IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

LARRY W. FAIRCLOTH
186 Diamante Drive
Inwood, WV, 25428

Plaintiff,

vs.

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

ROBERT CALIFF, M.D.,
Commissioner of Food and Drugs,
10903 New Hampshire Avenue Silver Spring, MD 20993,

and

SYLVIA MATHEWS BURWELL,
Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

Defendants.

Civil Action No. 2:16-CV-5267

COMPLAINT

Plaintiff Larry Faircloth (Plaintiff) brings this Complaint to set aside Defendants' unlawful final rule, "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule").

INTRODUCTION

1. This suit concerns FDA's regulation of vaping devices and e-liquids.

2. Vaping devices are innovative new products that do not contain tobacco and do not generate smoke. Instead, they use a heat source to convert e-liquid into a vapor, which the user inhales through a mouthpiece.

3. E-liquid is a liquid product consumed using a vaping device. E-liquid generally consists of propylene glycol, glycerol, and flavors. E-liquids contain nicotine derived from nontobacco sources.

4. Vaping devices are principally classified into two categories: open and closed systems. In closed systems, the amount of liquid, flavor, and nicotine content (if any) is set by the manufacturer and cannot be altered by the consumer. Closed system products are available in both disposable form for single use and "rechargeable" form for multiple use—for instance through the use of proprietary replacement cartridges containing e-liquid. In contrast, open systems, sometimes known as "tank systems," can be refilled by the consumer without restriction by the manufacturer. Consumers can fill the "tank" in an open-system vaping device with virtually any e-liquid produced by third parties, including retail outlets known as "vaping shops." E-liquids featuring a wide variety of flavors and nicotine levels (including e-liquids with zero nicotine and zero tobacco content) are currently on the market.

5. Peer-reviewed studies have concluded that vaping is much safer than using cigarettes, cigars, and other traditional forms of smoking, because the vaping devices do not generate the toxins associated with combustion of tobacco. In April 2016, a group of U.S. tobacco-

control experts (including a professor in the Department of Oncology at the Georgetown Lombardi Comprehensive Cancer Center) explained that vaping devices offer important public-health benefits, such as an alternative to cigarette smoking. Earlier in 2016, the Royal College of Physicians likewise concluded that vaping devices are likely to be beneficial to public health in Great Britain.

6. Plaintiff is a consumer of open-system vaping devices, closed-system vaping devices, and e-liquids.

7. Some of the e-liquids purchased by Plaintiff contain do not contain nicotine or tobacco.

8. None of the products purchased by Plaintiff contains tobacco.

PARTIES

9. Larry Faircloth is a resident of West Virginia and user of vaping devices and e-liquids described herein. While Plaintiff is a resident of Inwood, WV, he spends a substantial amount of time in Charleston for work and fulfilling his duties as a Member of the West Virginia Legislature.

10. Defendant FDA is an agency of the United States Government within the Department of Health and Human Services, with an office at 10903 New Hampshire Ave., Silver Spring, MD 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Act, 21 U.S.C. §§ 387a, 387a–1.

11. Defendant Robert Califf, M.D., is Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Califf maintains an office at 10903 New Hampshire Ave., Silver Spring, MD 20993.

12. Defendant Sylvia Mathews Burwell is Secretary of Health and Human Services and the official charged by law with administering the Act. She is sued in her official capacity. Secretary Burwell maintains an office at 200 Independence Avenue SW, Washington, DC 20201.

13. All defendants are collectively referred to hereinafter as "FDA" or "Defendants."

REGULATORY AND STATUTORY BACKGROUND

14. The Deeming Rule was adopted and publicly released by FDA on May 5, 2016, and was published in the Federal Register on May 10, 2016.

15. The Deeming Rule dramatically expands FDA's exercise of its regulatory authority under the Tobacco Control Act ("Act"), a statute enacted in 2009 that is designed to address the "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products." Pub. L. No. 111-31, 123 Stat. 1777, § 2(1) (2009); *see also id.* § 3 (reciting ten statutory purposes, each focused on "tobacco" or "tobacco products").

16. The Act appears in chapter IX of the Food, Drug, and Cosmetic Act ("FDCA") and grants FDA authority to regulate the manufacture, sale, and marketing of "tobacco products."

17. The Act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr).

18. Among other things, the Act: (i) imposes a rigorous premarket approval procedure, similar to the procedure for new drug applications under the FDCA, for many new tobacco

products; (ii) makes it unlawful to market misbranded or adulterated tobacco products; (iii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iv) requires manufacturers to register manufacturing facilities with FDA and open such facilities for biannual FDA inspections; (v) authorizes FDA to impose restrictions on the sale and distribution of tobacco products, and to require warning labels for tobacco products; (vi) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vii) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (viii) directs tobacco product manufacturers to keep certain records; (ix) requires manufacturers to obtain advance FDA approval before making a variety of advertising and labeling claims; and (x) grants FDA authority to promulgate testing requirements for tobacco products.

21 U.S.C. §§ 387a–387k, 387o, 387t.

19. These mandates "apply to all cigarettes, cigarette tobacco, roll-your own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary [of HHS] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b).

20. In the Deeming Rule, FDA purports to exercise the deeming authority provided in section 387a by subjecting "all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products," to regulation under the Act. The Deeming Rule concludes that vaping devices (or the constituent parts or components of vaping devices) are "tobacco products" subject to the Act's provisions, even though vaping devices (or their parts) are not made or derived from tobacco or intended for human consumption.

21. The breadth of the Deeming Rule's purported reach is staggering. Indeed, the Rule classifies as "tobacco products"—and thus asserts regulatory authority over—*inter alia*, "programmable software," "batteries," "digital display/lights," and "glass or plastic vial[s]."

JURISDICTION AND VENUE

22. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*; the FDCA, 21 U.S.C. § 301 *et seq.*; and the Act, 21 U.S.C. § 387 *et seq*. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 2201–02.

23. Judicial review is authorized by the APA, 5 U.S.C. § 701 *et seq.*, which provides for judicial review of final agency actions.

24. FDA's promulgation of the Deeming Rule constitutes final agency action within the meaning of 5 U.S.C. § 704.

25. Venue is proper under 28 U.S.C. § 1391(e).

THE DEEMING RULE'S EFFECTS ON PLAINTIFF

26. Once the Deeming Rule goes into effect on August 8, 2016, the overwhelming majority of vape products and e-liquids purchased by Plaintiff—including products that are neither made nor derived from tobacco nor intended for human consumption—will be subject to the premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements imposed by the Act.

27. Such regulation will severely burden manufacturers and their operations—costing millions of dollars. These overly burdensome regulations will cause a severe reduction of the availability of the products used by Plaintiff.

28. The Deeming Rule's premarket approval requirements will force manufacturers to discontinue existing product lines and will also prevent manufacturers from introducing new product lines after the Rule's effective date. The remaining products will likely be subject vastly increased product costs due to compliance costs resulting in severely increased

29. Plaintiff has used the various vapor and e-liquid products to quit using actual tobacco products such as cigarettes. Without the cost effective and ready availability of the vapor and e-liquids, Plaintiff will likely return to the unhealthy habit of using tobacco products.

30. By operation of the deeming rules limitation on the availability of vape and e-liquid products, Plaintiff's likely return to more dangerous tobacco products will result in healthcare costs to Plaintiff of approximately $35 per pack of cigarettes according to the American Cancer Society. As Plaintiff was a 2 pack per day smoker prior to use of vape products, and a conservative life expectancy of another thirty years, the effect of the defendants' action is to increase Plaintiff's healthcare costs by an estimated $766,500.

31. Defendants have usurped the power of the State of West Virginia to shift residents from more dangerous tobacco products to the healthier alternative of vape and e-liquid products in violation of the Tenth Amendment to the United States Constitution.

32. According to a recent study by State Budget Solutions, 67% of West Virginia's Medicaid population uses tobacco products. This usage drives up state tax costs significantly. As the vape industry has emerged, studies such as an August 2015 study by Public Health England, an executive agency of the Department of Health, show that substituting vape and e-liquid products for tobacco promotes health and saves healthcare costs to taxpayers.

33. By removing vape and e-liquid products from the marketplace or reducing the cost effective availability of the products from the marketplace, defendants are effectively forcing the

State of West Virginia to expend state tax dollars through Medicaid to pay the healthcare costs associated with use of tobacco tax when those costs are increasingly minimized by use of the vape and e-liquid products. These unlawful actions by defendants and the compelled expenditure of resources by the State of West Virginia is in violation of the Tenth Amendment.

34. Even if the Court ultimately sets aside the Deeming Rule, Plaintiff will suffer irreparable harm from its promulgation due to the immediate and irreparable consequences of the vapor and e-liquids products being removed from the market.

35. For these reasons and the others given in this Complaint, there exists an actual and justiciable controversy between Plaintiff and Defendants requiring resolution by this Court.

FIRST CLAIM FOR RELIEF

Violation of APA—Unlawful Statutory Interpretations

36. The above paragraphs are incorporated herein by reference.

37. The APA, 5 U.S.C. § 706(2)(A), (C), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."

38. The Deeming Rule violates those provisions because, *inter alia*, its definition of "tobacco product" and proposed reach of its provisions is unambiguously foreclosed by, and is an unreasonable construction of, the text of the Act.

SECOND CLAIM FOR RELIEF

Violation of APA—Arbitrary and Capricious Agency Action

35. The above paragraphs are incorporated herein by reference.

36. The APA, 5 U.S.C. § 706(2)(A), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Under this provision, agency action is unlawful if the agency failed to articulate a rational connection between the facts found and the choice made, failed to consider an important aspect of the problem, or offered an explanation for its decision that runs counter to the evidence. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

37. The Deeming Rule is unlawful when judged against that standard.

38. Under the Act, "tobacco products" may not be sold without prior approval from FDA. 21 U.S.C. § 387j(a)(2). The Act provides three options for obtaining FDA approval:

- The substantial equivalence ("SE") pathway, which requires the manufacturer to show that its product "is substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007," 21 U.S.C. § 387j(b)(2);

- The SE exemption pathway, under which the manufacturer must show that its product is only a "minor modification" of a tobacco product that was on the market as of February 15, 2007, and that the modification only involves a change in additive levels, *id.* §§ 387(j)(3), 387j(a)(2)(A)(ii); and

- The premarket tobacco application ("PMTA") pathway, under which the manufacturer must obtain FDA approval based on a detailed application documenting the product's health risks, ingredients, manufacturing methods, and other characteristics, *id.* § 387j(b)(1).

39. The PMTA process is similar to the new drug application (NDA) process set forth in the FDCA, which courts have described as "expensive and timeconsuming." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001). The language of the provision outlining the PMTA process repeats verbatim several portions of the provision governing the NDA process. *Compare* 21 U.S.C. § 355(b)(1) *with* 21 U.S.C. § 387j(b)(1).

40. The PMTA pathway is the only avenue open to the vast majority of vaping devices and e-liquids. Vaping devices and e-liquids generally were not on the market "as of February 15, 2007," and thus do not meet FDA's stringent test for the SE pathway. Similarly, vaping devices and e-liquids do not meet the criteria for the SE exemption pathway because they are not "minor modifications" of tobacco products that were marketed as of February 15, 2007.

41. Thus, under the Deeming Rule, manufacturers will be required to file and obtain FDA approval of PMTAs for hundreds of products, and for every new product that brought to market in the future. The Deeming Rule ignores the extraordinary burden this approval regime will have on consumers such as Plaintiff along with manufacturers and on FDA itself.

43. The Deeming Rule also arbitrarily discounts the safety benefits offered by vaping devices and e-liquids. As the Deeming Rule acknowledges, studies have concluded that (i) vaping devices enable "substantial reductions in the exposure to harmful constituents typically associated with smoking" when "compared to cigarettes"; (ii) "most of the chemicals causing smoking related disease from combusted tobacco use are absent" in the vapor generated by vaping devices; (iii) "the chemicals that are present" in vapor generated by vaping devices "present limited danger"; and (iv) vaping devices "are likely to be much less, if at all, harmful to users or bystanders" in comparison to cigarettes.

44. Despite that compelling safety data, the Deeming Rule subjects vaping devices and e-liquids to the same extensive regulatory regime designed for cigarettes and smokeless tobacco—products Congress has characterized as causing "over 400,000 deaths in the United States each year." Act § 2(13).

45. The Deeming Rule is particularly arbitrary in its treatment of new vaping devices and e-liquids introduced after the Rule's August 8, 2016, effective date. Although the Rule adopts

a compliance policy that will allow existing vaping devices and e-liquids to remain on the market temporarily, so long as the manufacturer timely files a corresponding PMTA, the Rule also mandates that products introduced after its effective date are "not covered by th[e] compliance policy" and therefore are "subject to [immediate] enforcement if marketed without" an approved PMTA. As a result, manufacturers will be unable to introduce new vaping devices and e-liquids for several years. The Deeming Rule does not articulate a reasoned basis for imposing such a *de facto* moratorium. Nor does the Deeming Rule recognize the reality that the lack of new vaping products, and removal of existing ones for non-compliance, will drive consumers back to cigarettes, thereby flying directly in the face the Act's objectives.

46. The ultimate result of the Deeming Rule is a regime that arbitrarily frustrates innovations and advances in public health while preserving a market dominated by cigarettes. The Deeming Rule does not explain how this result serves the public interest or the Act's goals of "promot[ing] cessation" of tobacco use and "reduc[ing] ... the social costs associated with tobacco-related diseases." Act § 3(9).

THIRD CLAIM FOR RELIEF

Violation of APA—Unlawful Cost-Benefit Analysis

47. The above paragraphs are incorporated herein by reference.

48. The APA, 5 U.S.C. § 706(2)(A), (C)–(D), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

49. The Deeming Rule's purported cost-benefit analysis violates the APA because it overstates the Rule's benefits, fails to quantify the *Rule*'s benefits, understates the Rule's tremendous costs, and erroneously concludes that the *Rule*'s benefits outweigh its costs.

50. Among other things, the Deeming Rule grossly underestimates the number of PMTAs that manufacturers will be required to file, and that FDA will be required to review. Although the Deeming Rule estimates that 750 PMTAs will be filed annually, West Virginia manufacturers alone may need to file many hundreds of PMTAs just to cover existing product offerings. Countless other manufacturers will also have to comply.

51. A proper cost-benefit analysis, as required by law, would demonstrate that the Deeming Rule imposes severe regulatory burdens on manufacturers, including West Virginia small businesses, by requiring compliance with extensive premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements. These costs vastly outweigh the benefits generated by the Deeming Rule, particularly given that vaping devices and e-liquids do not contain tobacco and/or do not pose the public-health risks associated with products that contain tobacco.

52. The Deeming Rule's flawed cost-benefit analysis permeates through the entire Rule, and therefore requires the Rule to be vacated and set aside, because FDA could not rationally have adopted the same regulatory scheme if it had performed a reasonable cost-benefit analysis.

FOURTH CLAIM FOR RELIEF

Violation of First Amendment

53. The above paragraphs are incorporated herein by reference.

54. The APA, 5 U.S.C. § 706(2)(B), provides that a reviewing court shall hold unlawful and set aside agency action that is "contrary to constitutional right, power, privilege, or immunity."

55. The Deeming Rule violates the First Amendment by prohibiting Plaintiff as a consumer manufacturers from receiving truthful and non-misleading statements regarding vaping devices, e-liquids, and related products from manufacturers.

56. The Deeming Rule violates the First Amendment by prohibiting Plaintiff as a consumer from receiving other forms of protected expression, including free samples of vaping devices or e-liquids from manufacturers.

FIFTH CLAIM FOR RELIEF

Violation of Tenth Amendment

57. The above paragraphs are incorporated herein by reference.

58. By effectively co-opting the State's ability to control its Medicaid budget through promotion of vape and e-liquid products over tobacco products, defendants compel the State of West Virginia to expend money it does not have on tobacco related healthcare costs.

59. The compelled expenditure of these funds deprives the State of its sovereignty and runs afoul of the Constitutional principle of federalism.

60. Such actions are violations of the Tenth Amendment.

RELIEF REQUESTED

WHEREFORE, Plaintiff asks this Court issue judgment in his favor and against Defendants, and to grant the following relief:

A. Vacate and set aside the Deeming Rule;

B. Declare that:

i. the Deeming Rule is contrary to and exceeds FDA's statutory authority under the Act and the FDCA;

ii. the Deeming Rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

iii. the Deeming Rule's cost-benefit analysis is unlawful;

iv. the Deeming Rule is contrary to the First Amendment; and

v. the Deeming Rule is contrary to the Tenth Amendment.

C. Issue a preliminary injunction enjoining enforcement of the Deeming Rule and prohibiting FDA from taking any action under the Deeming Rule pending resolution of this action on the merits;

D. Expedite resolution of this action on the merits;

E. Grant Plaintiff reasonable attorney's fees and expenses; and

F. Award such further relief as this Court deems just and proper.

Respectfully Submitted by
Larry Faircloth, Plaintiff
Through Counsel

Patrick Lane (WV 8566)
The Lane Law Firm
5402 Morning Dove
Cross Lanes, WV 25313
304-545-5263
patrick.lane@wvlanelaw.com