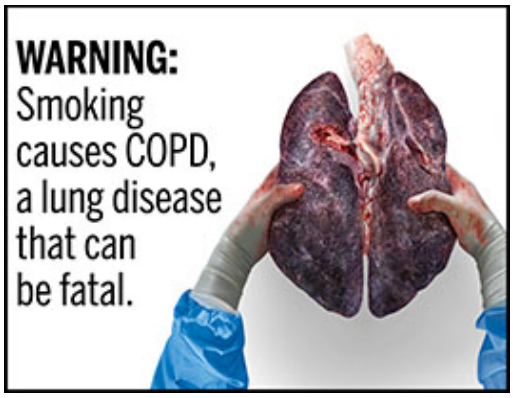

WARNING:
Smoking causes bladder cancer, which can lead to bloody urine.

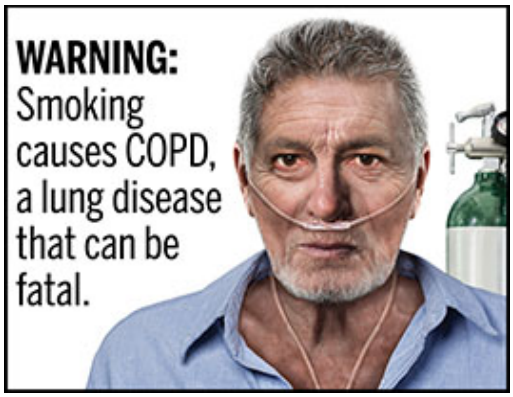

WARNING:
Smoking causes age-related macular degeneration, which can lead to blindness.


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


WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
175
OK


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





63. Just like their predecessors, these warnings used gruesome images that were designed to evoke negative emotions, such as fear and shock, and to convey the government's anti-smoking message. A recent survey, which is part of the administrative record, confirms this point. In that survey, respondents viewed five proposed warnings selected at random, and then answered questions about those warnings. This survey showed the following:

- 85.9% of respondents said that the warnings were "trying to make people feel afraid";
- 85.4% of respondents said that the warnings were "trying to shock people";
- 74.5% of respondents said that the warnings conveyed the message that people "should not smoke" cigarettes; and
- 68.2% of respondents said that the warnings conveyed the message that people "should not buy" cigarettes.

Reynolds Comments, Exh. E, Samantha Iyengar, Ph.D., NERA Survey: Consumer Perceptions of Cigarette Warning Labels, at ¶ 31 & Appendix 3 (the "Iyengar Report").

64. Also like their predecessors, the warnings misrepresent or exaggerate the potential effects of smoking. For example:

a. The "Sick Child" image appears to depict a "worst case scenario": "a child hospitalized due to an asthma attack caused by environmental tobacco smoke." Reynolds Comments, Exh. G, Decl. of Lawrence R. Brooks, MD ¶ 4. Moreover, the warning is "exaggerating" because it is "uncommon for a child with an asthma attack to require oxygen." *Id.* ¶ 5.

b. The "Diseased, Non-Smoker's Lungs" image depicts an "amount of black pigmentation" that "would likely result from many years of heavy direct smoking" and would be "very unusual … in a non-smoker." Reynolds Comments, Exh. I, Decl. of Mark O. Farber, MD ¶ 5. In addition, the image is misleading because the cancerous lesions appear on the surface of the lung (rather than deep within the lung), and because it would be "unusual" for a non-smoker to have three separate lesions of the size depicted. *Id.* ¶ 6.

c. The "Needle In Eyeball" image exaggerates the effects of smoking by emphasizing a condition—blindness—that occurs in only a small minority of cases of age-related macular degeneration. Comment Letter of Altria Client Services at 57, Docket No. FDA-2019-N-3065 (Oct. 15, 2019) (the "Altria Comments"). The image also misrepresents the treatment for macular degeneration, and gives the false impression that the treatment is painful. Comments, Exh. H, Decl. of Jonathan M. Davidorf, MD at 2 (the "Davidorf Decl.").

d. The "Diseased Feet" image suggests that the depicted condition is common, when in fact, it affects at most one in 1,000 smokers. Reynolds Comments, Exh. K, Decl. of Robert Wagmeister, MD ¶ 4.

e. The "Cataracts" image is "not a reasonable depiction of persons with cataracts in the US, because in the US the cataract would have been treated surgically long before it got to this stage." Davidorf Decl. at 3. The warning also emphasizes a condition—blindness—that occurs in only a small minority of cases (0.48%) of cataracts. Altria Comments at 61 (citing National Eye Institute, *Eye Health Data and Statistics*).

f. The "Neck Tumor" image misleadingly 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." Reynolds Comments, Exh. J, Decl. of Kim R. Jones, MD ¶ 5.

g. The "Open Heart Surgery" image misleadingly suggests that open heart surgery is the most common method of treating coronary artery disease, when in-patient percutaneous coronary interventions are at least 2.5 times more common. Reynolds Comments at 8.

h. The "Crying Baby" image is misleading because it shows a newborn infant weighing four pounds, when infants born to women who smoke cigarettes typically weigh more than five pounds. *Id.*

i. The "Bloody Urine" image is misleading. FDA itself cited "literature in which the association between bladder cancer and consistent smoking of up to ten cigarettes per day was not statistically significant." Comment Letter of ITG

Brands at 12, Docket No. FDA-2019-N-3065 (Oct. 15, 2019) (citing 84 Fed. Reg. at 42,774) ("ITG Comments") (attached as Ex. 4).

j. The "COPD Diseased Lung" image misleadingly conveys the relationship between cigarette use and the depicted image, as it "fails to convey that such lung pigmentation is unlikely to occur except after 'many years' of 'heavy' smoking." ITG Comments 14.

k. The "Erectile Dysfunction" image fails to "convey either the absolute or relative risk of erectile dysfunction associated with smoking," and misleadingly suggests that this outcome is commonplace for smokers. ITG Comments 15. In support of this image, "the Agency cite[d] a study which found that the correlation coefficient between erectile dysfunction and smoking "after adjusting for age . . . was attenuated, -0.09 ($p < 0.02$)."" ITG Comments 15 (citing 84 Fed. Reg. at 42,776).

l. The "COPD Nasal Cannula" image misleadingly "depicts a 'worst case scenario,' without any discussion in the administrative record of the proportion of smokers developing COPD who will require long-term oxygen therapy (or home oxygen), much less the proportion of all smokers who will require home oxygen." ITG Comments 14.

m. The "Finger Prick" image is "misleading in that it does not convey either the absolute or relative risk of diabetes as a result of smoking," and instead suggests that smoking will result in development of diabetes requiring the use of painful finger stick blood glucose monitoring. ITG Comments 16.

F. FDA's Qualitative And Quantitative Studies

65. In the Proposed Rule, FDA changed its rationale for requiring graphic warnings. Instead of saying that graphic warnings would reduce smoking, as FDA said in the 2011 Rule, FDA said that they would "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. FDA also commissioned several qualitative and quantitative studies in an effort to evaluate whether the FDA-created textual warnings or graphic warnings would advance that interest. The studies suffer from numerous design flaws, but even so they demonstrate that FDA's regulation fails to promote its stated aims.

Qualitative Study For The FDA-Created Textual Warnings

66. FDA first conducted "a series of 16 qualitative focus groups" to gather consumers' feedback about whether the ten FDA-created textual warnings would improve public understanding of the risks of smoking cigarettes. *Id.* at 42,767. These focus groups revealed three glaring problems.

67. *First*, the participants in the FDA study already understood many of the risks described in the textual warnings. For example, the warning "Smoking during Pregnancy Can Stunt Your Baby's Growth" was new information for *0%* of adults, and the warning "Tobacco smoke can harm your children" was new information for only 2.6% of adults. RTI International, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions*, at 33, 35 (July 2015) (the "First Qualitative Study Report").

68. *Second*, many of the textual warnings conveying that harm would occur (rather than can occur) were not believable. For example, the FDA study's "most prevalent finding" was that the study participants were more likely to believe statements that said smoking "can cause" a particular disease rather than that smoking "causes" that disease. *Id.* at 52; *see also id.* at 15, 17, 19, 26, 27, 31, 33, 34, 35, 36, 38, 45, 46 (expressing the concern that the word "causes" was not believable). Yet the vast majority of the textual warnings used the word "causes" rather than "can cause."

69. *Third*, the government had several less-restrictive means of achieving its goals. For example, the participants in the FDA study often remarked that "the warning statements on cigarette packs were less powerful" than other forms of education, such as television advertisements. *Id.* at 11.

Quantitative Study For The FDA-Created Textual Warnings

70. FDA next conducted a "quantitative consumer research study to assess which, if any, of the [FDA-created] warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to the [Tobacco Control Act's] statements." 84 Fed. Reg. at 42,767.

71. As an initial matter, this study was poorly designed. The U.S. Office of Management and Budget ("OMB") granted the study only a limited approval and noted that, "[d]ue to the study design, convenience sampling methodology, and methods of analyses—significant limitations exist with regard to the generalizability of results from this study." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv (the "OMB Notice"). "Because of these limitations, the relationship between treatment and outcomes [that FDA] find[s] in [its] study *may not generalize to the broader U.S. population*." *Id.* (emphasis added).

72. Even disregarding the "significant limitations" noted above, FDA's first quantitative study showed that the FDA-created textual warnings would *not* promote greater public understanding of smoking risks as compared to the Tobacco Control Act's statements. On the contrary, the study showed that *seven* of the nine FDA-created textual warnings in the Rule (the "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," "fetal growth," and "COPD" warnings) did not lead to a statistically significant increase in the public's knowledge of those risks relative to the Tobacco Control Act's statements after adjustments for multiple comparisons. RTI

International, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* at 2-2(17), 3-16–3-17(77–78) (Apr. 2018) (the "First Quantitative Study Report").[3]

73. Moreover, FDA's quantitative study revealed the same problems as the Agency's qualitative study. *First*, the study participants already understood many of the risks described in the textual warnings. The study showed that the "[Tobacco Control Act's] warning statements were new information to relatively few participants." *Id.* at 5(6). In addition, the study showed that *eight* of the nine FDA-created textual warnings in the Rule (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," and "fetal growth" warnings) were no more "informative" than the Act's warnings. *Id.* at 2-2(17), 3-11(72).

74. *Second*, many of the FDA-created textual warnings that are in the Rule were not believable. Indeed, the study showed that *six* of those statements (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," and "head and neck cancer" warnings) were less "believable" than the Act's warnings. *Id.* at 2-2(17), 3-9(70).

Qualitative Studies For The Graphic Images And Warnings

75. FDA also conducted "53 in[-]depth individual interviews" on early versions of the graphic images, as well as "a series of 20 qualitative focus groups" on the close-to-final graphic warnings. 84 Fed. Reg. at 42,770. Once again, these qualitative tests revealed several obvious problems.

76. *First*, many of the images frightened, shocked, and disgusted many of the participants in FDA's studies. Indeed, participants reported that several images were "grotesque," "gruesome," "disgusting," "heartbreaking," "startling," "powerfully disturbing," "scary," or "terrifying." Siegel+Gale, *FDA Graphic Health Warning Image Concept Testing* at 37, 62, 97, 126, 130, 138 (June 2016)

[3] This report, as well as the report pertaining to FDA's second quantitative study, were not consecutively paginated. For the Court's convenience, this Complaint provides both the labeled page number and the PDF page number (in parentheses) when citing those reports.

(the "Second Qualitative Study Report"). Participants also said that several images "send[] me into despair," "would really creep me out," "really just disgust[] me," had "shock value," or depicted "my worst nightmare." *Id.* at 24, 97, 130, 138. And one participant said that an image was "the perfect image to show somebody you don't want to smoke." *Id.* at 37.

77. *Second*, many of the images were misleading or confusing. For example, some participants thought the "Sick Child" image was misleading because it was "not a realistic outcome of secondhand smoke." RTI International, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* at 16 (Apr. 2018) (the "Third Qualitative Study Report"); *id.* at 30 (explaining that some participants thought the "Neck Tumor" image was misleading because "the lump was too large to be realistic"). As another example, some participants thought the "Diseased, Non-Smoker's Lungs" image was confusing because they did not know "why the person is holding the lungs." *Id.* at 41.

Quantitative Study For The Graphic Warnings

78. Finally, FDA conducted a "consumer research study" to "assess the extent to which any of the cigarette health warnings … increase understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,771.

79. As with the first quantitative study, this study was poorly designed. Although OMB had stressed that the first quantitative study may not generalize to the broader U.S. population because of its "design, convenience sampling methodology, and methods of analyses," OMB Notice, the second quantitative study repeated the same errors. Thus, FDA was again forced to admit that the second quantitative study's "results are not nationally representative." RTI International, *Experimental Study of Cigarette Warnings: Study 2 Report* at 4-2(118) (May 2019) (the "Second Quantitative Study Report").

80. Once again, even taken at face value, FDA's second quantitative study showed that the graphic warnings would *not* improve the public's understanding of smoking risks. The study tested

participants' knowledge about the health risks of smoking ("Session 1"), showed them the proposed warnings, and then tested their health beliefs again after one day ("Session 2") and after fourteen days ("Session 3"). *Id.* at 42,771–72. At the end of that process, five of the eleven warnings in the Rule (the "harm your children," "erectile dysfunction," "heart disease," "fetal growth," and "COPD" warnings) had *no* significant effect on the participants' knowledge about the health risks. *See* Second Quantitative Study Report at 3-15–3-17(111–13). In addition, five more warnings had a small effect on the respondents' knowledge after one day, but a much smaller effect after fourteen days. *See id.* at 3-10–3-11(106–07), 3-14–3-15(110–11) (showing that the alleged increase in knowledge had dropped by 66% for "diabetes," 50% for "head and neck cancer," 50% for "cataracts," 40% for "bladder cancer," and 34% for "amputation").[4] In other words, out of eleven warnings, five had no effect on participants' knowledge, and five more had only a small effect that quickly began to dissipate. This indicates that FDA's purported "health beliefs assessment" was not actually testing participants' understanding or acceptance of the information, and was at most capturing their ability to recall it.

FDA's Refusal To Test The Warnings' Emotional Impact Or Less-Restrictive Alternatives

81. As discussed above, FDA's own qualitative and quantitative tests demonstrate that the graphic warnings will not further FDA's asserted interest. In addition, these studies are just as significant for what they failed to test.

82. As explained above, the D.C. Circuit recognized that FDA's first set of graphic warnings were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *R.J. Reynolds*, 696 F.3d at 1217. FDA nonetheless decided *not* to ask study

[4] These percentages are derived by comparing the increase in mean health beliefs from Session 1 to Session 2 to the increase in mean health beliefs from Session 1 to Session 3. For example, for diabetes, the study found a .74 increase in knowledge between Session 1 and Session 2, and a .25 increase in knowledge between Session 1 and Session 3. *Id.* at 3-11(107), 3-15(111). A reduction from .74 to .25 is a 66% reduction.

participants whether its second set of graphic warnings suffered from this same deficiency. When developing the Proposed Rule, FDA conducted "16 qualitative focus groups" and a "quantitative consumer research study" regarding the textual warnings, 84 Fed. Reg. at 42,767, and "53 in[-]depth individual interviews," "20 qualitative focus groups," and another "consumer research study" regarding the graphic images and warnings, *id.* at 42,770–71. FDA did not ask a single question, however, about whether the warnings would evoke negative emotions. And when participants in these studies *volunteered* that the warnings made them feel afraid, shocked, or disgusted, FDA chose to withhold those responses from the public at the time the Proposed Rule was released. *See supra* ¶¶ 75–77; *infra* ¶¶ 95–98.

83. FDA also refused to test possible alternatives to the Proposed Rule. Approximately nine months before the Proposed Rule, Reynolds urged FDA to "test whether FDA could increase public understanding by making less-burdensome changes to the existing warnings." Comment Letter of RAI Services Co. at 4, Docket No. FDA-2018-N-3552 (Nov. 16, 2018). Specifically, Reynolds urged FDA to "show one group of participants a [cigarette] package with the current Surgeon General's warnings, show 16 groups a package with the new textual warnings, and show 16 more groups a package with the new textual warnings *and* graphic images." *Id.* That approach "would allow FDA to determine how much the graphic images contribute, if at all, to FDA's stated goal." *Id.* But FDA refused to test any alternative.

G. FDA's Preliminary Regulatory Impact Analysis

84. The Proposed Rule also included a preliminary regulatory impact analysis, which ostensibly analyzed the Proposed Rule's benefits and costs. *See* FDA, *Preliminary Regulatory Impact Analysis* (Aug. 2019). But this analysis was flawed.

85. As an initial matter, FDA expressly disclaimed any attempt to quantify the Proposed Rule's benefits. FDA said that "there is a high level of uncertainty around quantitative economic

benefits" and therefore chose to "describe them qualitatively." *Id.* at 2. As a result, FDA could not "compare benefits and costs directly." *Id.* at 8.

86. FDA's refusal to quantify the Proposed Rule's benefits stands in sharp contrast with the Agency's approach in other contexts. For example, just *four days* after FDA issued the Proposed Rule, FDA asserted that *The Real Cost* had "prevented up to 587,000 youth nationwide from initiating smoking," and would purportedly "save more than $53 billion for youth, their families and society at large by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity and increased disability." Reynolds Comments at 40 (citing Norman E. Sharpless, Press Announcement (Aug. 20, 2019), https://tinyurl.com/y3kmouoa).

87. Instead of attempting to quantify the Proposed Rule's benefits, FDA decided to rely on a "break-even calculation." After estimating the Proposed Rule would impose costs of "about $1.6 billion," 84. Fed. Reg. at 42,756, FDA concluded that the Proposed Rule would be beneficial on net "[i]f the information provided by the cigarette health warning on each cigarette package were valued at about $0.01," Reynolds Comments at 40. But FDA provided no reason to believe that the informational benefit is worth $0.01 or more per pack. Thus, the preliminary regulatory impact analysis relied on nothing more than speculation.

H. Comments On The Proposed Rule

88. Reynolds, Santa Fe, ITG Brands, and Liggett (the "manufacturer Plaintiffs") submitted extensive comments on the Proposed Rule. *See* Reynolds Comments; ITG Comments; Comment Letter of Liggett Group, Docket No. FDA-2019-N-3065 (Oct. 15, 2019) ("Liggett Comments") (attached as Ex. 5).

89. The comments explained that, whatever the standard of review, the Proposed Rule and the Tobacco Control Act's graphic-warnings requirement would violate the First Amendment for at least three reasons. Reynolds Comments, Executive Summary at 3–4; ITG Comments at 4; Liggett

Comments at 2. *First*, the government lacks a legally sufficient governmental interest to justify the Proposed Rule (or the graphic-warnings requirement in the Tobacco Control Act). Reynolds Comments at 2. FDA said that it wanted to "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But the warnings were not necessary to prevent consumer deception, and would not have any real-world effect on how consumers behave. In other words, FDA wanted to give people information for information's sake, which was not a compelling or substantial interest.

90. *Second*, even if the government had asserted a valid interest, the Proposed Rule and the graphic-warnings requirement in the Tobacco Control Act would not sufficiently advance it. The public already knew that smoking is harmful and can cause serious diseases. Reynolds Comments at 14–17; ITG Comments at 19–20. And to the extent that FDA had found a few diseases with which the public was less familiar, FDA could not show that graphic warnings would remedy that purported problem. Reynolds Comments at 18–22. The comments also raised concerns that the graphic warnings would be confusing and misleading to consumers. Reynolds Comments at 7–8; ITG Comments at 7–17.

91. *Third*, the Proposed Rule and the graphic-warnings requirement in the Tobacco Control Act were insufficiently tailored. *Id.* at 25–34; ITG Comments at 17–20; Liggett Comments at 5. The warnings were extremely burdensome: they occupied the top 50% of both the front and back of all cigarette packages and the top 20% of all cigarette advertising, as well as using grotesque images that pull people's attention away from the manufacturer Plaintiffs' speech. In addition, the government had many less-restrictive alternatives to achieve its goals, such as less-intrusive warnings and public-education campaigns.

92. The comments also explained that FDA had violated the Tobacco Control Act by revising the language of the Act's textual warnings, and by increasing the number of warnings from nine to thirteen. Reynolds Comments at 36–38.

93. Finally, the comments explained that FDA had violated the Administrative Procedure Act in multiple ways, such as relying on unreliable analyses and studies, failing to support its findings with substantial evidence, ignoring contrary evidence, failing to consider reasonable alternatives, and failing to disclose key data and information on which FDA had relied. *Id.* at 39–45; ITG Comments at 20–22; Liggett Comments at 5–8.

94. Other manufacturers and interested parties raised similar objections. For example, Altria Client Services submitted comments arguing that "the text and graphic warnings proposed by this rule would violate free speech protections guaranteed by the First Amendment of the U.S. Constitution" and that, "without substantial changes, the Proposed Rule would violate the Administrative Procedure Act ('APA') on multiple grounds." Altria Comments at 1. And the Washington Legal Foundation submitted a comment arguing that the *Zauderer* standard is inapplicable because the Rule does not target commercial deception and that, in any event, the Rule failed under both the *Zauderer* and *Central Hudson* standards. Comment Letter of Washington Legal Foundation at 2–7, Docket No. FDA-2019-N-3065 (Oct. 15, 2019).

I. FDA Releases The Qualitative Study Reports And Re-Opens The Docket

95. During the initial comment period, several manufacturers criticized FDA for failing to release key information and data. For example, Reynolds criticized FDA for failing "to release any information about its qualitative studies," which "were critical to the development of the proposed warnings." Reynolds Comments, Executive Summary at 5. Altria echoed these concerns, and also noted that "FDA has failed to provide the final data sets from the quantitative studies to allow for

replication and verification of the statistical analyses or examination of data quality." Altria Comments at 27–28.

96. On November 12, 2019, nearly a month after the comment period closed, FDA placed additional materials regarding the qualitative studies in the docket. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966 (Nov. 12, 2019). Specifically, FDA released four reports regarding "qualitative focus groups and interviews" that the Agency used "to test and refine image concepts and obtain feedback on which textual statements should be selected for further study." *Id.* at 60,967.

97. FDA failed to provide a coherent explanation about why it had failed to release these reports along with the Proposed Rule. FDA acknowledged that it had "used" these reports to "inform" the development of the proposed warnings. *Id.* At the same time, however, FDA said that it "did not originally include the [reports] in the docket as FDA did not rely on [them] as part of the rulemaking." *Id.*

98. Although these reports spanned nearly 600 pages, FDA gave the public only "15 days to allow comment on the additional materials." *Id.*

J. Comments On The Qualitative Study Reports

99. On November 25, 2019, Reynolds submitted comments on the additional materials. *See* Comment Letter of RAI Services Company, Docket No. FDA-2019-N-3065 (Nov. 25, 2019) (attached as Ex. 3). As the comments explained, the additional materials "confirm[ed] what should be clear to all objective observers: FDA designed the proposed warnings to evoke negative emotions, such as fear, disgust, and distress, and to trumpet the government's preferred ideological message: don't smoke." *Id.* at 1–2. The additional materials also revealed that FDA had notice of—and failed to consider—three other constitutional problems. *First*, FDA "ignored evidence that the proposed warnings were confusing and misleading." *Id.* at 2. *Second*, FDA "failed to consider whether the

proposed warnings would actually remedy a real-world harm." *Id.* And *third*, FDA "ignored evidence that the proposed warnings were broader than reasonably necessary." *Id.*

100. The comments also explained that, "[i]n addition to these problems, FDA's handling of the additional materials violated the Administrative Procedure Act. FDA relied on these materials when it developed the proposed rule, which means that the public should have had them during the initial comment period." *Id.* at 2. Thus, "FDA's failure to release those materials along with the proposed rule deprived the public of a meaningful chance to comment," and the Agency could not "undo that deprivation by reopening the comment period for a mere fifteen days." *Id.* at 2–3.

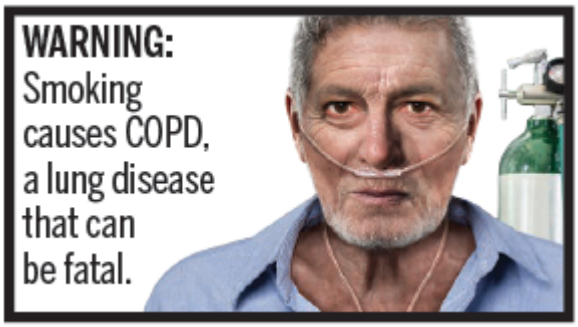
101. Once again, other manufacturers and interested parties raised similar objections. For example, Altria argued that the additional materials "cast yet further doubt on FDA's claim that the proposed graphic health warnings would promote greater public understanding of the negative health consequences of cigarette smoking," and that the "study reports d[id] not resolve APA violations." Comment Letter of Altria Client Services at 4, Docket No. FDA-2019-N-3065 (Nov. 27, 2019). In addition, Altria criticized FDA for again "not releas[ing] other critical data underlying the Proposed Rule," which "def[ied] legal requirements and ma[de] it impossible for interested parties to adequately evaluate the proposed text or graphics, the process for developing them, or FDA's claims about its research results and decisions." *Id.*

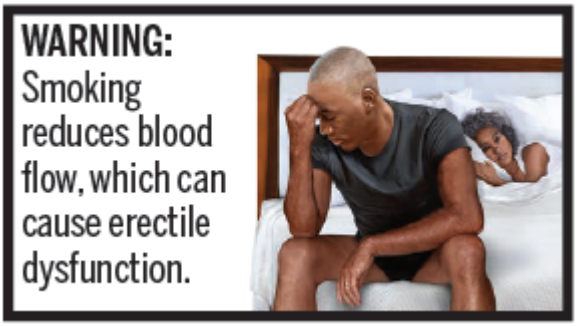
K. FDA's Final Rule

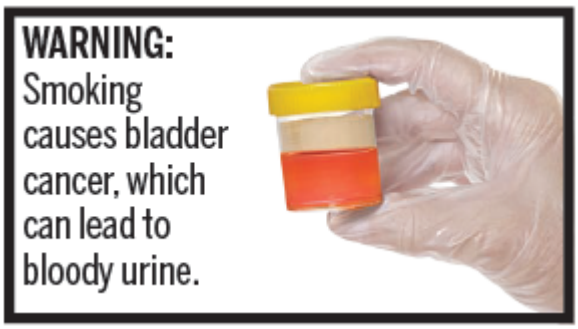
102. Despite being advised of the many constitutional and statutory flaws with the Proposed Rule, FDA promulgated the final Rule on March 18, 2020. *See* 85 Fed. Reg. at 15,638–710. The Rule made few meaningful changes to the Proposed Rule.

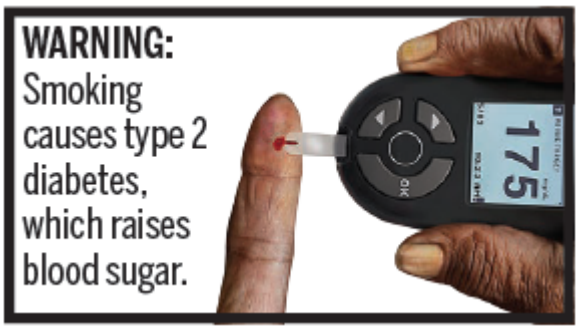
103. The Rule largely requires the same textual warnings with the same graphic images as the Proposed Rule. However, it omits two of the Proposed Rule's required warnings: the macular degeneration warning (with the "Needle in Eyeball" image) and the COPD warning that included the

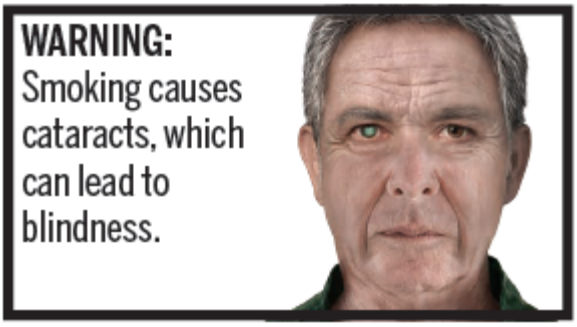
"COPD Diseased Lung" image. The Rule also revised the "Crying Baby" image. It made the "4.00 lbs." weight on the scale more pronounced by "increas[ing] the contrast and size of the weight display in the image." 85 Fed. Reg. at 15, 677. Thus, the eleven required warnings under the Rule are:

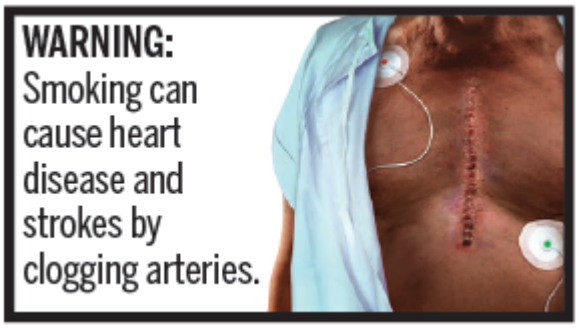












104. In the Rule, FDA noted that it received a comment that its "two quantitative consumer research studies were not credible because they did not go through a peer review process." 85 Fed. Reg. 15,661. It responded that its studies had—*subsequent* to the Proposed Rule—gone through the peer review process and that the reviewers were largely positive, providing only minor suggestions "to improve the clarity of the study reports." *Id.*

105. Contrary to FDA's characterization, the peer reviewers raised serious, substantive concerns about FDA's studies. *See* 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), available at https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews ("Peer Review Report") (attached as Ex. 7). *First*, reviewers noted that both quantitative studies lacked an adequate theoretical framework. Reviewers commented that both studies required an "overarching conceptual framework to bring coherence to the outcomes assessed and interpretation of results." *Id.* at 12, 19 (Reviewer 2). One reviewer noted that the lack of a theoretical framework for the first study, combined

with the study's attempt "to make the case . . . as it presents the results," makes the study "look[] a little like *post-hoc rationalization*." *Id.* at 7 (Reviewer 1); *see id.* at 5 ("[T]he lack of an appropriate theoretical framework to the document means that it is not clear how the nature of the different outcomes being addressed relate to each other."); *see also id.* at 57 (Reviewer 6) (suggesting a "theoretical expansion on some of the constructs measured"). Other reviewers criticized "[t]he lack of an overarching framework" in the second study and concluded that FDA's "explanation is neither based in empirical evidence nor theory." *Id.* at 23 (Reviewer 2); *see id.* at 43 (Reviewer 4) (noting "the study needs greater levels of conceptual and empirical motivation") *id.* at 60 (Reviewer 6) (similar).

106. *Second*, reviewers questioned and criticized the measures FDA used to test understanding in both studies. Reviewers were concerned that FDA did not use "standard" measures in the studies, and failed to demonstrate the validity of its novel measures. *Id.* at 12, 15, 19, 20 (Reviewer 2); *see id.* at 9 (Reviewer 1) ("The problem with the outcome measures is that there is no presentation of a theory on why they are important. Of particular concern is the relevance of health beliefs."); *id.* at 27 (Reviewer 3) ("weak criterion"); *id.* at 43 (Reviewer 4) (criticizing the measures as not being "linked to any specific study or research program," which makes "it difficult to evaluate their utility and validity"). Reviewers were particularly critical of the "primary outcomes" FDA used to measure understanding—self-reported learning and new information—and noted the lack of "prior research showing the validity and meaningfulness" of those measures to assess understanding. *Id.* at 18 (Reviewer 2); *see id.* at 25 (Reviewer 3) ("I am concerned that the measures deployed . . . are not convincing measures of the underlying constructs that the research is targeting."). As one reviewer explained, self-reported learning and newness "do not tap into understanding in any sense of what the word understanding ordinarily means conceptually, in ordinary discourse, or in scientific measures of comprehension." *Id.* at 27–28 (Reviewer 3). Reviewers also found FDA's decision to differentiate between "primary" and "secondary" outcomes in the first study to be "arbitrary." *Id.* at 14 (Reviewer

2) ("Decisions to treat [credibility measures] as secondary appears even more arbitrary after reading Study 2, where all measures are treated equally (i.e., no distinctions are made between primary and secondary measures.)."); *see id.* (concluding that "'informativeness' and 'factuality' appear to overlap with the conceptualization of understanding" and questioning why such "credibility" measures are not treated as "primary"); *id.* at 40 (Reviewer 4) (criticizing FDA for failing to explain its "decision to parse outcomes into primary and secondary" and its characterization of "number of health conditions" as a secondary outcome).

107. *Third*, reviewers criticized FDA for failing to use representative samples (and instead using convenience samples with significant asymmetries). Reviewers noted that using a convenience sample "brings with it a host of potential biases and limits to the generalizability versus employing a representative sample." *Id.* at 40 (Reviewer 4); *see id.* at 38 (concluding "the sampling frame and sampling design" is a "key limitation"); *id.* at 44 ("The sampling frame is a significant weakness for this research."); *id.* at 45 (describing sampling as a "quite serious" limitation); *id.* at 48 (Reviewer 5) (noting the study's use of "a convenience sample" was a limitation); *see also id.* at 28 (Reviewer 3) (highlighting the "significant asymmetries in male-female distribution" in the first study); *id.* at 34 (noting "the adult sample has a significant asymmetry in age distribution with 35-55 underrepresented" in the second study). Additionally, reviewers were "puzzled why non-smoking adults were studied." *Id.* at 52 (Reviewer 5); *see id.* at 57, 60 (Reviewer 6) (seeking an explanation for why FDA included non-smokers in the second study, especially when they were not included in the first study, as would be expected since "the intended audience is smokers").

108. *Fourth*, reviewers raised a host of other analytical concerns. For example, reviewers were concerned FDA's testing method primed study participants and skewed the results. *See id.* at 32 (Reviewer 3) (explaining that FDA asking about beliefs "at baseline distorts the way people process the information given in the labels cuing them into the content to be processed"); *id.* ("In our message

work we never ask the key outcome measures at baseline BEFORE the messages to be processed as we believe that . . . distorts how content is handled – priming, focusing, differential attention, etc."); *id.* at 33 (concluding FDA's process created "the likelihood" that study participants "are reacting to the content of the warning label in ways that they would not in the absence of pretest measures of negative health consequences"); *id.* at 60 (Reviewer 6) ("[T]here might be a priming effect of the health belief assessment for those participants in the treatment condition."). Another reviewer expressed a similar concern that FDA's baseline questions turned its analysis into a test of participants' "memory and test taking skills" rather than their "understanding." *Id.* at 15 (Reviewer 2). That same reviewer was concerned about the "many . . . examples of inconsistent results," such as the "data for the revised statement on erectile dysfunction," *id.* at 18, and was concerned about the conclusions FDA drew from the data because the revised warnings were ranked "lower" on "factualness" than the Surgeon General's warnings, *id.* at 23. A different reviewer shared this concern, describing the "[f]acticity" results as a "problem with the new warnings in Study 1" and in the second study. *Id.* at 33 (Reviewer 3). That reviewer further concluded FDA's failure to include the believability criterion in the second study to be "problematic," "because these results undermined the legitimacy and utility of the warnings." *Id.* at 33.

109. Despite the fundamental flaws identified by the reviewers, FDA made only the most minimal effort to address their comments. Indeed, FDA made clear that it would not make substantive revisions to the studies. For example, in responding to a suggestion that additional measures be used, FDA curtly replied that "Study 1 is complete, and we are unable to include new measures in this study." FDA, Response to External Peer Review of Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act, at 8 (Feb. 4, 2020), available at https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews. FDA likewise did not add new measures to its second study

and defended its use of novel measures. *Id.* at 16. Similarly, FDA did not resolve the problems with the studies' samples, or address any of the other structural defects identified by the reviewers.

110. Instead, FDA merely "updated the study reports" with "clarifying details," while emphasizing that "none of these updates … changes the results, findings, or conclusions of either study." 85 Fed. Reg. 15,661. For example, FDA added certain citations to scientific literature and claimed that the "selection of study variables" was guided by the theories in that literature. *See* FDA, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report, at 11–12 (Feb. 2020) ("Revised First Quantitative Study Report"); FDA, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 2 Report, at 15–16 (Feb. 2020) ("Revised Second Quantitative Study Report"). Because these revised reports were released along with the Rule, the public was unable to comment either on the new material included in the reports, or on FDA's failure to address the reviewers' criticisms.

111. Notably, FDA was forced to clarify the report accompanying its second quantitative study in a way that highlighted that the revised warnings were perceived as less factual relative to the control condition. *Compare* Revised Second Quantitative Study Report, at ES-4 ("[H]alf of the cigarette health warnings (8 of 16) were rated as lower on Perceived Factualness relative to the control condition, [and] the other half of the half of the cigarette health warnings were rated similar on Perceived Factualness relative to the control condition."), *with* Second Quantitative Study Report at 4(5) ("[H]alf of the cigarette health warnings (8 of 16) were rated as higher on *Factualness* by more participants relative to the control condition.").

112. FDA also released a Final Regulatory Impact Analysis. FDA, Final Regulatory Impact Analysis, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, Docket No. FDA-2019-N-3065 (2020). It largely tracked the preliminary regulatory impact analysis; in particular, FDA continued to make no effort to quantify the rule's benefits, opting instead to rely on

a speculative "break-even analysis." FDA also continued to estimate that the rule's costs would be approximately $1.6 billion. *Id.* at 7.

L. The Rule and the Tobacco Control Act's Graphic-Warnings Requirement Will Impose Concrete And Particularized Harm On Plaintiffs

113. The Rule and the Act's graphic-warnings requirement will directly cause at least four forms of concrete injury to Plaintiffs.

114. *First*, Plaintiffs will be severely injured by the placement of the new graphic warnings on their packages and advertising, since the warnings violate their rights under the First Amendment to the United States Constitution, the APA, and the Tobacco Control Act.

115. *Second*, the warnings undermine the manufacturer Plaintiffs' ability to compete with other cigarette manufacturers. The cigarette industry is highly competitive. Overall use is declining, and the manufacturer Plaintiffs compete heavily against one another, as well as against other manufacturers, for market share. In addition, cigarette packages and advertising are two of the primary means by which the manufacturer Plaintiffs engage in such inter-brand competition. By severely undermining the manufacturer Plaintiffs' ability to communicate their truthful messages to adult cigarette consumers through packages and advertising, the Rule and the Act's graphic-warnings requirement undermine these Plaintiffs' ability to convince adult consumers currently choosing their competitors' brands to switch.

116. *Third*, the warnings will cause Plaintiffs Neocom, Inc., Rangila Enterprises Inc., Rangila LLC, Sahil Ismail, Inc., and Is Like You Inc. (the "retailer Plaintiffs") to lose business from smokers, non-smokers, or both. The retailer Plaintiffs currently display cigarette packages and advertising in their convenience stores. After the Rule takes effect, however, those packages and advertising will necessarily contain grotesque images that are designed to frighten, shock, and disgust people who look at them, including smokers and non-smokers. If the retailer Plaintiffs continue to display cigarette packages and advertising, non-smokers will be more likely to shop in stores that do not

display those packages and advertising, and thus do not contain these offensive images. Customers who continue to shop at their stores will be less likely to purchase certain non-cigarette items, such as food items that are displayed at the counter within view of the graphic cigarette packages and advertising. If the retailer Plaintiffs stop displaying cigarette packages and advertising, smokers will be more likely to shop in stores that do display those packages and advertising. Either way, the retailer Plaintiffs are likely to suffer financial harm.

117. *Fourth*, to comply with the Rule on its effective date of June 18, 2021, the manufacturer Plaintiffs will need to undertake costly and extensive compliance efforts that necessarily must begin well before the effective date. For example, Reynolds and Santa Fe have taken or plan to take the following steps:

a. Reynolds and Santa Fe would be forced to modify approximately 390 individual package designs.

b. The Rule requires that all eleven warnings be "randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed." 85 Fed. Reg. at 15,709 (codified at 21 C.F.R. § 1141.10(g)(1)). Reynolds and Santa Fe employees have already spent more than 1,000 hours working with suppliers to overhaul the current printing process to comply with this requirement.

c. Reynolds and Santa Fe will need to purchase approximately 6,000 printing cylinder bases and additional tools to print the redesigned packages. Reynolds and Santa Fe will then need to have the cylinders engraved so they can be used to apply the ink on the new cigarette packages. *Id.* The costs of the cylinders, tools, and engraving is expected to exceed $15 million. The work to engrave

the cylinders will take several months and must begin within six months after the Rule is published.

d. Reynolds and Santa Fe will need to hire a graphics design firm to design the new labeling. This design work will cost at least $1 million and take several months, and approximately 3,000 hours of employee and supplier time, to complete.

e. Reynolds and Santa Fe will need to begin the internal approval process for the new package designs. The approval process will be extensive given the nature of the label changes and the number of individual designs. Numerous departments—including Consumer Marketing, Consumer Relations, Legal, Manufacturing, Operations, Procurement, and Trade Marketing—will need to review and approve approximately 390 individual designs. Reynolds and Santa Fe anticipate that this approval process will take several months, and 300 hours of employee time, to complete.

f. The Rule also requires revised warnings to appear in advertising. Reynolds and Santa Fe will thus need to modify existing brand advertising that appears on their websites and retail point-of-sale advertising. Collectively, Reynolds and Santa Fe will need to redesign, print, and replace point-of-sale advertising at approximately 200,000 retailers. Redesigning the advertising and implementing the new advertisements online and in stores will cost approximately $10 million and involve thousands of hours of employee and supplier time.

g. In anticipation of the Rule becoming effective, Reynolds and Santa Fe will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date. If the Rule is then

invalidated, Reynolds and Santa Fe will be unable to lawfully sell those cigarettes because they will not carry the correct FDA-mandated warnings and be considered "misbranded under the Act. This will cost Reynolds and Santa Fe over $200 million.

h. All these time estimates are based on normal business operations. The full extent of the coronavirus's impact on business operations is currently unclear. Based on current interruptions in the normal work environment, however, the time estimates for Reynolds and Santa Fe will likely need to be increased, perhaps by 10 to 20 percent.

118. ITG Brands will similarly have to undertake costly and extensive compliance efforts that necessarily must begin well before the effective date of June 18, 2021. For example, ITG Brands has taken or plans to take the following steps:

a. ITG Brands would be forced to modify approximately 121 individual package designs.

b. ITG Brands will need to purchase between 263 and 976 printing cylinder bases and additional tools to print the redesigned packages. ITG Brands will then need to have the cylinders engraved so they can be used to apply the ink on the new cigarette packages. The costs of the cylinders, tools, and engraving is expected to be between $2.9 and $3.8 million. The work to engrave the cylinders will take several months and must begin within twelve months after the Rule is published.

c. ITG Brands will need to hire a graphics design firm to design the new labeling. This design work will cost at least $945,000 and take several months, and approximately 5,000 hours of employee and supplier time, to complete.

d. ITG Brands will need to begin the internal approval process for the new package designs. The approval process will be extensive given the nature of the label changes and the number of individual designs. Numerous departments—including Consumer Marketing, Consumer Relations, Legal, Manufacturing, Operations, Procurement, and Trade Marketing—will need to review and approve approximately 121 individual designs. ITG Brands anticipates that this approval process will take several months, and 10,000 hours of employee time, to complete.

e. The Rule also requires revised warnings to appear in advertising. ITG Brands will thus need to modify existing brand advertising that appears on their websites and retail point-of-sale advertising. Collectively, ITG Brands will need to redesign, print, and replace point-of-sale advertising at approximately 102,000 retailers. Redesigning the advertising and implementing the new advertisements online and in stores will cost approximately $945,000 and involve approximately 182 hours of employee and supplier time.

f. In anticipation of the Rule becoming effective, ITG Brands will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date. If the Rule is then invalidated, ITG Brands will be unable to lawfully sell those cigarettes because they will not carry the correct FDA-mandated warnings and be considered "misbranded" under the Act. This will cost ITG Brands over $61.7 million.

119. Likewise, Liggett will have to undertake costly and extensive compliance efforts that necessarily must begin well before the effective date of June 18, 2021. For example, Liggett has taken or plans to take the following steps:

a. Liggett manufactures approximately 100 separate cigarette styles, each packaged into a pack and carton. To accommodate the Rule's new warnings, Liggett will therefore need to modify approximately 200 pack and carton packaging designs.

b. Liggett will also be required to purchase an additional 565 printing cylinder bases to accommodate printing of the new warnings. The estimated total cost of these purchases is over $672,000. This is in addition to the 346 cylinders Liggett has already purchased in anticipation of the Rule, at a total cost of $1,476,000. Liggett will also need to have these cylinders engraved. Liggett anticipates that engraving the necessary 911 cylinders will cost over $1,066,000.

c. Liggett will need to work with its outside design agency to develop the new pack and carton designs. Liggett will also be required to solicit comments from many of its private-label customers, who may require additional changes to the packaging. This design work is currently estimated to cost over $425,000 and will demand over 2,000 employee and agency hours. This is in addition to the $270,382 Liggett has already incurred to achieve compliance. In total, the Rule will cost Liggett over $650,000 in package design expenses.

d. Given the nature of the packaging changes and the number of individual designs, Liggett will need to put in place an extensive internal review and approval process. Numerous departments—including Marketing, Sales, Manufacturing, Legal, Purchasing, as well as senior executive management—will need to be involved in the review and approval process. Liggett estimates that under ideal circumstances this review process will consume significant employee time and resources and will require over 1,700 hours.

e. Liggett will need to redesign, print, and replace all point-of-sale communications at each of approximately 35,000 retailers. New warning-compliant advertising will need to be designed, printed, and installed (removing non-compliant advertising in the process) for point of sale. Liggett expects that the cost of updating its website will total $45,000 and require at least 150 employee hours. In total, the design and replacement of all marketing platforms is estimated to take Liggett's 110 sales representatives at least 90 business days to remove all point-of-sale communications. Liggett anticipates point-of-sale materials will cost approximately $800,000 to produce, deliver, and store.

f. In addition to the foregoing costs, Liggett will need to spend thousands of person-hours on coordinating the tasks between now and the 2021 deadline. Based on its best estimates of normal business operations, Liggett will incur between $4.5 and $5 million in costs to comply with the Rule, not counting millions of dollars in anticipated inventory write-offs. Due to the restrictions and uncertainty caused by the coronavirus, there will likely be substantial disruptions and complications that will increase Liggett's estimated costs and delay each step described above.

120. The retailer Plaintiffs may incur costs to alter the manner in which cigarette packs and cartons are displayed to their customers.

121. Plaintiffs fear that, if they do not conform their behavior to the requirements of the Rule, FDA will seize their products. *See* 21 U.S.C. § 334(g). FDA has not disavowed an intention to enforce the Rule.

CLAIM I

The Rule Violates The First Amendment

122. Plaintiffs incorporate and re-allege the preceding paragraphs here.

123. The Rule violates the First Amendment, and each of the warnings—taking into account factors such as their images, text, size, and placement—is unlawful.

124. The Rule's warnings compel Plaintiffs to express the government's anti-smoking message, and are therefore subject to strict scrutiny.

125. The warnings do not substantially advance a compelling governmental interest. Indeed, the warnings are unlikely to have any material impact on the public's smoking behavior or beliefs.

126. The warnings are not narrowly tailored to achieve the government's asserted interest. The warnings are extremely burdensome: compelling Plaintiffs to use large portions of cigarette packages and advertising to disseminate the government's emotionally-charged anti-smoking message. And the government has numerous alternatives that would impose lesser burdens on Plaintiffs' speech but would be at least as effective as graphic warnings.

127. The warnings are not subject to the standard of scrutiny set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), because they are not "reasonably related to the State's interest in preventing deception of consumers," and do not convey "purely factual and uncontroversial information." *Zauderer*, 471 U.S. at 651.

128. Even if the warnings were subject to the *Zauderer* standard, however, they would still violate the First Amendment.

129. The warnings do not advance any substantial governmental interest, for the same reasons they do not advance any compelling governmental interest.

130. The warnings are "unjustified" because they will not remedy a real-world harm. *Id.*

131. The warnings are also "unduly burdensome" because, despite having few if any benefits, they compel Plaintiffs to disseminate the government's anti-smoking message even though the government has many less-restrictive alternatives for achieving its objectives. *Id.* The burdens are especially pronounced in light of the many restrictions on cigarette manufacturers' speech.

132. The warnings are not subject to the standard of scrutiny set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), and would not satisfy that standard of scrutiny in any event.

133. Plaintiffs therefore seek the entry of a judgment declaring the Rule unconstitutional, setting it aside, and preliminarily and permanently enjoining Defendants from enforcing it.

CLAIM II

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

134. Plaintiffs incorporate and re-allege the preceding paragraphs here.

135. The Tobacco Control Act requires FDA to issue a graphic-warnings rule.

136. FDA has now issued two graphic-warnings rules, and both violated the First Amendment. This is because the Act itself directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333(d)[1]. And the Act itself requires that the warnings occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. *Id.* § 1333(a)(2), (b)(2). The whole point of those requirements is to shock the viewer and convey the government's anti-smoking message.

137. Accordingly, any graphic-warnings rule issued pursuant to the Act will necessarily suffer from the same constitutional problems as the current Rule. As a result, "no set of circumstances exists under which the [Act's graphic-warnings requirement] would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987).

138. Plaintiffs therefore seek the entry of a judgment declaring the Act's requirement unconstitutional, and permanently enjoining Defendants from enforcing it.

CLAIM III

FDA Acted Arbitrarily And Capriciously In Violation Of 5 U.S.C. § 706(2)(A)

139. Plaintiffs incorporate and re-allege the preceding paragraphs here.

140. In promulgating the Rule, FDA acted arbitrarily and capriciously by relying on unreliable analyses and studies, failing to support its findings with substantial evidence, ignoring contrary evidence, failing to consider reasonable alternatives, performing an insufficient cost-benefit analysis, failing to make changes in response to important criticisms from peer reviewers, and failing to address significant comments.

141. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(A), and preliminarily and permanently enjoining FDA from enforcing it.

CLAIM IV

FDA Failed To Provide Meaningful Notice Under 5 U.S.C. § 553(b)(3)

142. Plaintiffs incorporate and re-allege the preceding paragraphs here.

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

144. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(D), and preliminarily and permanently enjoining FDA from enforcing it.

CLAIM V

FDA Failed To Provide A Meaningful Opportunity To Comment Under 5 U.S.C. § 553(c)

145. Plaintiffs incorporate and re-allege the preceding paragraphs here.

146. In promulgating the Rule, FDA failed to give the public a meaningful opportunity to comment as required under 5 U.S.C. § 553(c). FDA disclosed nearly 600 pages of key data and information after the comment period had closed, even though that information was available at the time the Notice of Proposed Rulemaking was published. After releasing the additional data and information, FDA gave the public only fifteen additional days to comment.

147. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(D), and preliminarily and permanently enjoining FDA from enforcing it.

CLAIM VI

The Rule Violates The Tobacco Control Act

148. Plaintiffs incorporate and re-allege the preceding paragraphs here.

149. In promulgating the Rule, FDA violated the Tobacco Control Act by changing the language of the Act's textual warnings, as well as the total number of warnings, without authority.

150. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(C), and preliminarily and permanently enjoining FDA from enforcing it.

CLAIM VII

The Effective Dates For The New Textual Warnings And The Related Requirements Do Not Take Effect Until Fifteen Months After FDA Issues A Legally Valid Rule

151. Plaintiffs incorporate and re-allege the preceding paragraphs here.

152. As explained above, *see supra* ¶ 47, the Act provides for a single effective date for the graphic-warnings rule, the new textual warnings, and the related requirements: specifically, "15 months after the issuance of [the graphic-warnings rule]." Pub. L. No. 111-31, § 201(b) (setting the effective date for the amendments to 15 U.S.C. § 1333); *id.* § 103(q)(5) (using identical text to set the effective date for the related requirements in 21 U.S.C. § 387c(a)(2)); *id.* § 301 (using identical text to set the effective date for the related requirement in 21 U.S.C. § 387t(a)).

153. Congress's use of a single implementation date for the graphic-warnings rule, the new textual warnings, and the related requirements demonstrates an intent that manufacturers not be subjected to multiple, costly overhauls of their packages and advertising. In light of this intent, the Act must be read to tie the effective dates of all cigarette packages and advertising changes to the "issuance" of a graphic-warnings rule that is constitutionally, statutorily, and procedurally valid. Any contrary reading would frustrate the congressional intent reflected in the Act and create the anomaly that an invalid Rule would have substantial and detrimental legal effect.

154. Plaintiffs therefore seek a declaration that the new textual warnings and the related requirements cannot take effect until FDA issues a legally valid Rule.

REQUEST FOR RELIEF

Plaintiffs request that this Court grant the following relief:

(A) enter a judgment declaring that the Rule violates the First Amendment to the United States Constitution and setting aside the Rule in its entirety;

(B) enter a judgment declaring that the Tobacco Control Act's graphic-warnings requirement violates the First Amendment to the United States Constitution;

(C) enter a judgment declaring that the Rule violates the APA and setting aside the Rule in its entirety;

(D) enter a judgment declaring that the Rule violates the Tobacco Control Act and setting aside the Rule in its entirety;

(E) enter a preliminary injunction enjoining Defendants from enforcing the Rule and postponing its effective date until fifteen months after Plaintiffs' claims are resolved on the merits;

(F) enter a permanent injunction enjoining Defendants from enforcing the Rule and the Tobacco Control Act's graphic-warnings requirement, as well as enjoining the new textual warnings and the related requirements until fifteen months after FDA issues a legally valid rule; and

(G) grant Plaintiffs such additional or different relief as the Court deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

Respectfully submitted,

April 3, 2020

/s/ Autumn Hamit Patterson

Autumn Hamit Patterson
Texas Bar No. 24092947
JONES DAY
2727 North Harwood Street, Suite 500
Dallas, TX 75201-1515
Telephone: 214-220-3939
Facsimile: 214-969-5100
ahpatterson@jonesday.com

Ryan J. Watson*
D.C. Bar No. 986906
Lead Attorney
Christian G. Vergonis*
N.Y. Bar No. 2715993
Alex Potapov*
D.C. Bar No. 998355
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001-2113
Telephone: 202-879-3939
Facsimile: 202-626-1700
rwatson@jonesday.com
cvergonis@jonesday.com
apotapov@jonesday.com

Counsel for Plaintiffs R.J. Reynolds Tobacco Co., Santa Fe Natural Tobacco Co., Neocom, Inc., Rangila Enterprises Inc., Rangila LLC, Sahil Ismail, Inc., and Is Like You Inc.

* application for admission *pro hac vice* forthcoming

Philip J. Perry (D.C. Bar No. 148696)*
Richard P. Bress (D.C. Bar No. 457504)*
Monica C. Groat (D.C. Bar No. 1002696)*
Nicholas L. Schlossman (D.C. Bar No. 1029362)*
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 1000
Washington, DC 20004
Tel: (202) 637-2200
Fax: (202) 637-2201
philip.perry@lw.com
rick.bress@lw.com
monica.groat@lw.com
nicholas.schlossman@lw.com

Attorneys for Plaintiff ITG Brands, LLC

Meaghan VerGow*
D.C. Bar No. 977165
Scott Harman-Heath*
D.C. Bar No. 1671180
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
Telephone.: 202-383-5504
Facsimile: 202-383-5414
mvergow@omm.com
sharman@omm.com

Counsel for Plaintiff Liggett Group LLC