UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

MOOSE JOOCE, MOUNTAIN VAPORS, RUSTIC VAPORS, and DUTCHMAN VAPORS,

Moose Jooce
8953 Lake Station Avenue
Lake, MI 48632

Mountain Vapors
83 South Stewart Street, Suite 206
Sonora, CA 95370

Rustic Vapors
1021 West Washington Street
Marquette, MI 49855

Dutchman Vapors
418 North Washington Street
Grand Forks, ND 58203

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION; SCOTT GOTTLIEB, M.D., Commissioner of Food and Drugs; ALEX AZAR, Secretary of Health and Human Services,

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Scott Gottlieb, M.D.
Commissioner of Food & Drugs Admin.
10903 New Hampshire Avenue
Silver Spring, MD 20993

Alex Azar
Secretary of Health & Human Servs.
200 Independence Avenue SW

Case No. _____

COMPLAINT

Washington, DC 20201

Defendants.

INTRODUCTION

1. The Food and Drug Administration's Deeming Rule[1] enables the FDA to treat a variety of non-tobacco vaping products as if they were tobacco products regulated by the Tobacco Control Act, 21 U.S.C. §§ 387-387u. The Deeming Rule thus triggers burdensome regulatory requirements, including a ban on truthful speech unless the speaker obtains government preapproval for each statement. As alleged herein, the Deeming Rule is unconstitutional because the FDA employee who issued it had no constitutional authority to do so, and because the rule violates the First Amendment's free speech protections.

2. The authority to issue rules like the Deeming Rule is a significant power that the Constitution reserves for "Officers of the United States." *Buckley v. Valeo*, 424 U.S. 1, 140-41 (1976). Because the issuance of a rule is final, because a rule binds the government and the regulated public, and because a rule cannot be easily reversed, only a principal officer of the United States—one who has been nominated by the President and confirmed by the Senate—may exercise such authority. *See Edmond v. United States*, 520 U.S. 651, 663 (1997). Limiting this power to principal officers who are subject to Senate confirmation ensures democratic accountability when the government issues rules that have the force of law and bind the public. But even if inferior officers, who though subject to the Appointments Clause do not need Senate confirmation, could exercise this power, mere agency employees may not.

3. No principal officer of the United States issued the Deeming Rule. Nor did any inferior officer. Instead, the rule was issued by Ms. Leslie Kux, a career FDA employee. Ms. Kux is not an officer of the United States; she is simply one of the nearly two million civilian employees

[1] "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-2014N-0189, 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule").

currently working for federal agencies, employees who cannot constitutionally be vested with the power to enact binding rules such as the Deeming Rule.

4. Independent of the constitutional infirmities in its promulgation, the Deeming Rule imposes significant restrictions on truthful, non-misleading speech, restrictions which violate the First Amendment. Thanks to the Deeming Rule, anyone who manufacturers or sells a vaping product must obtain FDA's preapproval before engaging in truthful speech concerning that product's health and related effects. Moreover, it is the would-be speaker who must bear the burden of convincing the agency that the truthful speech will improve public health. Such restrictions on truthful speech are presumed unconstitutional under the First Amendment, and it is the government—not the speaker—which must bear the heavy burden to overcome that presumption. The Deeming Rule unconstitutionally shifts that burden from the government to speakers.

5. Because the Deeming Rule violates the Appointments Clause and the First Amendment, Plaintiffs Moose Jooce, Mountain Vapors, Rustic Vapors, and Dutchman Vapors—all vape shops regulated under the Deeming Rule—seek declaratory and injunctive relief against the rule.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction); § 2201 (authorizing declaratory relief); § 2202 (authorizing injunctive relief); and 5 U.S.C. § 702 (providing for judicial review of agency action under the Administrative Procedure Act).

7. Venue is proper under 28 U.S.C. § 1391(e) because at least one Defendant is located in this District.

PARTIES

Plaintiffs

8. **Moose Jooce**, operates two vape shops in Michigan. It was founded by Kimberly Manor after her husband passed away from lung cancer. It caters to middle-aged and older smokers struggling to stop smoking cigarettes. Moose Jooce manufacturers its own line of vaping liquids and sells vaping equipment as well. Some of that equipment must be assembled before use. New customers in particular need help learning how to use the equipment, so Moose Jooce regularly teaches consumers how to properly assemble vaping devices.

9. Moose Jooce has helped hundreds of people quit smoking and would like to promote these benefits. But potential customers are less willing to switch from smoking cigarettes to vaping, unless Moose Jooce can truthfully explain the differences between cigarettes and vaping, the studies supporting vaping as a smoking cessation aid, and other vaping-related benefits. Because of the Deeming Rule, Moose Jooce is prohibited from providing this information without government preapproval.

10. **Mountain Vapors** is a vape shop operated by William S. Green in Sonora, California. Green was a 2+ pack-a-day smoker for 30 years. His doctors warned that he was developing emphysema because of smoking. A few years ago, a friend of his wife gave her a vaping pen, which Green then tried; he quit smoking that same day. Unfortunately, because Green lives in a remote part of California, there was no nearby place at that time to obtain equipment or supplies. Green therefore decided to found Mountain Vapors to fill that void, initially as a side hustle, but it has since grown into his full-time job. The shop is small and caters to people curious about vaping, particularly people looking to quit smoking cigarettes. To help educate potential customers, Mountain Vapors previously offered samples of vaping liquids and would assemble re-

buildable dripping atomizers—a popular type of vaping pen known for maximizing flavor. Since the Deeming Rule went into effect, Mountain Vapors has lost many of its popular liquids, because their small manufacturers were driven out of business by the regulation's costs. Also, Mountain Vapors has stopped assembling devices for customers, a service which had previously drawn customers to the store rather than shopping online. If a customer assembles a rebuildable dripping atomizer incorrectly, it can malfunction and harm the user.

11. Mountain Vapors' costumers are most interested in the differences between cigarettes and vaping, and the health consequences of those differences. Prior to the Deeming Rule, a big part of Mountain Vapors' service to customers was to answer these questions. In particular, Green would explain that (i) vaping liquids do not contain several carcinogens present in cigarettes, (ii) vaping liquids helped him and many, many others quit smoking, and (iii) studies show that vaping liquids are much safer than cigarettes. Today, thanks to the Deeming Rule, Green cannot communicate this truthful information to inquiring customers.

12. **Rustic Vapors**, operates a vape shop in Marquette, Michigan, which sells vaping liquids and equipment. Prior to the Deeming Rule, Rustic Vapors also helped customers by building, maintaining, and repairing vape pens. For example, Rustic Vapors would build dripping atomizers for customers and periodically replace the device's coil, which is the key part that heats vaping liquid. Since the Deeming Rule went into effect, Rustic Vapors has been unable to perform this service, despite the fact that a customer who incorrectly assembles a device could be injured.

13. Rustic Vapors also would like to communicate truthful information to its customers about the differences between vaping and cigarettes. But it has had to cease doing so since the Deeming Rule went into effect. Worse, when customers reference some misinformation from the

internet, Rustic Vapors cannot provide them more reliable information, but instead must allow them to remain misinformed, often to the customers' detriment.

14. **Dutchman Vapors** operates four vape shops in North Dakota. Through an affiliated company, it produces vaping liquid and is registered with the FDA as a manufacturer. In addition to selling that liquid and other vaping products, the store used to assemble devices and build coils for customer devices. It has had to suspend those services because of the Deeming Rule. To continue that work, Dutchman Vapors would have to register as a manufacturer for each type of coil that it builds. Because different devices require slightly different coils, complying with the registration requirement would be prohibitively expensive. Like most other small vape shops, Dutchman Vapors has had to give up this part of its business because of the Deeming Rule. Owing to the Deeming Rule's restriction of Dutchman Vapors' truthful advertising, the company's growth in new customers has declined dramatically. Prior to the rule, its customer base was growing by 22 percent, but now that growth rate has declined to 7 percent. Thanks to the Deeming Rule, Dutchman Vapors cannot, without obtaining the government's preapproval, advertise or explain to customers the differences between cigarettes and vaping, or even correct clear misinformation that potential customers have obtained from the Internet.

Defendants

15. The **Food and Drug Administration** is an agency within the Department of Health and Human Services, with an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Tobacco Control Act.

16. **Scott Gottlieb, M.D.**, is Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Gottlieb maintains an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

17. **Alex Azar** is Secretary of Health and Human Services and the official charged by law with administering the Act. He is sued in his official capacity. Secretary Azar maintains an office at 200 Independence Avenue SW, Washington, District of Columbia 20201.

LEGAL BACKGROUND

The Appointments Clause

18. The Appointments Clause of the United States Constitution provides that the President "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint" all principal officers of the executive branch. This appointment procedure is required for all principal officers of the executive branch, but Congress may by law vest the appointment of "inferior Officers . . . in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, § 2, cl. 2.

19. Anyone "exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed by" the Appointments Clause. *Buckley v. Valeo*, 424 U.S. 1, 126 (1976).

20. The authority to issue a binding rule is an exercise of significant authority pursuant to the laws of the United States. *See Buckley*, 424 U.S. at 140-41. "[R]ulemaking, advisory opinions, and determinations of eligibility for funds and even for federal elective office itself . . . [each] represents the performance of a significant governmental duty exercised pursuant to a public law. . . . These administrative functions may therefore be exercised only by persons who are 'Officers of the United States.'" *Id*. (quoting U.S. Const. art. II, § 2, cl. 2).

21. Indeed, the power to issue a final rule on one's own authority is so significant an exercise of executive power that the Constitution reserves such power to principal officers alone, *i.e.*, those who have been appointed by the President with the advice and consent of the Senate. *See Ass'n of Am. R.R.s v. U.S. Dep't of Transp.*, 821 F.3d 19, 39 (D.C. Cir. 2016) (citing *Edmond v. United States*, 520 U.S. 651, 663 (1997)) (holding that, because arbitrators under the Passenger Rail Investment and Improvement Act have the power to take "final agency action[s]," and "promulgat[e] metrics and standards" without "any procedure by which the arbitrator's decision is reviewable" by a superior, those arbitrators must be principal officers to exercise such power constitutionally).

The First Amendment

22. The First Amendment forbids, among other things, government action that abridges the freedom of speech. *See* U.S. Const. amend. I.

23. This protection extends to the right of merchants to propose transactions and to explain the nature of their goods to consumers. *See In re R.M.J.*, 455 U.S. 191, 203 (1982) ("Truthful advertising related to lawful activities is entitled to the protections of the First Amendment.").

24. A restriction on truthful advertising is permissible under the First Amendment only if, *inter alia*, it "directly and materially advances the interest" asserted by the government. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

25. Under this framework, "[i]t is well established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) (quoting *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71 n.20 (1983)). "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body

seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Id.* at 770-71.

The Tobacco Control Act

26. In June, 2009, Congress enacted the Tobacco Control Act ("The Act"). The Act applies "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary [of Health and Human Services] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b). The Act imposes a variety of duties and prohibitions on retailers and manufacturers. The latter are defined broadly to include even those who merely assemble or label prefabricated tobacco products. *See id*. § 387(20)(A).

27. One of the Act's most significant strictures is its regulation of so-called modified risk tobacco products, 21 U.S.C. § 387k. With respect to such products, the Act imposes an extraordinary prior restraint on the speech of their manufacturers, as well as retailers who wish to add their own label or packaging to such products. In all cases, permission must be obtained from the FDA before the product can be put into commerce with any labeling or marketing that "represents explicitly or implicitly that" the product "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products," that the product "or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance," or that the product "or its smoke does not contain or is free of a substance." *Id*. § 387k(b)(2)(A)(i).

28. Proving that such a statement is truthful is not enough to win government approval to speak. In addition, the manufacturer or retailer must demonstrate to the government's satisfaction "that such product, as it is actually used by consumers, will—(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health

of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." 21 U.S.C. § 387k(g)(1). Alternatively, a manufacturer or retailer may avail itself of marketing that is limited to claims of reduced exposure to a substance if, but only if, FDA finds that current scientific evidence on use of the product "demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies," and that approval of the marketing "is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 387k(g)(2)(A)(iv).

29. In either case, the Tobacco Control Act places the burden of proof on speakers to show that their truthful speech will create a net benefit before the government will permit them to speak. Thus, even if such truthful speech would harm no one, it would still fall short of the government's demand that the speech must provide a net benefit to the human population.

30. The Tobacco Control Act's restrictions on truthful speech apply not just to the labeling of the product and its ads, but also to "any action directed to consumers through the media or otherwise." 21 U.S.C. § 387k(2)(A)(iii). Thus, statements that appear in magazines or even scientific journals may fall within the Act's ambit, if the government decides that those publications are "directed to consumers."

31. In addition to its advertising gag provisions, the Act regulates covered products through a variety of registration, data collection, and marketing review requirements. For example, the Act requires each covered manufacturer to provide FDA a list of all ingredients and compounds added to its products, as well as any and all documentation pertaining to the products' health and related effects. 21 U.S.C. § 387d(a)-(b). The Act also requires manufacturers to register their places of business and their product lists with the agency. *Id.* § 387e. The Act prohibits, among

other things, the marketing of any covered (and not otherwise grandfathered) product unless FDA has given its approval. *Id*. § 387j. This premarket approval process requires the development and submission of substantial amounts of data, *see id*. § 387j(b), an arduous undertaking that FDA itself has estimated may cost the vaping industry hundreds of thousands of dollars or more per product. *See* FDA, Final Regulatory Impact Analysis 87-88 Tbls. 11(a) & 11(b) (2016). Failure to comply with these provisions can result in a variety of serious consequences for manufacturers and retailers, including the designation of one's products as misbranded or adulterated, *see id.* §§ 387b, 387c, which in turn can trigger substantial civil penalties and imprisonment, *id*. §§ 331, 333, as well as seizure of the offending products, *id*. § 334.

ALLEGATIONS

The Purported Promulgation of the Deeming Rule by FDA Employee Leslie Kux

32. As noted above, in May, 2016, FDA purported to issue a rule that "deemed" several non-tobacco products to be subject to the Tobacco Control Act. These products include not only "dissolvables . . . gels, waterpipe tobacco . . . cigars, and pipe tobacco," but also "electronic nicotine delivery systems" (ENDS), which include "e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes." Deeming Rule, 81 Fed. Reg. at 28,976. The Deeming Rule thus subjects the manufacturers and retailers of non-tobacco vaping devices to nearly all the requirements previously imposed on cigarettes, including the Act's speech and premarketing approval provisions.

33. The Deeming Rule was not issued by a principal officer, or even an inferior officer. Rather, FDA employee Leslie Kux, the agency's Associate Commissioner for Policy, issued it. *See* 81 Fed. Reg. at 29,016 (final rule issued by the authority of Leslie Kux); "Meet Leslie Kux," https://www.fda.gov/AboutFDA/CentersOffices/ucm304642.htm.

34. Ms. Kux has neither been nominated nor appointed as a principal officer by the President. *See* United States Government Policy and Supporting Positions (Plum Book), 2016, page 70 (noting that Ms. Kux's position is not subject to presidential appointment). Because the President has never nominated her, the Senate has never consented to Ms. Kux's exercising of the power to issue legislative rules that bind the public. Thus, Ms. Kux is not a principal officer and cannot exercise the power reserved to such officers, such as rulemaking authority under the laws of the United States.

35. Neither is Ms. Kux an inferior officer of the United States. No statute creates her position, and Congress has never provided for the means of appointing an FDA Associate Commissioner for Policy. Thus, Congress has not provided "by law" that such an appointment be vested "in the President alone, in the Courts of Law, or in the Heads of Departments." *See* U.S. Const. art. II, § 2, cl. 2 (limiting the power to appoint inferior officers to these circumstances).

36. Moreover, even if the position of Associate Commissioner for Policy were established by law and its appointment procedure authorized by Congress, Ms. Kux still would not qualify as an inferior officer of the United States, because she has not been appointed by the President, a court of law, or the head of a department. In fact, according to the FDA's own Staff Manual, the Associate Commissioner for Policy is an employee selected by the FDA Commissioner or Deputy Commissioner. *See* FDA Staff Manual Guide 1431.23.[2] Neither the Commissioner nor the Deputy Commissioner is the "head of a department." Rather, both are inferior commissioners within the Department of Health and Human Services. *Cf. Freytag v. C.I.R.*, 501 U.S. 868, 886 (1991) ("This Court for more than a century has held that the term

[2] https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM274936.pdf.

"Department" refers only to a part or division of the executive government, as the Department of State, or of the Treasury, expressly created and given the name of a department by Congress. . . . Accordingly, the term "Heads of Departments" does not embrace inferior commissioners and bureau officers.") (quoting *United States v. Germaine*, 99 U.S. 508, 510-11 (1878) (quotation marks and alterations omitted)).

37. Thus, rather than exercising significant authority under the laws of the United States pursuant to a valid officer's commission, Ms. Kux exercises this power pursuant to an unconstitutional delegation. Through the Tobacco Control Act, Congress delegated authority to issue rules under the statute to the HHS Secretary, a principal officer. Through a staff manual, the HHS Secretary sub-delegated this power to the FDA Commissioner. FDA Staff Manual Guide 1410.10. Then the FDA Commissioner sub-sub-delegated this power to the Associate Commissioner for Policy. *See* FDA Staff Manual Guide 1410.21 (authorizing the Associate Commissioner for Policy to assume the FDA Commissioner's authority to issue "proposed and final regulations"). *See also* "Meet Leslie Kux," *supra* ("[Ms. Kux] oversees, directs, and coordinates the [FDA's] rulemaking activities."). Relying on this unconstitutional delegation, Kux has issued nearly 200 final FDA rules, including the Deeming Rule.

The Effects of the Deeming Rule on Plaintiffs

38. Enforcement of the Deeming Rule has significantly injured Plaintiffs' businesses. The overwhelming majority of their products are now subject to the premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements imposed by the Tobacco Control Act.

39. Moose Jooce is regulated as a manufacturer under the Deeming Rule, because it blends a line of vaping liquids. As a result, Moose Jooce's ability to communicate truthful

information to its customers is heavily restricted. If Moose Jooce wishes to convey such information, it must seek permission from FDA first and would bear the burden of proving that the information is not only truthful but also would provide a net public health benefit.

40. Mountain Vapors and Rustic Vapors have had to cease assembling and repairing vaping products because doing so would subject the companies to the Deeming Rule's costly and burdensome manufacturer regulations. Foregoing these services has hurt the ability of both companies to attract new customers.

41. Dutchman Vapors has suffered both injuries under the Deeming Rule. Because the company blends its own vaping liquids, it must undergo the time-consuming and expensive registration process as a manufacturer. But, because that process is so cumbersome, Dutchman Vapors also must forego providing many other lucrative services, including assembling devices and building replacement coils.

42. All Plaintiffs are also restricted in how they truthfully advertise their businesses, products, and services. Before they may truthfully state, for instance, that the vaping liquids they sell do not have several carcinogens found in cigarettes, they must suffer the cost and delay of seeking FDA's preapproval for each statement.

DECLARATORY AND INJUNCTIVE RELIEF ALLEGATIONS

43. Moose Jooce, Mountain Vapors, Rustic Vapors, and Dutchman Vapors each has a significant interest in whether the Deeming Rule was lawfully promulgated. The Deeming Rule's regulations have prevented, and will continue to prevent, Plaintiffs from bringing new products to market, from servicing their customers' already-purchased products, and from communicating truthful information to their customers. A decision declaring the Deeming Rule void as unlawfully

promulgated under the Appointments Clause would remedy these injuries by restoring Plaintiffs' freedom to bring products to market and communicate freely with their customers.

44. Further, a decision striking down the preapproval process under the First Amendment would vindicate Plaintiffs' interest in communicating truthful information to their customers.

45. An actual and substantial controversy exists between Plaintiffs and Defendants over whether the Deeming Rule is in fact a constitutionally promulgated rule that Plaintiffs must comply with and, if it is, whether the preapproval process mandated by the Deeming Rule comports with the First Amendment. Plaintiffs contend that the Deeming Rule is unconstitutional, whereas Defendants, based on their continuing enforcement of the Rule, believe that the Rule is constitutional.

46. This case is currently justiciable because Plaintiffs have already refrained from taking actions that they wish to take in order to comply with the Deeming Rule and avoid a real threat of future enforcement actions.

47. Plaintiffs have no plain, speedy, and adequate remedy at law, as money damages are not available against Defendants for their continuing violation of Plaintiffs' constitutional rights.

48. Therefore, declaratory and injunctive relief is appropriate to resolve this controversy.

FIRST CLAIM FOR RELIEF

I
PROMULGATION OF A RULE BY A NON-OFFICER

(Violation of the Appointments Clause, U.S. Const. art. II, § 2, cl. 2)

49. The above paragraphs are incorporated herein by reference.

50. The Administrative Procedure Act provides for judicial review of final agency action. *See* 5 U.S.C. § 704. The Deeming Rule is a final agency action because it represents the consummation of Defendants' decision-making as to the applicability of the Tobacco Control Act to vaping products, and because it affects legal rights and obligations, by subjecting such devices to the Act's strictures.

51. The Deeming Rule was issued by FDA employee Leslie Kux, who is neither a principal nor an inferior officer of the United States.

52. The issuance of a rule like the Deeming Rule, which imposes a significant and burdensome regulatory regime on the manufacturers and retailers of a wide array of commercial products, is an exercise of significant authority constitutionally reserved to officers of the United States. *See Buckley*, 424 U.S. at 140-41. Because the Deeming Rule was promulgated by an employee, rather than an officer of the United States, it is therefore contrary to constitutional right, power, privilege, or immunity, and therefore must be set aside. *See* 5 U.S.C. § 706(2)(B).

SECOND CLAIM FOR RELIEF

II
ABRIDGMENT OF THE FREEDOM OF SPEECH

(Violation of the First Amendment, U.S. Const. amend. I)

53. The above paragraphs are incorporated herein by reference.

54. The Tobacco Control Act prohibits manufacturers and retailers from making several types of truthful statements unless the manufacturers and retailers can demonstrate a public health benefit from the making of such statements. 21 U.S.C. § 387k.

55. The Tobacco Control Act thereby places the burden of proof on *speakers* to show that their truthful speech is "beneficial" before they are permitted to speak. *See* 21 U.S.C. § 387k(g)(1)-(2).

56. This procedure for approval of truthful "Modified Risk Statements," made applicable to vaping manufacturers and retailers by the Deeming Rule, impermissibly inverts the constitutionally required burden of proof, under which the *government*, not the speaker, must demonstrate that a restriction on speech directly and materially advances a valid interest asserted by the government. *See Edenfield*, 507 U.S. at 770.

57. The Deeming Rule thus violates the First Amendment by prohibiting vaping manufacturers and retailers, including Plaintiffs, from making truthful and non-misleading statements regarding vaping devices, e-liquids, and related products. Therefore, the Deeming Rule is contrary to constitutional right, power, privilege, or immunity, and must be set aside. *See* 5 U.S.C. § 706(2)(B).

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for relief as follows:

1. As to the First Claim for Relief, a judgment declaring that the Deeming Rule violates the Appointments Clause;

2. As to the First Claim for Relief, a preliminary and permanent prohibitory injunction setting aside the Deeming Rule, and forbidding Defendants from enforcing it, because it violates the Appointments Clause;

3. As to the Second Claim for Relief, a judgment declaring that the Deeming Rule violates the First Amendment;

4. As to the Second Claim for Relief, a preliminary and permanent prohibitory injunction setting aside the Deeming Rule's application of the Tobacco Control Act's "Modified Risk Statement" approval procedure to vaping devices, because such application violates the First Amendment;

5. As to both Claims for Relief, an award of reasonable attorney fees and costs, pursuant to 28 U.S.C. § 2412, or any other applicable authority; and

6. As to both Claims for Relief, any other relief that the Court determines to be just and proper.

DATED: January 30, 2018.

Respectfully submitted:

/s/ Jonathan Wood

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