IN THE UNITED STATES DISTRICT COURT DISTRICT FOR THE MIDDLE DISTRICT OF ALABAMA NORTHERN DIVISION

CYCLOPS VAPOR 2, LLC,
455 Dexter Ave., Ste. 4050
Montgomery, AL 36104

TIGER VAPOR, LLC
3715 Pepperell Parkway
OPELIKA, AL 36801

KARMA S CLOUDS, LLC, d/b/a OPERATION VAPOR
886 N. Daleville Ave.
Daleville, AL 36322

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave.
Silver Spring, MD 20993

ROBERT CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs

and

SYLVIA M. BURWELL, in her official Capacity as Secretary of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Defendants.

CIVIL ACTION NO 2:16cv-556

JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. **CYCLOPS VAPOR 2, LLC; TIGER VAPOR, LLC;** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** bring this action against Defendants the

UNITED STATES FOOD AND DRUG ADMINISTRATION ("FDA"), ROBERT CALIFF, and **SYLVIA BURWELL** (collectively, "Defendants") 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").

I. INTRODUCTION

2. This action concerns the FDA's regulation of vaping devices and e-liquids.

3. Vaping devices and e-liquids do not contain tobacco and do not generate smoke.

4. A vaping device is an innovative electronic device used to convert e-liquid into vapor. It provides the user with a sensation similar to that of smoking a traditional cigarette, without exposing the user to the combustion of tobacco.

5. There are two types of vaping devices, open and closed systems. Open systems are customizable. They come in a wide array of options including look and performance. Any e-liquid may be used in the open system device. In open systems, any third party e-liquid can be used.

6. Closed system devices cannot be altered by the end users. Closed system devices operate as manufactured, and are manufactured as either rechargeable or disposable. The disposable vaping devices are single use devices. Rechargeable systems may be reused, but only as the manufacture allows.

7. E-liquid is a liquid that is converted into vapor by the vaping device and inhaled by the user. The liquid typically consists of plant based propylene glycol and/or glycerin, flavoring, and nicotine. E-liquids may contain tobacco-derived nicotine, non-tobacco derived nicotine, or synthetic nicotine. Some e-liquids contain no nicotine or tobacco derivatives at all.

8. **CYCLOPS VAPOR 2, LLC** distributes e-liquids throughout the United States and in numerous foreign countries for sale in retail stores.

9. Some of the e-liquids distributed by **CYCLOPS VAPOR 2, LLC** contain nicotine made or derived from tobacco, while other e-liquids distributed by **CYCLOPS VAPOR 2, LLC** do not.

10. **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** sell open and closed system vaping devices and manufacture e-liquids for retail purchase. **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** also manufacture their own e-liquids for retail purchase.

11. Some of the e-liquids manufactured by **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** contain nicotine made or derived from tobacco, whiler other e-liquids manufactured and distributed by **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** do not.

12. None of the products sold by **CYCLOPS VAPOR 2, LLC, TIGER VAPOR, LLC,** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** contain tobacco.

II. PARTIES

13. **CYCLOPS VAPOR 2, LLC** is an Alabama limited liability company with a principal place of business at 455 Dexter Ave., Ste. 4050, Montgomery, AL

36104. **CYCLOPS VAPOR 2, LLC** distributes e-liquids throughout Alabama, the United States, and in 17 foreign countries. **CYCLOPS VAPOR 2, LLC** is a small entity under the Regulatory Flexibility Act ("RFA").

14. **TIGER VAPOR, LLC** is an Alabama limited liability company with a principal place of business at 3715 Pepperell Parkway, Opelika, AL 36801, with retail stores at 7857 Vaughn Rd, Montgomery, AL 36116 and 3146 Ross Clark Circle, Dothan, AL 36302. **TIGER VAPOR, LLC** sells open and closed system vaping devices and manufactures e-liquids for retail purchase. **TIGER VAPOR, LLC** is a small entity under the RFA.

15. **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** is an Alabama limited liability company with a principal place of business at 886 N. Daleville Ave., Daleville, AL 36322. **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** sells open and closed system vaping devices and manufactures e-liquids for retail purchase. **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** is a small entity under the RFA.

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

17. 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.

18. 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.

III. JURISDICTION AND VENUE

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

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).

IV. REGULATORY AND STATUTORY BACKROUND

23. The Deeming Rule at issue was adopted and published by FDA on May 5, 2016 and was published in the Federal Register on May 10, 2016.

24. The Deeming Rule expands FDA authority over "tobacco products" beyond the statutory limits of the Tobacco Control Act ("TCA"), a 2009 statute that granted FDA broad regulatory authority over the manufacture, marketing, and distribution of "tobacco products." The purpose of TCA was to address the "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products." Pub. L. No. 111-31, 123 Stat. 1777, § 2(1) (2009); see also id. § 3 (reciting ten statutory purposes, each focused on "tobacco" or "tobacco products").

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

26. Among other things, the Act: (i) imposes a rigorous premarket approval procedure, similar to the procedure for new drug applications under the FDCA, for many new tobacco products; (ii) makes it unlawful to market misbranded or adulterated tobacco products; (iii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iv) requires manufacturers to register manufacturing facilities with FDA and open such facilities for biannual FDA inspections; (v) authorizes FDA to impose restrictions on the sale and distribution of tobacco products and to require warning labels for tobacco products; (vi) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vii) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (viii) directs tobacco product manufacturers to keep certain records; (ix) requires manufacturers to obtain advance FDA approval before making a variety of advertising and labeling claims; and (x) grants FDA authority to promulgate testing requirements for tobacco products. 21 U.S.C. §§ 387a–387k, 387o, 387t.

27. The Act initially granted FDA authority to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). However, the Secretary could deem additional "tobacco products", and those newly deemed tobacco products would be subject to regulation pursuant TCA.

28. Under the Deeming Rule, FDA attempts to exercise the deeming authority in section 21 U.S.C. § 387a by subjecting "all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products," to regulation under the Act.

29. The Deeming Rule defines as "tobacco products" vaping devices (and their constituent parts or components, such as electronics and batteries) and most e-liquids, including those containing non-tobacco derived nicotine. As such, the Deeming Rule subjects these products to the Act's provisions, even they are not made or derived from tobacco or intended for human consumption.

V. THE DEEMING RULE'S EFFECT ON PLAINTIFFS

30. On August 8, 2016, the Deeming Rule will go into effect and the vast majority of Plaintiff's products—including hundreds of products not made from or derived from tobacco or intended for human consumption—will be subject to the premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements imposed by the Act.

31. Such regulation will severely and unnecessarily burden the legitimate business operations of Plaintiffs and threaten to put Plaintiffs out of business.

32. Under the Deeming Rule's premarket approval requirement, Plaintiffs will be forced to discontinue existing product lines, and Plaintiffs will be prohibited from introducing new product lines after the Rule's effective date.

33. Plaintiffs will be forced to redirect significant resources from day-to-day business operations to comply with the Deeming Rule's premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, and other requirements.

34. Even if this Court sets aside the Deeming Rule, Plaintiffs will suffer immediate irreparable harm as a result of undergoing unlawful regulations that deprive Plaintiffs of their constitutional rights.

COUNT I: Violation of APA – Unlawful Statutory Interpretation

35. Paragraphs 1 through 34 are incorporated herein by reference.

36. Under the Administrative Procedures Act ("APA"), 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." 5 U.S.C. § 706(2)(A).

37. Under the TCA, the term "tobacco product" is defined to mean, in part, "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr).

38. The Deeming Rule violates those provisions of the APA, because it defines as "tobacco product" products and devices that are not "made or derived from tobacco" or "intended for human consumption," and its provisions are an unreasonable construction of the plain language of the Act.

39. Because the Deeming Rule ignores the health benefits of vaping products, as opposed to tobacco products, the burdens imposed by the Deeming Rule appear to be nothing more than an arbitrary and capricious regulatory system designed to regulate the entire vaping industry out of existence

COUNT II: Violation of APA – Arbitrary and Capricious Agency Action

40. Paragraphs 1 through 39 are incorporated herein by reference.

41. The APA provides that a reviewing court shall hold "unlawful and set aside, findings, and conclusions of agency action that are arbitrary, capricious, an abuse

of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A).

42. A court shall hold unlawful and set aside government action that is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (U.S. 1983). "[A] court is not to substitute its judgment for that of the agency, but the agency must examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choices made." Id. at 32.

43. Under that standard, the Deeming Rule cannot be held lawful.

A. Pre-Market Tobacco Application Process

44. Under the Act, "tobacco products" may not be sold without prior approval from FDA. 21 U.S.C. § 387j(a)(2). The Act provides three options for obtaining FDA approval through the Act's Pre-Market Tobacco Application Process ("PMTA"):

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

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

and,

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

45. None of the vaping devices or e-liquids manufactured and/or sold by Plaintiffs are "substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007," because none of the vaping devices or e-liquids on the market today were being manufactured and/or sold in the United States as of February 15, 2007.

46. Likewise, because none of the vaping devices or e-liquids on the market today were being manufactured and/or sold in the United States as of February 15, 2007, Plaintiffs cannot show that their products are only a "minor modification" of a tobacco product that was on the market as of February 15, 2007.

47. The only path to pre-market approval for the vaping devices or e-liquids manufactured and/or sold by Plaintiffs is the PMTA.

48. The PMTA process mirrors the new drug application process in the FDCA, which courts have described as "expensive and time consuming." Am. Biosience, Inc. v. Thomspon, 293 F. 3d 1077, 1079 (D.C. Cir. 2001). In fact, the language outlining the PMTA process repeats verbatim several portions of the NDA process. Compare, 21 U.S.C. § 355(b)(1) with 21 U.S.C. § 387j(b)(1).

49. FDA estimates a single PMTA will cost hundreds of thousands of dollars. Most small retailers, like **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR**, produce dozens of e-liquids, and most larger

manufacturer/distributers, like **CYCLOPS VAPOR 2, LLC**, produce many more e-liquids, each of which would have be individually approved through the PMTA.

50. Given the extreme burden of the PMTA, the Deeming Rule threatens to regulate the entire vaping industry out of existence, because the majority of manufacturers and retailers will be unable to afford the regulatory expense already acknowledged by FDA and the courts.

B. Arbitrary Disregard of Health Benefits

51. Congress enacted the TCA to combat "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products." Pub. L. No. 111-31, § 2(1), 123 Stat. 1776, 1777 (2009). Congress further intended to encourage healthy innovations in the tobacco industry by "provid[ing] new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4), 123 Stat. 1776, 1782 (2009).

52. In short, Congress intended to reduce the most preventable cause of death in America; while recognizing the addictive nature of nicotine and reducing tobacco use among minors. Guided by these purposes, Congress struck a balance between eliminating a harmful product and providing regulations to reduce tobacco use while leaving leeway for healthier products. Congress never intended to stifle the innovation of healthier products.

53. Studies confirm reduced health risk by consuming nicotine via vaping devices, because they eliminate the toxins from tobacco combustion. A report from the Royal College of Physicians concluded that vaping products are not likely to exceed 5% of the health risk caused by cigarettes.

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

55. FDA recognizes that "completely switching [to vaping devices] from combusted cigarettes ... may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products;" that "clinical studies to date indicate that e-cigarettes generally are well-tolerated and do not produce serious adverse events following use;" and, further, "[a]grees that the majority of reported adverse events [from the use of vaping devices] appear not be serious."

56. Despite recognizing their health benefits, the Deeming Rule subjects vaping devices and e-liquids to the same extensive regulatory regime designed for cigarettes and smokeless tobacco—products Congress has characterized as causing "over 400,000 deaths in the United States each year" and causing illness in approximately 8,600,000 Americans. Act § 2(13).

57. The Deeming Rule is particularly arbitrary in its treatment of new vaping devices and e-liquids introduced after the Rule's August 8, 2016, effective date. Although the Rule adopts a compliance policy that will allow existing vaping devices and e-liquids to remain on the market temporarily, so long as the manufacturer timely files a corresponding PMTA, the Rule also mandates that products introduced after its effective date are "not covered by th[e] compliance policy" and therefore are "subject to

[immediate] enforcement if marketed without" an approved PMTA. As a result, manufacturers will be unable to introduce new vaping devices and e-liquids for several years. The Deeming Rule does not articulate a reasoned basis for imposing such a de facto moratorium. Nor does the Deeming Rule come to grips with the reality that the lack of new vaping products, and removal of existing ones for non-compliance, will drive consumers back to cigarettes, thereby undercutting the Act's objectives.

58. The net effect of the Deeming Rule is a regime that arbitrarily frustrates innovations and advances in public health while preserving the status quo that existed in 2007, i.e., a market dominated by cigarettes. The Deeming Rule does not explain how this result serves the public interest or the Act's goals of "promot[ing] cessation" of tobacco use and "reduc[ing] ... the social costs associated with tobacco-related diseases." Pub. L. No. 111-31, § 3(9), 123 Stat. 1776, 1782 (2009).

59. Because the Rule ignores the health benefits of vaping products, as opposed to tobacco products, the burdens imposed by the Deeming Rule appear to be nothing more than an arbitrary and capricious regulatory system designed to regulate the entire vaping industry out of existence.

COUNT III: Violation of APA and RFA – Unlawful Cost-Benefit Analysis

60. Paragraphs 1 through 58 are incorporated herein by reference.

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

62. Specifically, the Deeming Rule grossly underestimates the number of PMTAs manufacturers will be required to file, and that FDA will be required to review.

FDA estimates that 750 PMTAs will be filed annually, but Plaintiffs[1] alone will be required to file hundreds of PMTAs just to cover its existing product offerings.

63. 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 Plaintiffs, by requiring compliance with extensive premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements. These costs vastly outweigh the benefits generated by the Deeming Rule, particularly given that vaping devices and e-liquids do not contain tobacco and do not pose the public-health risks associated with products that do.

64. Additionally, The Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 et seq., requires that agencies consider the impact of their regulatory proposals on small business entities, analyze significant alternatives to reduce any significant impact on a substantial amount of such entities, and provide a fact-based rationale for their regulatory decisions.

65. RFA requires analysis and consideration of "differing compliance and or reporting requirements, or time-tables that take into account the resources available to small entities; . . . and an exemption from coverage of the rule, or any part thereof, for such small entities." 5 U.S.C. § 603b.

66. The Small Business Association Office of Advocacy stated, "the FDA estimates that upfront costs for small businesses will measure approximately $390,000 - $759,000 and that annual compliance costs for small businesses will measure approximately $450,000 - $541,000." 79 Fed. Reg. 23,142 (April 25, 2014).

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[1] Plaintiff **CYCLOPS VAPOR 2, LLC** is exclusively a distributer, but **TIGER VAPOR, LLC** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR**, produce dozens of e-liquids and would be considered manufacturers as well for purposes of those e-liquids.

67. Absent any specific findings in the Rule, it is clear FDA did not take into consideration the impact the Rule would have on small businesses, which make up the vast majority of the vaping industry.

COUNT IV: Violation of the First Amendment

68. Paragraphs 1 through 67 are incorporated herein by reference.

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

70. Restrictions on commercial speech that are not misleading are not permissible unless: (i) the government's interest is substantial; (ii) the restriction directly promotes a government interest; and (iii) it is no more restrictive than necessary to accomplish that interest. Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

71. The Rule violates the First Amendment by subjecting Plaintiffs to illegal restrictions of protected commercial speech. The Rule specifically prohibits manufacturers and retailers, including Plaintiffs, from making truthful and nonmisleading statements about their vaping devices, e-liquids, and related products.

72. Under the Deeming Rule, Plaintiffs cannot: (i) make any representation in a tobacco product's "label, labeling or advertising" that "explicitly or implicitly" state that a product is less harmful than other tobacco products or contains less of any substance; or (ii) take "any action directed to consumers through the media or otherwise . . . respecting the product that would be reasonably expected to result in 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. 21 U.S.C. § 387k(b)(2)(A).

73. The Deeming Rule further violates the First Amendment by prohibiting retailers and manufacturers, including Plaintiffs, from engaging in other forms of protected expression, including distributing free samples of vaping devices or e-liquids.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs **CYCLOPS VAPOR 2, LLC; TIGER VAPOR, LLC;** and **KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR** ask this Court to grant the following relief:

A Vacate and set aside the Deeming Rule;

B Declare:

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

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

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

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

C Expedite resolution of this action on the merits;

D Grant Plaintiffs reasonable attorney's fees and expenses; and

E Award such further relief as the court deems just and proper.

PLAINTIFFS DEMAND TRIAL BY STRUCK JURY

Respectfully Submitted,

Joseph Lister Hubbard, Jr. (HUBBJ5825)
J. Willis Garrett, III (GARRJ7452)
Attorneys for Plaintiffs CYCLOPS VAPOR 2, LLC; TIGER VAPOR, LLC; and KARMA S CLOUDS, LLC, d/b/a/ OPERATION VAPOR

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