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LOST ART LIQUIDS, LLC

**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

LOST ART LIQUIDS, LLC, a California limited liability company,

Plaintiff,

v.

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.

Case No.

Ctrm:

Judge:

LOST ART LIQUIDS, LLC ("Lost Art " or "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").

**BACKGROUND**

1. Lost Art was created in 2014 by two innovative entrepreneurs from Los Angeles, who recognized the growing demands of the emerging global vaping community; they enthusiastically embraced the opportunity to provide adult consumers with high quality vaping products, i.e., e-liquids and personal electronic vaporizers ("PEV") that convert e-liquid into an inhalable aerosol mist.

2. The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), which grants the FDA broad authority to regulate the manufacturing, distribution, and marketing of tobacco products, was premised exclusively on the harm caused by the tobacco industry and traditional tobacco products.

3. The FDA's Deeming Rule attempts to unlawfully expand the scope of the FDA's regulatory authority under the Tobacco Control Act to include vaping products such as those sold by Plaintiff.

4. The vaping of e-liquids has an appearance, smell and taste that is very different than smoking tobacco products such as cigarettes, and is otherwise distinct, socially, physiologically, psychologically, physically, chemically, and toxicologically.

5. Lost Art has grown into a vapor life style brand that highlights and celebrates vaping culture and vaping technology through Lost Art's unique line of products, branding, social media,

and involvement in the vaping community. Its core business is the production and distribution of e-liquids, some of which do contain nicotine. It also sells PEVs, which are available in a wide range of designs and forms, but usually are comprised of ceramic, acrylic, metals, circuitry and wiring.

6. New and innovative PEVs are constantly being introduced into the marketplace and Lost Art sells many of them and makes and sells many innovative e-liquids for use with these PEVs.

7. As the legislative history makes clear, Congress never intended to grant FDA the authority to regulate vaping products under the Tobacco Control Act.

8. Defendants' have unlawfully, and in the absence of Congressional authority, enacted sweeping regulations that confuse and conflate e-liquid, PEVs, and their related software and technologies with "tobacco products" as that term is defined under the Tobacco Control Act.[1]

9. Congress enacted the Tobacco Control Act on June 22, 2009 to regulate the tobacco industry because of the serious and undisputed adverse health effects of tobacco smoking.

10. The Tobacco Control Act was not enacted to regulate technology products such as PEVs, e-liquids, or their component parts.

11. Proof of Congress' intent is found throughout the Tobacco Control Act, starting explicitly in the factual findings which serve as the predicate for the Act.[2]

12. For example, Finding No. 13 states that tobacco use "causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related

[1] "The term 'tobacco product' means 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)(1).

[2] *See* Tobacco Control Act § 2 (Emphasis added)

to **smoking**" and Finding No. 14 indicates that a 50% reduction in youth **smoking** would "result in approximately $75,000,000,000 in savings attributable to reduced health care costs."[3]

13. Vaping products do not have the same undisputed or adverse health effects of tobacco smoking or of tobacco use as contemplated by Congress in the Tobacco Control Act. In fact, FDA has publically stated "If a current smoker, otherwise unable or unwilling to quit, completely substituted all of the combusting cigarettes that they smoked with an electronic cigarette at the individual level, that person would probably be significantly reducing their risk."[4]

**PARTIES**

14. Lost Art Liquids LLC is a limited liability company with its principal place of business at 155 West Washington Boulevard, Suite 1109, Los Angeles, California 90015. Lost Art manufacturers and distributes e-liquids, and sells PEVs, and various PEV parts under the Arctic, Aspire, Cubis, Kanger, Innokin, Joytech, Wismech, eLeaf and other brand names. Lost Art is a small entity under the Regulatory Flexibility Act ("RFA").

15. Defendant, Food and Drug Administration, 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.

[3] *Id.*

[4] Mitch Zeller, Director, Center for Tobacco Products (full interview located at http://thedianerehmshow.org/shows/2014-01-21/new-health-risks-cigarette-smoking/transcript

16. 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.

17. 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.

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

**JURISDICTION AND VENUE**

19. This action arises under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 et seq., Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*; the FDCA, 21 U.S.C. § 301 *et seq.*; and the Tobacco Control Act, 21 U.S.C. § 387 *et seq*. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 2201–02.

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

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

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

**FIRST CAUSE OF ACTION**

**Violation of the RFA- §601 et seq.**

23. The Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 et seq., requires federal agencies to consider the impact of their regulatory proposals on small entities, and, inter alia, to analyze effective alternatives that minimize small entity impacts.

24. The FDA failed to satisfy this obligation, and Plaintiff is and will continue to be adversely affected and aggrieved by the Deeming Regulations, which constitute final agency action.

Accordingly, Plaintiff is entitled to judicial review of the FDA compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with [5 U.S.C. § 701, et seq.]."[5]

25. Because the Deeming Regulations "have a significant economic impact on a substantial number of small entities," the RFA requires that FDA perform a full regulatory flexibility analysis that includes a discussion of each element identified in §603(b) of the RFA. Section 603(b) of the RFA provides in pertinent part that:

> "Each initial regulatory flexibility analysis [IRFA] required under this section shall contain—
>
> 1) a description of the reasons why action by the agency is being considered;
>
> 2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
>
> 3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
>
> 4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
>
> 5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule."[6]

[5] 5 U.S.C. § 611(a).

26. The keystone of an IRFA, however, is the description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize the rule's economic impact on small entities.

27. It is the development and adoption of these alternatives that provide regulatory relief to small entities.

28. Rather than focus on the overall costs and benefits of a particular regulation, the RFA requires the agency to undertake an analysis that determines the impacts of the rule on small entities and then considers alternatives that reduce or minimize those impacts.

29. Possible alternatives vary widely based on the regulatory objective and the characteristics of the regulated industry. However, section 603(c) of the RFA gives agencies some alternatives that they must consider, at a minimum:

> "Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—
>
> 1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(…continued)

[6] 5 U.S.C. §603(b).

2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

3) the use of performance rather than design standards; and

4) an exemption from coverage of the rule, or any part thereof, for such small entities."[7]

30. The FDA's IRFA lacked the essential information required under the Regulatory Flexibility Act (RFA), 5 USC §601 et seq.

31. The FDA Analysis neither discusses the quantitative or qualitative costs of the proposed rule on many potentially affected small entities, nor adequately considers or explains significant alternatives that accomplish the Act's objectives while minimizing the significant economic impact on small entities.

32. The alternatives considered would make marginal changes, at best, to the overall compliance costs to small entities such as Lost Art.

33. Plaintiff is not alone in its assessment of FDA failure's to comply with the RFA. In its comments to the IRFA, the Office of Advocacy of the U.S. Small Business Administration ("SBA") wrote:

"Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA). Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially

[7] 5 U.S.C. §603(c).

> affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking."[8]

34. The FDA did not supplement its IRFA in order to cure these blatant deficiencies. Rather, in its Final Regulatory Flexibility Analysis, the FDA merely stated: "We disagree that the proposed rule's IRFA is deficient or that a Supplemental IRFA should be published."[9]

35. The Deeming Rule therefore violates the provisions of 5 U.S.C. § 601 et seq. because FDA failed to adequately consider or explain significant alternatives which accomplish the stated FDA objectives of protecting the public health while minimizing the significant and extremely harmful economic impact of the proposed Deeming Rule and the Final Rule on small entities such as Lost Art.

36. The FDA should have cured these deficiencies before proceeding with its rulemaking so that public could have been adequately informed about the possible impact of the Deeming Regulation on small entities and whether there are less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives.

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[8] www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.

[9] See, Docket No. FDA-2014-N-0189, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis, May 2016, p. 54.

37. FDA received over 70,000 comments to the proposed Deeming Rule, and many of those comments suggest less burdensome significant alternatives FDA should have adequately considered before advancing its rulemaking, but did not.

38. Examples of significant, less burdensome alternatives include but are not limited to FDA's ability to employ investigational use exemptions per 21 U.S.C. § 387(j)(g), and FDA's ability to request Congress to create a separate regulatory authority and a separate regulatory framework specifically for Vapor Products, outside of the Tobacco Control Act.

39. FDA is obligated per the RFA to tailor its regulations so as to mitigate the economic impact on Lost Art and other small and medium sized businesses.

40. FDA's initial Regulatory Flexibility Act analysis acknowledged that the Deeming Rule would have a significant economic impact on a substantial number of small entities. However, the Small Business Administration determined that the costs are likely understated and that the rule "may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses."[10]

41. In a 2014 review of FDA's Regulatory Impact Analysis of the Deeming Regulations, the economics research firm John Dunham and Associates concluded that based on established economic parameters, "[i]n fact, the analysis shows that [FDA's Proposed Rule] would likely even lead to an increase in the sale or consumption of even more harmful products – namely traditional cigarettes."[11]

[10] www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.

[11] See John Dunham and Associates Report, (Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements,

(continued…)

42. Senator Ron Johnson, the Chairman of the Committee of Homeland Security and Governmental Affairs echoed this concern in a recent letter to Defendant, Robert Califf, M.D.. "The costly impact the rule will have on e-cigarette manufacturers will stifle innovation and make it harder for e-cigarette companies to continue to offer products that serve as an alternative to smoking. It is possible that without a cost-effective alternative, some consumers will resort to traditional cigarettes." [12]

43. FDA's application of the Tobacco Control Act's "self-executing provisions" as applied to Vapor Products via the Deeming Rule, including pathways to market for new tobacco products, the economic impact will amount to making small and medium-sized companies like Lost Art obsolete, as they are unable to absorb the significant cost of such applications.

44. In fact, the only vapor products companies that can reasonably afford a new product application are the major tobacco companies who have been creating and adjusting internal Tobacco Control Act compliance programs since enactment.

45. While compliance with the above provisions would be prohibitively expensive, small and medium-sized businesses would also lack the ability to comply in the time frame provided , if ever, due to burdensome costs and unrealistic compliance periods.

**SECOND CAUSE OF ACTION**

**Violation of the APA-FDA's Unlawful Cost Benefit Analysis**

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(…continued)
A Review of the Food and Drug Administration's Regulatory Impact Analysis & A Revised Regulatory Impact Analysis That Follows the Guidelines Established by the Office of Management and Budget) attached to Comment from The Coalition of Independent Tobacco Manufacturers of America (CITMA): Deeming Tobacco Products Report Final at https://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-82598.

[12] See May 16, 2016 Letter from Senator Ron Johnson to Defendant, Robert Califf, M.D., www.hsgac.senate.gov/media/majority-media/johnson-seeks-answers-from-fda-on-burdensome-e-cigarette-regulations.

46. The above paragraphs are incorporated herein by reference.

47. 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."

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

49. 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) and the attendant costs.

50. The Deeming Rule speciously estimates that 750 PMTAs will be filed annually. Lost Art, one of thousands of small-scale manufacturers of e-liquids, , will alone need to file over 200 PMTAs if it wishes to keep all of its current products on the market.

51. As indicated in Senator Johnson's letter, ". . .the new requirements would force e-cigarette companies to complete a burdensome and costly application process. Some manufacturers could spend more than 5,000 hours to complete an application, with a minimum cost of $330,000 per e-cigarette product, according to some estimates. As a result of these expensive and time-consuming applications, many e-cigarette manufacturers—most of which are reportedly small businesses—could close down."[13]

[13] *Id.*

52. If Senator Johnson's estimates are accurate, Lost Art, alone, would have to expend over 100,000 man hours and $66,000,000 to maintain its current portfolio of products.

53. A proper cost-benefit analysis, as required by law, would demonstrate that the Deeming Rule imposes severe regulatory burdens on manufacturers, including small businesses such as Lost Art, by requiring compliance with extensive premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements.

54. As Senator Johnson emphasized in his letter, ". . .the new FDA rule would have more than just a burdensome impact on the e-cigarette industry, the effect of the rule would be 'catastrophic'".[14]

55. In that: (1) vaping products do not contain tobacco and when consumed as intended do not produce the harm caused by the inhalation of tobacco combustion, (2) the removal of vaping products from the market will have a negative impact on the population as a whole because consumers will revert to more harmful, combustible tobacco products, and (3) less restrictive and less costly regulation can achieve the stated goals of the Tobacco Control Act, an accurate accounting of the billions of dollars in potential administrative compliance costs would certainly demonstrate that the cost associated with the Deeming Regulations, as currently formulated, outweigh the benefits.

56. The cognitive and policy biases of the FDA pervade and have resulted in a defective cost-benefit analysis in violation of the APA, which requires that the Deeming Regulations be vacated.

[14] *Id.*

57. Quoting Christian Berkey, the Chief Executive Officer of Johnson Creek Vapor Company, Senator Johnson stated in his letter to Dr. Califf that, "the FDA e-cigarette regulations would 'extinguish a multi-billion-dollar industry and put tens of thousands of people out of business.'"[15]

58. "Unfortunately, the FDA's attempt to improve the public's health by scrutinizing the e-cigarette industry could ultimately result in negative unintended health consequences. . . .The costly impact the rule will have on e-cigarette manufacturers will stifle innovation and make it harder for e-cigarette companies to continue to offer products that serve as an alternative to smoking. It is possible that without a cost-effective alternative, some consumers will resort to traditional cigarettes."[16]

59. Some of the biggest costs are those that are unseen: the businesses that will fail and will never start, the people who will not be hired by those businesses, the existing products that will not be improved, innovative products that will not be developed, or introduced to the market, and the better lives that consumer might have lived had they had access to these innovative or "better" products.

**THIRD CAUSE OF ACTION**

**Violation of First and Fifth Amendments**

60. The above paragraphs are incorporated herein by reference.

[15] *Id.*

[16] *Id.*

61. The Tobacco Control Act imposes unprecedented restrictions on Plaintiff's First Amendment rights by limiting its ability to disseminate truthful information about its products to adult consumers, who have an interest in receiving such information.

62. The Tobacco Control Act does not limit these restrictions to restraints on advertising, promotion, and other traditional forms of commercial speech.

63. It goes much farther: astonishingly, it even prohibits Plaintiff from making truthful statements about its products in scientific, public policy, and political forums.

64. The Tobacco Control Acts expansive restrictions apply to "any action directed to consumers through the media or otherwise."[17]

65. Plaintiff cannot: (1) make any representation in a tobacco product's "label, labeling or advertising" that "explicitly or implicitly" represents that the product is less harmful than other tobacco products or contains a reduced level (or is free) of harmful substances, or (2) take "any action directed to consumers through the media or otherwise . . . respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may" be less harmful than other tobacco products or presents a reduced exposure to (or is free of) harmful substances, unless (3) the FDA provides advance approval of such speech.[18]

66. The Tobacco Control Act thus allows the sale of reduced-risk products, but prohibits truthful description of them absent prior Government approval.

67. Under the Tobacco Control Act, the FDA is under no time constraints and will not grant such advance approval regarding truthful, non-misleading statements unless the product at

[17] 21 U.S.C. § 387k(b)(2)(A)(iii).

[18] 21 U.S.C. § 387k(a)(1), (b)(1)).

issue will: (1) "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," and (2) "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."[19]

68. Thus, even if Plaintiff's products were proven—to a reasonable scientific certainty—to "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," Plaintiff would nevertheless be absolutely barred from informing consumers of this truthful information if the FDA determines that it would not "benefit the health of the population as a whole."

69. Under this vague and sweeping "population standard", if in the FDA's view dissemination of truthful information regarding a reduced risk product could offer a level of reassurance that may encourage some tobacco users to "switch" to a less harmful product -- rather than quit altogether -- the Tobacco Control Act precludes publication of the information.

70. "[T]he Constitution," however, "is most skeptical of supposed state interests that seek to keep the people in the dark for what the government believes to be their own good."[20]

71. Under the overly broad Modified Risk Tobacco Product Provision, Plaintiffs' executives presumably may not engage in public political or public policy debates, nor may scientists on its behalf publish papers or participate in scientific debates regarding the relative health benefits of different tobacco products. (At a minimum, such speech is chilled under the threat of being accused of directing their comments to consumers.)

[19] 21 U.S.C. § 387k(g)(1) (emphasis added).

[20] *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 497 (1995) (Stevens, J., concurring) (citation omitted).

72. It is well established that Congress may not impose limitations on truthful commercial speech unless the Government proves that: (1) the restrictions are intended to further a substantial government interest, (2) the restrictions directly advance the asserted government interest, and (3) the restrictions are narrowly tailored such that they are "not more extensive than is necessary" to advance the asserted substantial government interest.[21]

73. It is similarly well established that Congress may not impose limitations unless the restriction is "narrowly tailored to promote a compelling Government interest. If a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative. To do otherwise would be to restrict speech without an adequate justification."[22]

74. The Tobacco Control Act imposes numerous limitations without exceptions on commercial and non-commercial speech.

75. The Government's primary purported justification for the Act is to reduce youth smoking.[23]

76. Yet, much of the Tobacco Control Act is not even remotely directed at that asserted goal.

77. Instead, the Tobacco Control Act broadly and indiscriminately restricts speech regardless of whether it is directed at adults or at youth or advances the Act's asserted goal of reducing youth smoking.

[21] *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980).

[22] *United States v. Playboy Entm't Group*, 529 U.S. 803, 813 (2000) (citation omitted).

[23] 21 U.S.C. §387, et seq.

78. To the extent the Tobacco Control Act also is secondarily predicated on preventing the health consequences of adult tobacco use, it is well established that there is no "vice" exception to the First Amendment, and "a 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity."[24] Indeed, the Supreme Court has repeatedly rejected governmental attempts to equate less information with better decision-making.

79. The Tobacco Control Acts restraints on free speech are subject to, and invalid under, strict scrutiny, regardless of whether the speech it restricts is viewed (correctly) as core speech or (erroneously) as limed to only commercial speech.

80. The Tobacco Control Acts restraints on free speech are unconstitutional even under the test that applied to content-neutral, commercial-speech restrictions.

81. The modified risk provisions of the Tobacco Control Act constitute a prior restraint, which renders it presumptively invalid.

82. The modified risk provisions of the Tobacco Control Act lack the procedural and substantive safeguards required for prior restraints.

83. The Tobacco Control Act confiscates Plaintiffs' packaging, advertising, and intellectual property by requiring excessive space to be devoted to Government messages, some of which will certainly confuse consumers, thereby denying Plaintiff due process in violation of the Fifth Amendment.

84. By requiring that excessive space be devoted to Government messages, the Tobacco Control Act likewise violates Plaintiff's rights under the 1st Amendment by significantly diminishing

[24] *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 514 (1996) (plurality op.).

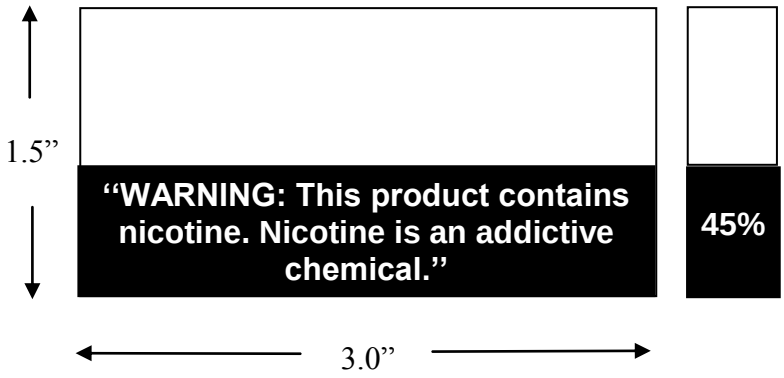
its ability to communicate with its consumer through its packaging, advertising, and intellectual property.

85. Plaintiff has invested heavily in its packaging and trademarked logos, and the law recognizes its commercially valuable property rights in its packaging.

86. In addition to devoting no less than 30 percent of each primary panel to a "warning," which must be in no less than a 12-point font, Plaintiff must prominently and conspicuously place on its packaging, inter alia, (1) a mandatory statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco, (2) the product's "established name" (a term not yet explained or defined by the FDA), "name and place of business of the tobacco product manufacturer, packer, or distributor", (3) "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count", and if the FDA should require (4) "directions for use".[25]

87. Plaintiff's product label is 3" x 1 ½". Without even addressing all of the additional label content required under 21 U.S.C. §§ 387c(a)(2)(A)-(C), 387c(a)(3)-(5), the warning in the requisite 12-point font size alone occupies 45% -- rather than 30% -- of Plaintiff's label. With the other content, which must also be prominently and conspicuously displayed, it is highly likely that consumers will no longer be able to recognize Plaintiff's branding if FDA is permitted to confiscate such a large portion of Plaintiff's packaging.

[25] 21 U.S.C. §§ 387c(a)(2)(A)-(C), 387c(a)(3)-(5).




88. Plaintiff’s e-liquid labels have always prominently and conspicuously stated the relevant concentration of nicotine, if any, as well as each ingredient; accordingly, consumers are neither misled nor confused as to any product’s content.

89. There is no evidence to indicate that e-liquid consumers have been misled or are unaware of the nicotine content in their products based on current markings. Likewise, there is no evidence to indicate that e-liquid consumers have been misled or are unaware of the addictive properties of nicotine.

90. The FDA has not meaningfully explored alternate solutions that would not result in Plaintiff’s loss of its competitive advantage via recognition of it logo and other packaging elements.

91. Although the Deeming Regulations presumably offer an alternative to products sold in “small packages”, i.e., placement of the warning on “the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package”, this so-called “exemption” is meaningless to Plaintiff and other sellers of e-liquid because no such alternate surfaces exist or are only slightly larger than the product label itself.

**FOURTH CAUSE OF ACTION**

**Violation of APA-Abuse of Discretion**

92. The above paragraphs are incorporated herein by reference.

93. The APA 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."[26]

94. The Supreme Court has explained that the arbitrary-and-capricious standard "require[s] the reviewing court to engage in a substantial inquiry."[27] In particular, the reviewing court must determine whether the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[28]

95. "In reviewing that explanation, [the court] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."[29]

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

97. Under 5 U.S.C. §706(2)(A), agency action is also unlawful if the agency failed to articulate a rational connection between the facts found and the choice made, failed to consider an

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[26] 5 U.S.C. §706(2)(A), (C). See *City of Kansas City v. Department of Housing & Urban Development*, 923 F.2d 188, 189 (D.C. Cir. 1991) (even "assuming [] arguendo" that the agency had ample statutory authority, its action was devoid of "reasoned decision-making," and was therefore arbitrary and capricious); see also *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983) ("an agency must cogently explain why it has exercised its discretion in a given manner").

[27] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971).

[28] *Motor Vehicle Mfr. Ass'n*, 463 U.S. at 43.

[29] *Id.* (internal quotation marks and citation omitted).

important aspect of the problem, or offered an explanation for its decision that runs counter to the evidence.[30]

98. The Deeming Rule is unlawful when judged against this standard.

99. Under the Tobacco Control Act, "tobacco products" may not be sold without prior approval from FDA.[31]

100. The Tobacco Control Act provides three options for obtaining FDA approval:

i. 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,"[32]

ii. 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[33]; and

iii. 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.[34]

101. The PMTA process is similar to the FDA's new drug application (NDA) process, which courts have described as "expensive and time consuming."[35]

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[30] *Id.*

[31] 21 U.S.C. § 387j(a)(2).

[32] 21 U.S.C. § 387j(b)(2).

[33] 21 U.S.C. §§ 387(j)(3), 387j(a)(2)(A)(ii).

[34] 21 U.S.C § 387j(b)(1)

[35] *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001).

102. The PMTA process for tobacco is almost identical to that governing the NDA process.[36]

103. The PMTA requires small entities such as Plaintiff to conduct, inter alia, nonclinical studies regarding toxicity, abuse liability, carcinogenicity, and studies in adult human subjects regarding patterns of use, tobacco use topography, toxicant exposure and biological effect, abuse potential, and consumer perceptions.

104. The PMTA pathway is the only realistic avenue open to the vast majority of vaping products, and the only avenue open to Plaintiff's products.

105. Unfortunately, the PMTA "pathway" is more aptly described as a nebulous, bankrupting "dead-end": the Tobacco Control Act mandates denial of PMTA application if in the FDA's judgment the applicant has not demonstrated that the product is "appropriate for the protection of the public health".

106. Vaping products were not on the market "as of February 15, 2007," and thus do not meet FDA's stringent test for the SE pathway.

107. Similarly, vaping products 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.

108. Thus, under the Deeming Rule, Plaintiff will be required to file and obtain FDA approval of PMTAs for hundreds of its products, and for every new product that it brings to market in the future.

[36] See 21 U.S.C. § 355(b)(1) and 21 U.S.C. § 387j(b)(1).

109. Thousands of other manufacturers will likewise be required to go through the PMTA process for all of the vaping products that the FDA now deems to fall within the definition of a tobacco product.

110. The Deeming Rule fails to address the extraordinary burden these requirements will place on small entities such as Plaintiff.

111. The Deeming Rule does not appropriately contemplate the significantly reduced health risks offered by vaping products.

112. "The Royal College of Physicians recognizes that electronic cigarettes and other novel nicotine devices can provide an effective, affordable and readily available retail alternative to conventional cigarettes. These innovations could make harm reduction a reality for smokers, as proposed in our 2007 report."[37]

113. As even the FDA acknowledges, various scientific studies have demonstrated that (i) vaping products 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 "pose limited danger"; and (iv) vaping devices "are likely to be much less, if at all, harmful to users or bystanders" in comparison to cigarettes.[38]

114. Despite the compelling nature of these studies, the FDA has seemingly abandoned its obligations to the protection of human and health and safety by subjecting vaping products to the

[37] www.rcplondon.ac.uk/news/rcp-statement-e-cigarettes.

[38] 81 F.R. 29030-29031.

same extensive regulatory regime designed for cigarettes and smokeless tobacco—products to which Congress has attributed "over 400,000 deaths in the United States each year."[39]

115. Although currently marketed products, regardless of their nature or quality, are permitted to remain on the market for a matter of years into the future if the manufacturer files either an SE or PMTA, the Deeming Rule completely forecloses the introduction of new products after its effective date, August 8, 2016, without prior approval of the FDA.

116. The PMTA process will certainly take many years: (1) as outlined above, the regulatory burdens are significant and costly and (2) the FDA has struggled to administer it obligations with regard to cigarettes and smokeless tobacco and (absent the failure of thousands of vaping products businesses) will undoubtedly be overwhelmed with the added burdens of regulating all of the newly deemed products, which include but are not limited to flavor stones, pipes (hundreds of styles), pipe mouthpieces, hookah pipes, hookah bowls, hookah stem air valve blockers, hookah hoses, hookah mouthpieces (with and without filters), flavored ice for water bowls, cold alcohol for bowls, mouthpiece covers, charcoal, flavor powders for water bowls, color powders for water bowls, hookah pipe cartridges for hookah pipe atomizer heads, vaping product software, vaping product glass tank parts, vaping product mouthpieces, vaping product heating coils, pass-through vaporizer devices, USB-powered liquid clearomizers, cell phone battery cases with integrated liquid clearomizer/tanks, wall powered vaporizer devices, table top vaporizer devices, mixing vials, needles for liquid vials, battery chargers USB interface cables, support collars for larger cartomizers and tanks, end stops for mouthpieces, cotton for dripping liquids, ventilation necks, o-seals, replacement wicks, self-build kits, OHM meters, electronic interface platforms for device operation

[39] Tobacco Control Act § 2(13).

and measurement, flavor vials, killet plates for atomizers, bubble tanks for atomizers, battery sleeves and skins, liquid vaporizers, tobacco vaporizers, gel vaporizers, glass/ceramic/silicon screens, clearomizers, mouthpiece filters, tanks (single, double triple), batteries (disposable and rechargeable-integrated and non-integrated), replacement Atomizers Humidity/Flavor stones, cigars (large and small), cigar sticks/piercing rods, cigar syringes (moisture enhancers and flavor enhancers),and pipe tobaccos.

117. The Deeming Rule does not articulate any basis for imposing such a short deadline on the introduction of new products: products that may well have already been in the manufacturers' pipeline for many years; products that are likely to be innovative or have a reduced risk profile.

118. The Deeming Rule also does not address the public health consequences of removing vaping products from the market. The unavailability of such products will undoubtedly cause many consumers to revert to traditional tobacco products, such as cigarettes.

119. The net effect of the Deeming Rule, which now subjects products known to be less harmful to the same onerous burdens placed on cigarettes, is to solidify the stability of "big tobacco" and traditional products, namely cigarettes. New companies, like Plaintiff and thousands of other small entities, will struggle to survive the flood of administrative and clinical burdens, while the "big tobacco" companies will leverage these same burdens and the benefits of their hundreds of grandfathered (and significantly more harmful) products.

## RELIEF REQUESTED

WHEREFORE, Lost Art Liquids asks this Court issue judgment in its 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; and

iv. the Deeming Rule is contrary to the First and Fifth Amendments.

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 Lost Art Liquids reasonable attorney's fees and expenses; and

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

Respectfully submitted,

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