IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MINNESOTA

JEN HOBAN d/b/a MASTERPIECE VAPORS; THE PLUME ROOM LLC; J.H.T. VAPE LLC; LAKES VAPE SUPPLY LLC; and TOBACCO HARM REDUCTION 4 LIFE,

Plaintiffs,

v.

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

Defendants.

Case No. _____

COMPLAINT

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 (Tobacco Control Act or Act). The Deeming Rule thus triggers burdensome regulatory requirements, including a ban on truthful speech unless the speaker obtains government pre-approval 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.

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[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 or Rule).

2. Vaping-related items that meet the statutory definition of "tobacco products" under the Deeming Rule and the Tobacco Control Act comprise a variety of currently marketed products. These include such products as dissolvables not already regulated by the FDA, gels, waterpipes, tobacco, as well as electronic nicotine delivery systems (ENDS), which in turn encompass e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes. Deeming Rule, 81 Fed. Reg. at 28,976. As this list shows, there is more than one way to vape. Plaintiff Jen Hoban's customers, for example, generally use equipment consisting of an inhaler-cartridge that contains flavored e-liquids, an atomizer activated by a heating coil, and a battery. When the atomizer is heated, the flavored e-liquid is vaporized and can be inhaled.

3. 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.

4. 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

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

5. 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 manufactures or sells a vaping product must obtain FDA's pre-approval 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, which requires that the *government*—not the speaker—must bear the heavy burden to overcome the presumption. The Deeming Rule unconstitutionally shifts that burden from the government to speakers.

6. Because the Deeming Rule violates the Appointments Clause and the First Amendment, Plaintiffs Jen Hoban d/b/a Masterpiece Vapors, The Plume Room LLC, J.H.T. Vape LLC, Lakes Vape Supply LLC, and Tobacco Harm Reduction 4 Life seek declaratory and injunctive relief barring the Deeming Rule's enforcement.

JURISDICTION AND VENUE

7. 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).

8. Venue is proper under 28 U.S.C. § 1391(e), because Plaintiff Jen Hoban resides in this District, and because Plaintiffs The Plume Room LLC, J.H.T. Vape LLC, and Lakes Vape Supply LLC maintain their principal place of business in this District. *See also* 5 U.S.C. § 703

(venue for actions under the Administrative Procedure Act generally proper in "a court of competent jurisdiction").

PARTIES

Plaintiffs

9. **Jen Hoban** is an individual residing in Detroit Lakes, Minnesota. Hoban is the sole proprietor of **Masterpiece Vapors**, which operates two e-cigarette retail shops located at 157 1st Avenue South, Perham, Minnesota 56573, and at 119 Lake Road, Detroit Lakes, Minnesota 56501.

10. **The Plume Room LLC** is a Minnesota limited liability company, with its principal place of business at 5560 144th Avenue NW, Ramsey, Minnesota 55303. The Plume Room is a manufacturer of e-liquids and sells 32 flavors that have been registered with the FDA.

11. **J.H.T. Vape LLC** is a Minnesota limited liability company, with its principal place of business at 823 Washington Street, Brainerd, Minnesota 56401. J.H.T. Vape operates an e-cigarette retail shop in Brainerd, Minnesota.

12. **Lakes Vape Supply LLC** is a Minnesota limited liability company, with its principal place of business at 821 Washington Street, Brainerd, Minnesota 56401. Lakes Vape Supply is a manufacturer of e-liquids.

13. **Tobacco Harm Reduction 4 Life** (**THR4Life**) is a non-profit corporation, pursuant to 26 U.S.C. § 501(c)(3), incorporated under the laws of the State of Colorado. THR4Life, which has three board members who reside in Minnesota, is active in Minnesota and throughout the United States. Its mission is to help smokers regain control over their lives by providing balanced and accurate information about tobacco harm reduction. THR4Life is dedicated to bringing tobacco harm reduction to the public based on factual and scientific data. THR4Life supports any form of tobacco-harm-reducing products, and it believes that vaping is currently the

most widely used means of tobacco-harm reduction and the most successful method of permanent tobacco abstinence. THR4Life advocates for the dissemination of truthful information concerning tobacco-harm-reduction products and their health benefits compared with tobacco products.

14. Hoban d/b/a Masterpiece Vapors, The Plume Room, J.H.T. Vape, and Lakes Vape Supply shall be referred to collectively as the "Vaping Manufacturers and Retailers."

Defendants

15. **FDA** is an agency of the United States government 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 purported to delegate to FDA the authority to administer the Tobacco Control Act, 21 U.S.C. §§ 387a, 387a-1.

16. **Scott Gottlieb, M.D.**, is Commissioner of Food and Drugs and is the senior official of 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 Tobacco Control Act. He is sued in his official capacity. Secretary Azar maintains an office at 200 Independence Avenue SW, Washington, D.C. 20201.

18. All Defendants are collectively referred to hereinafter as "FDA."

LEGAL BACKGROUND

The Appointments Clause

19. The Appointments Clause of the U.S. 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.

20. 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*, 424 U.S. at 126.

21. The authority to issue a binding federal 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.'").

22. 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.Rs v. U.S. Dep't of Transp.*, 821 F.3d 19, 39 (D.C. Cir. 2016) (citing *Edmond*, 520 U.S. at 663) (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

23. The First Amendment forbids the government from abridging the freedom of speech. *See* U.S. Const. amend. I.

24. This protection extends to the right of merchants to propose transactions and 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.").

25. A restriction on truthful advertising violates the First Amendment unless 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).

26. 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 Prods. 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." *Edenfield*, 507 U.S. at 770-71.

The Tobacco Control Act

27. In June 2009, Congress enacted the Tobacco Control 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).

28. 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 FDA before the product can be put into commerce with any labelling 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." 21 U.S.C. § 387k(b)(2)(A)(i).

29. 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).

30. 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." 21 U.S.C. § 387k(g)(2)(A)(iv).

31. 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.

32. 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(b)(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."

33. 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. 21 U.S.C. § 387e. The Act prohibits, among other things, the marketing of any covered (and not otherwise grandfathered) product unless FDA has given its approval. 21 U.S.C. § 387j. This pre-market approval process requires the development and submission of substantial amounts of data, *see* 21 U.S.C. § 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).

34. Failure to comply with the above-described 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* 21 U.S.C. §§ 387b, 387c, which in turn can trigger substantial

civil penalties and imprisonment, 21 U.S.C. §§ 331, 333, as well as seizure of the offending products, 21 U.S.C. § 334.

ALLEGATIONS

Purported Promulgation of the Deeming Rule by FDA Employee Leslie Kux

35. 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.

36. The Deeming Rule was not issued by a principal officer, or even by an inferior officer. Rather, FDA employee Leslie Kux, the agency's Associate Commissioner for Policy, issued it. *See* 81 Fed. Reg. 29,016 (final rule issued by the authority of Leslie Kux); FDA.gov, "Meet Leslie Kux."[2]

37. 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 the

[2] https://www.fda.gov/AboutFDA/CentersOffices/ucm304642.htm.

power to issue legislative rules that bind the public.[3] Thus, Ms. Kux is not a principal officer and cannot exercise the power reserved to principal officers, such as rulemaking authority under the laws of the United States.

38. 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).

39. Moreover, even if the position of Associate Commissioner for Policy was 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.[4] 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 '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

[3] *See* Congress.Gov, search for "Leslie Kux" in "Nominations," https://www.congress.gov/search?q=%7B%22source%22%3A%22nominations%22%2C%22search%22%3A%22%5C%22leslie%20kux%5C%22%22%7D&searchResultViewType=expanded (finding no results).

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

bureau officers.") (quoting *United States v. Germaine*, 99 U.S. 508, 510-11 (1878) (quotation marks and alterations omitted)).

40. 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.[5] Then the FDA Commissioner sub-sub-delegated this power to the Associate Commissioner for Policy. *See* FDA Staff Manual Guide 1410.21[6] (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

41. Enforcement of the Deeming Rule has significantly injured each of the Vaping Manufacturers and Retailers' 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.

42. Before the Deeming Rule, Vaping Manufactures and Retailers provided free samples of their e-liquid products. Because of the Deeming Rule, they are now largely precluded

[5] https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManual%20Guides/UCM273771.pdf.

[6] https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManual%20Guides/UCM273783.pdf

from giving away free samples. 21 U.S.C. § 387a-1(a). This prohibition harms the Vaping Manufacturers and Retailers' ability to market their products and harms their goodwill with customers.

43. Any "tobacco" products that were not commercially marketed in the United States as of February 15, 2007, or

> any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007

are subject to a "premarket review," which involves an onerous application process, before these products may be introduced into the United States market. 21 U.S.C. § 387j.

44. As noted above, the Vaping Manufacturers and Retailers are prohibited from providing accurate information to their clients. 21 U.S.C. § 387k.

45. Plaintiff Hoban, and the owners of The Plume Room and J.H.T. Vape, and Lakes Vape Supply are all former smokers who were able to quit smoking through vaping as an alternative. They all know that they were able to quit because of vaping—a healthier, viable alternative to smoking.

46. Plaintiffs are aware of studies, including the 2016 report of the Royal College of Physicians, entitled "Nicotine without smoke: Tobacco harm reduction," that show vaping to be likely beneficial to public health.

47. Because of the Deeming Rule, the Vaping Manufacturers and Retailers are prohibited from explaining to their clients the results of these studies.

48. More generally, again, the Vaping Manufacturers and Retailers are subject to extraordinary prior restraints on their speech with respect to product labelling 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." 21 U.S.C. § 387k(b)(2)(A)(i).

49. These prior restraints on truthful speech apply not just to the labelling of the product and its ads, but also to "any action directed to consumers through the media or otherwise." 21 U.S.C. § 387k(b)(2)(A)(iii). Thus, the Vaping Manufacturers and Retailers may not produce advertisements or statements in magazines or even scientific journals for fear that such expression may fall within the Act's ambit, if the government decides that those publications are "directed to consumers."

50. Plaintiffs Lakes Vape Supply and The Plume Room would like to create and sell more flavors of e-liquids. But the time and costs imposed by the law are prohibitively expensive. The Tobacco Control Act also requires manufacturers of new tobacco products to obtain premarket approval from FDA before they may be sold. 21 U.S.C. § 387j(a)(2). For products not substantially similar to those on the market prior to 2007, this requires that manufacturers submit a separate, detailed application documenting the product's ingredients, manufacturing methods, potential health risks, and other characteristics. 21 U.S.C. § 387j(b)(1).

51. These pre-approval regulations have harmed the retailer Plaintiffs as well. Before the Deeming Rule, Masterpiece Vapors and J.H.T. Vape not only provided samples to their retail customers, they also provided their clients with custom-made flavors. Masterpiece Vapors and J.H.T. Vape can no longer provide this valuable service to their clients, and they are therefore severely restricted in the flavors they may offer to their customers.

52. Further, the law casts such a wide net that "tobacco products" includes not only the e-liquids used in vaping, but also any mechanisms used by vapers—such as a heating coil in an atomizer. Before the Deeming Rule was in effect, the Vaping Manufacturers and Retailers helped their clients assemble and repair their vaping equipment. Now, they are precluded from doing so. This ban has prevented the Vaping Manufacturers and Retailers from providing the client-service their customers had come to expect. The ban also prevented the Vaping Manufacturers and Retailers from assisting their clients in understanding the safe use of vaping products and equipment.

53. The Vaping Manufacturers and Retailers are also required to expend time and resources to obtain pre-approval of statements they make on the label of their "tobacco" products—even though none of their products contain tobacco. 21 U.S.C. § 387c(b).

54. Plaintiffs Lakes Vape Supply and The Plume Room, which manufacture e-liquids, are required to spend time and money collecting detailed information about their products. They must also submit this information to the Secretary of Health and Human Services, including certain health information. 21 U.S.C. § 387d. And at the request of the Secretary of Health and Human Services, Lakes Vape Supply and The Plume Room must submit additional, highly detailed information. 21 U.S.C. § 387d(b). These requirements cost Lakes Vape Supply and The Plume Room significant time and money—that could be better spent on growing their businesses.

55. Lakes Vape Supply and The Plume Room must register with the FDA, and as part of this registration, manufacturers must file a list of "tobacco" products they manufacture. 21 U.S.C. §§ 387e(b), (i). Again, these requirements cost Lakes Vape Supply and The Plume Room valuable time and money that could be spent creating new products and growing their businesses.

Declaratory and Injunctive Relief Allegations

56. Each Plaintiff 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.

57. Further, a decision striking down the pre-approval process under the First Amendment would vindicate Plaintiffs' interest in communicating truthful information.

58. 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 pre-approval 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.

59. 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.

60. 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.

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

FIRST CLAIM FOR RELIEF

PROMULGATION OF A RULE BY A NON-OFFICER

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

62. The above paragraphs are incorporated herein by reference.

63. 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 FDA's 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 products to the Act's strictures.

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

65. 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.

66. Because the Deeming Rule was promulgated by an employee, not an officer, of the United States, it is therefore contrary to constitutional right, power, privilege, or immunity, and must be set aside. *See* 5 U.S.C. § 706(2)(B).

SECOND CLAIM FOR RELIEF

PRIOR RESTRAINT ON TRUTHFUL SPEECH

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

67. The above paragraphs are incorporated herein by reference.

68. 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.

69. 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).

70. 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.

71. 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. *See* 5 U.S.C. § 706(2)(B). Therefore, the Deeming Rule is unconstitutional and must be set aside.

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:

By s/James V. Dickey

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