

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]).<sup>1</sup> 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

---

<sup>1</sup> 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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.