**UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF WISCONSIN**

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| WISCONSINITES FOR ALTERNATIVES TO SMOKING & TOBACCO, INC., JHH 5 BROTHERS LLC d/b/a DISTRO GUYS WHOLESALE, TRUVIBE, INC. d/b/a THE SUPPLY PLUS, JOHNNY VAPES LLC, VISFOT INC. d/b/a NARA SMOKE SHOP, WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION, KURT WYLIE, and GERMAINE CARMODY,<br><br>Plaintiffs,<br><br>v.<br><br>DAVID CASEY, Secretary of the Wisconsin Department of Revenue, in his official capacity,<br><br>Defendant. | Case No. 25-CV-552<br><br>**VERIFIED COMPLAINT**<br>(Preliminary Injunction Requested) |

Plaintiffs Wisconsinites for Alternatives to Smoking & Tobacco, Inc., JHH 5 Brothers LLC d/b/a Distro Guys Wholesale, TruVibe, Inc. d/b/a The Supply Plus, Johnny Vapes LLC, Visfot Inc. d/b/a Nara Smoke Shop, Wages and White Lion Investments, LLC d/b/a Triton Distribution, Kurt Wylie, and Germaine Carmody bring this Verified Complaint for declaratory and injunctive relief against David Casey, in his official capacity as the Secretary of the Wisconsin Department of Revenue. In support of their Verified Complaint, Plaintiffs state as follows:

## INTRODUCTION

1. Plaintiffs bring this Complaint to preliminarily and permanently enjoin Defendant David Casey, the Secretary of the Wisconsin Department of Revenue, from implementing and enforcing Wisconsin Statutes § 995.15. A copy of Section 995.15 is attached hereto as Exhibit A for reference.

2. Section 995.15 was enacted as Section 64a of 2023 Wisconsin Senate Bill 268 ("S.B. 268") in November 2023. The Governor signed S.B.268 into law as 2023 Wisconsin Act 73 on December 6, 2023.

3. Section 995.15 directs the Wisconsin Department of Revenue to take enforcement actions (including the issuance of fines and forfeitures) against the manufacturers and sellers of electronic nicotine delivery systems (also known as "ENDS," "e-cigarettes," and "vapor products") that have not received marketing authorization from the United States Food and Drug Administration ("FDA").

4. Section 995.15 contains an exception for ENDS that were on the market as of August 8, 2016—the date ENDS containing tobacco-derived nicotine became subject to the Federal Food, Drug, and Cosmetic Act ("FDCA")—and that had a premarket tobacco product application ("PMTA") filed with the FDA by September 9, 2020, that is still undergoing FDA review or has been stayed by a court and so has not taken effect.

5. Section 995.15 contains no such exception for ENDS containing non-tobacco-derived nicotine for which PMTAs were timely filed when ENDS containing non-tobacco-derived nicotine became subject to the FDCA in 2022.

6. Most ENDS on the market today do not yet have FDA authorization. Because the FDA recognizes that ENDS are less harmful than traditional cigarettes and that ENDS have helped many adult smokers quit smoking, the FDA exercises its discretion to enforce the FDCA's premarket authorization requirement for ENDS on a "case-by-case" basis. In other words, based on its enforcement discretion, the FDA chooses not to take regulatory or enforcement action regarding some unauthorized ENDS on the market.

7. As a result of Section 995.15, starting no later than September 1, 2025, Plaintiff WiscoFAST's distributor and retailer members will be unable to sell many of their products in Wisconsin, Plaintiffs JHH 5 Brothers LLC d/b/a Distro Guys Wholesale and Wages & White Lion Investments, LLC d/b/a Triton Distribution will be unable to distribute many of their products to Wisconsin businesses, Plaintiffs TruVibe, Inc. d/b/a The Supply Plus, Johnny Vapes LLC, and Visfot Inc. d/b/a Nara Smoke Shop will be unable to sell many of their products to retail customers in Wisconsin, and Plaintiffs Wylie and Carmody will be unable to purchase in Wisconsin the ENDS products on which they rely to keep from reverting to traditional cigarettes.

8. Section 995.15 violates the Supremacy Clause of the United States Constitution and the Equal Protection Clause of the Fourteenth Amendment.

9. The Supremacy Clause allows Congress to preempt State law. Preemption occurs when State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Section 995.15 is preempted here because the legislation frustrates Congress' intent to give the Federal Government the exclusive authority to enforce the FDCA.

10. Moreover, the Equal Protection Clause of the Fourteenth Amendment prohibits a State from treating similarly situated persons differently when that differential treatment lacks a rational basis. Section 995.15 violates the Equal Protection Clause because it treats manufacturers, sellers, and consumers of certain ENDS with tobacco-derived nicotine differently than it treats manufacturers, sellers, and consumers of ENDS containing non-tobacco-derived nicotine, even though there is no rational basis for such differential treatment.

11. Because the Department of Revenue's planned enforcement of Section 995.15 would require sellers of ENDS products in Wisconsin, including several Plaintiffs, to either run the risk of incurring substantial fines and forfeitures for sales of ENDS products not eligible for

sale under the statute or shut down because they cannot maintain a profitable business with the limited range of ENDS products that would be eligible for sale under the statute, and because Section 995.15 would deprive consumers, including Plaintiffs Wylie and Carmody, of the ability to purchase and consume their preferred ENDS products because those products will not be eligible for sale, Plaintiffs seek preliminary and permanent injunctions against enforcement of Section 995.15.

## PARTIES

12. Plaintiff Wisconsinites for Alternatives to Smoking & Tobacco, Inc. ("WiscoFAST") is a vapor product industry trade association incorporated under the laws of Wisconsin with a pending application for 501(c)(6) non-profit status. WiscoFAST's principal place of business is at 2652 N. Packerland Drive, Suite C, Green Bay, Wisconsin 54303. WiscoFAST's members include distributors, wholesalers, and retailers of ENDS products from across the State of Wisconsin, including ENDS products containing non-tobacco-derived nicotine that are the subject of timely filed PMTAs pending before the FDA that are still undergoing FDA review. WiscoFAST educates lawmakers, other government officials, and the public on the facts about ENDS products and the impact that legislative and regulatory proposals relating to ENDS products would have on public health in Wisconsin.

13. Plaintiff JHH 5 Brothers LLC d/b/a Distro Guys Wholesale ("Distro Guys Wholesale") is a limited liability company organized under the laws of Wisconsin with a principal place of business at 5801 S. Pennsylvania Ave, Unit 101, Cudahy, Wisconsin 53110. Distro Guys Wholesale is a wholesaler of ENDS products to Wisconsin retailers, including ENDS devices and bottled "e-liquids" containing non-tobacco-derived nicotine that are used in certain refillable ENDS devices and other ENDS products which do not yet have FDA marketing authorization. Distro Guys Wholesale is a member of WiscoFAST.

14. Plaintiff TruVibe, Inc. d/b/a The Supply Plus ("The Supply Plus") is a corporation incorporated under the laws of Wisconsin with a principal place of business at 501 West Johnson Street, Fond du Lac, Wisconsin 54935. The Supply Plus is a retailer of ENDS products to individual consumers, including ENDS products that contain non-tobacco-derived nicotine and other ENDS products that do not yet have FDA marketing authorization. The Supply Plus also operates two other retail stores located in Oshkosh and Jackson, Wisconsin. The Supply Plus is a member of WiscoFAST.

15. Plaintiff Johnny Vapes LLC ("Johnny Vapes") is a limited liability company organized under the laws of Wisconsin with a principal place of business at 2652 N. Packerland Drive, Green Bay, Wisconsin 54313. Johnny Vapes is a retailer of ENDS products to individual consumers, including ENDS products that contain non-tobacco-derived nicotine and other ENDS products that do not yet have FDA marketing authorization. Johnny Vapes also operates three other retail stores located in Manitowoc, Bellevue, and Weston, Wisconsin. Johnny Vapes is a member of WiscoFAST.

16. Visfot Inc. d/b/a Nara Smoke Shop ("Nara Smoke") is a corporation incorporated under the laws of Wisconsin with a principal place of business at 806 W. Layton Avenue, Milwaukee, Wisconsin 53221. Nara Smoke is a retailer of vapor products to individual consumers, including ENDS products that contain non-tobacco-derived nicotine and other ENDS products that do not yet have FDA marketing authorization. Nara Smoke is a member of WiscoFAST.

17. Plaintiffs Wages and White Lion Investments, LLC d/b/a Triton Distribution ("Triton") is a limited liability company organized under the laws of the State of Texas with its principal place of business in Richardson, Texas. Triton is a manufacturer of bottled e-liquids

that contain non-tobacco-derived nicotine that are used in certain refillable ENDS devices. Triton's PMTAs for those e-liquids were timely filed with the FDA when ENDS containing non-tobacco-derived nicotine became subject to the FDCA in 2022 and those PMTAs remain under FDA review. Triton sells those e-liquids to distributors and retailers in Wisconsin.

18. Plaintiff Kurt Wylie is an individual citizen and resident of St. Croix Falls, Wisconsin. Plaintiff Wylie, who is 50 years old, smoked combustible cigarettes for over 30 years before he began using ENDS products. Plaintiff Wylie relies on his continued ability to purchase and use certain ENDS products that do not yet have FDA marketing authorization to avoid regressing into use of combustible cigarettes. Enforcement of Section 995.15 would deprive Plaintiff Wylie of the ability to purchase and use these ENDS products on which he relies.

19. Plaintiff Germaine Carmody is an individual citizen and resident of Manitowoc, Wisconsin. Plaintiff Carmody, who is 78 years old, smoked combustible cigarettes for approximately 55 years before she began using ENDS products. Plaintiff Carmody relies on her continued ability to purchase and use certain ENDS products that do not yet have FDA marketing authorization, including ENDS products that contain non-tobacco-derived nicotine, to avoid regressing into use of combustible cigarettes. Enforcement of Section 995.15 would deprive Plaintiff Carmody of the ability to purchase and use these ENDS products on which she relies.

20. Defendant David Casey, who is sued in his official capacity, is the Secretary of the Wisconsin Department of Revenue. His office is located at 2135 Rimrock Road, Madison, Wisconsin 53713.

## JURISDICTION AND VENUE

21. This action arises under and asserts claims based on violations of the United States Constitution. The Court therefore has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1331.

22. The Declaratory Judgment Act authorizes the Court to grant Plaintiffs' request for declaratory relief. 28 U.S.C. §§ 2201-2202.

23. Because this action seeks to enjoin a state official from implementing and enforcing a state statute that violates the United States Constitution, the Eleventh Amendment to the United States Constitution does not prohibit this Court from deciding this action. *See Ex Parte Young*, 209 U.S. 123, 159-60 (1908).

24. This Court has personal jurisdiction over Defendant Casey in his official capacity as the Secretary of the Wisconsin Department of Revenue because his office is in Madison, Wisconsin.

25. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391(b)(1) because this is the judicial district in which the only Defendant resides.

## LEGAL AND FACTUAL BACKGROUND

### A. The Supremacy Clause of the United States Constitution provides that federal law preempts conflicting state law.

26. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citing U.S. Const., Art. VI, cl. 2).

27. Federal law preempts state law "in three circumstances." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990).

28. "First, Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* This is referred to as "express preemption." *Mason v. Smithkline Beecham Corp.*, 596 F. 3d 387, 390 (7th Cir. 2010). "Second, in the absence of explicit statutory language, state law is preempted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English*, 496 U.S. at 79. This is referred to as "field preemption." *Id*.

29. Third, and relevant to this action, "even if Congress has not occupied the field, state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby*, 530 U.S. at 372. This "implied conflict preemption" occurs where, *inter alia*, "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

**B. The Fourteenth Amendment to the United States Constitution prohibits a State from denying persons the equal protection of the laws.**

30. The Equal Protection Clause of the Fourteenth Amendment provides that no State shall "deny any person within its jurisdiction the equal protection of the laws." U.S. Const. Art. XIV, § 1.

31. A State violates the Equal Protection Clause when it treats similarly situated persons differently and there is no "rational basis" for the differential treatment. *Nordlinger v. Hahn*, 505 U.S. 1, 11 (1992).

**C. The Federal Food, Drug, and Cosmetic Act of 1938 gives the Federal Government the exclusive authority to enforce the Act.**

32. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (the "FDCA" or "Act"). *See* 75 Pub. L. 717, 52 Stat. 1040 (1938).

33. Section 301(a) of the 1938 Act prohibited the interstate distribution of "adulterated" or "misbranded" foods, drugs, medical devices, and cosmetics. 52 Stat. 1040, 1042.

34. The 1938 Act defined the terms "adulterated" and "misbranded." *See, e.g.*, 52 Stat. at 1049 (stating a drug or device is "adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance"); *id.* at 1050 (stating a drug or device is "misbranded if its labeling is false or misleading in any particular").

35. On numerous occasions since 1938, Congress has amended the definitions of "adulterated" and "misbranded" to include situations in which the product fails to comply with an FDCA requirement even if the failure to meet that requirement does not render the product defective or the product's labeling inadequate. *See*, *e.g.*, 21 U.S.C. § 351(a)(2)(B) & (h), 21 C.F.R. pts. 210, 211, 820; 21 U.S.C. § 352(ff).

36. The 1938 Act provided three enforcement tools to address "adulterated" and "misbranded" products—a district court criminal prosecution of the person distributing the products, a district court injunction restraining the person from distributing the products, and a district court-ordered seizure and destruction of the products. *See* 52 Stat. at 1043-44. Those three enforcement tools still exist today. *See* 21 U.S.C. §§ 332, 333, 334.

37. However, section 307 of the 1938 Act made clear that *only* the Federal Government could enforce the Act. *See* 52 Stat. 1046 ("All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States.").

38. In the eighty-six years since it enacted the FDCA, Congress has provided for only one exception to the Federal Government's exclusive authority to enforce the Act. In 1990,

Congress amended the Act to allow a State, in limited circumstances, to bring a civil action to enforce some of the Act's provisions relating to food.[1]

**D. Congress attempts to reduce smoking by amending the Federal Food, Drug, and Cosmetic Act to regulate cigarettes.**

39. In 2009, Congress amended the FDCA through the Family Smoking Prevention and Tobacco Control Act ("TCA") to grant the FDA authority over certain traditional tobacco products, including cigarettes. Pub. L. No 111-31, Div. A, 123 Stat. 1776; 21 U.S.C. § 387a(b).

40. Congress granted this authority to the FDA because cigarettes "cause cancer, heart disease, and other serious adverse health effects." TCA § 2(2), 123 Stat. 1776, 1777 (codified at 21 U.S.C. § 387 note).

41. Indeed, Congress found that the use of cigarettes "is the foremost preventable cause of premature death in America," that it "causes over 400,000 deaths in the United States each year," and that "approximately 8,600,000 Americans have chronic illness relating to smoking." TCA § 2(13), 123 Stat. 1776, 1777. Congress also found that a 50 precent "reduction in youth smoking" would save "over 3,000,000" minors "from premature death due to tobacco-related disease" and "would result in approximately $75,000,000,000 in savings attributable to reduced health care costs." TCA § 2(13), 123 Stat. 1776, 1777.

42. However, the TCA prohibits the FDA from "banning all cigarettes." 21 U.S.C. § 387g(d)(3)(A). In fact, cigarette manufacturers can market "new" cigarettes—defined as cigarettes that were not commercially marketed in the United States as of February 15, 2007—if the manufacturer can demonstrate to the FDA that the new cigarette is "substantially equivalent

[1] Section 310 of the current FDCA, 21 U.S.C. § 337(a), states: "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." Subsection (b) allows a State, in limited circumstances, to bring a civil action to enforce some of the Act's food provisions.

to" one marketed in the United States before that date. 21 U.S.C. § 387j. The FDA has authorized the marketing of hundreds of new cigarettes through the issuance of "substantially equivalent" orders.[2]

43. Many of those newly authorized cigarettes are manufactured by the "Big Tobacco" companies—*e.g.*, companies operated by Altria Group Inc. and Reynolds American Inc. Altria's operating companies include Phillip Morris (the largest cigarette manufacturer in the United States and the maker of Marlboro, Benson & Hedges, and Virginia Slims cigarettes). Reynolds American's operating companies include the R.J. Reynolds Tobacco Company (the second largest cigarette manufacturer in the United States and the maker of Camel, Lucky Strike, and Newport cigarettes).

44. According to the Federal Trade Commission, the major cigarette manufacturers sell approximately 170 billion cigarettes in the United States every year. Federal Trade Commission Cigarette Report for 2022 at 3 (Oct. 30, 2023).[3]

**E. The FDCA's tobacco product requirements are extended to electronic nicotine delivery systems.**

45. The FDCA's tobacco product requirements originally extended only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." *See* 21 U.S.C. § 387a(b). The requirements were extended to ENDS products containing tobacco-derived nicotine in August 2016, *see* 81 Fed. Reg. 28974 (May 10, 2016); and the requirements were extended to ENDS products "containing nicotine from any source" (including non-tobacco-derived nicotine) in April 2022, *see* Pub. L. 117-103, § 111(a)(1); 21 U.S.C. § 321(rr)(1).

[2] *See* FDA Searchable Products Database, available at https://www.accessdata.fda.gov/scripts/searchtobacco/ (last accessed on June 26, 2025).
[3] Available at https://perma.cc/7V37-QNTV (last accessed June 30, 2025).

46. ENDS, also known as electronic cigarettes, heat a solution containing nicotine, flavorings, and other ingredients (called "e-liquid") into an aerosol that the user inhales. Unlike traditional cigarettes, ENDS do not contain any tobacco leaf, do not rely on combustion, and do not generate smoke.

47. As the top officials from the National Institutes of Health ("NIH") and the FDA recently noted, "Many adults who smoke have used e-cigarettes to quit smoking."[4] Moreover, according to the FDA, "ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents" than cigarettes and "biomarker studies demonstrate significantly lower exposure to [those harmful constituents] among current exclusive ENDS users than current smokers."[5] Thus, "smokers who switch completely to ENDS will have reduced toxic exposures and this likely leads to less risk of tobacco-related diseases."[6]

48. And, while the nicotine found in ENDS is not harmless, the FDA has emphasized that "the nicotine in cigarettes is *not* directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year . . . . [Rather], it's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death."[7] As the FDA has explained, "If you could

[4] H. Harraich, et al., Opportunities for Innovation in Smoking Cessation Therapies: A Perspective from the National Institutes of Health and the U.S. Food and Drug Administration, Annals of Internal Medicine, Oct. 15, 2024, at 3.
[5] FDA v. Wages and White Lion Investments, L.L.C., No. 23-1038, App. to Pet. Cert. 251a-252a (U.S. Mar. 19, 2024).
[6] FDA, Technical Project Lead (TPL) Review of PMTAs at 6 (May 12, 2022), https://perma.cc/7BGZ-DUEH.
[7] FDA Commissioner Scott Gottlieb, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (June 28, 2017), https://tinyurl.com/4zjcmvjb (emphasis added).

take every adult smoker . . . and fully switch them to e-cigarettes, that would have a substantial public health impact."[8]

**F. The FDA exercises enforcement discretion regarding unauthorized ENDS.**

49. When ENDS containing tobacco-derived nicotine became subject to the FDCA in August 2016, they became "adulterated" tobacco products until the manufacturer obtained an FDA marketing granted order through the premarket tobacco product application, or PMTA, process. 21 U.S.C. §§ 387b(6)(A), 387j(a)(2)(A).

50. Similarly, when ENDS containing non-tobacco-derived nicotine became subject to the FDCA in April 2022, they became "adulterated" tobacco products until the manufacturer obtained an FDA marketing granted order through the PMTA process. 21 U.S.C. §§ 387b(6)(A), 387j(a)(2)(A).

51. However, there were already countless ENDS with tobacco-derived nicotine on the market in August 2016; likewise, there were countless ENDS with non-tobacco-derived nicotine on the market in April 2022.

52. The FDA has recognized that immediately forcing all unauthorized ENDS off the market while manufacturers go through the PMTA process could result in many ENDS users reverting to traditional cigarettes. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 498 (6th Cir. 2020) (noting the FDA's view that removing all unauthorized ENDS from the market too quickly "creates a genuine risk of migration from potentially less harmful [e-cigarette] products back to combustible products," and that this would be a "public health outcome that should be avoided if at all possible").

[8] CSPAN, *FDA Commissioner on E-Cigarettes and Public Health Concerns*, at 10:25 (Sept. 25, 2018), https://tinyurl.com/mujce8hr.

53. Therefore, "[t]hrough enforcement [discretion] policies that FDA *has revised over time*, the agency has sought to strike a balance between the serious risk that e-cigarettes pose to youth and their potential benefit in helping adult smokers completely transition from or significantly reduce smoking combustible cigarettes." (Exhibit B, Letter from the FDA to the U.S. International Trade Commission, dated October 27, 2023, at 2) (emphasis added).

54. Indeed, since ENDS became subject to the FDCA in 2016, the FDA has revised its enforcement discretion policy no less than seven times. Those revisions were as follows:

a. **May 2016**: When the FDA announced the finalization of its rule "deeming" ENDS products with tobacco-derived nicotine to be subject to the FDCA, the FDA also announced that its policy would be to exercise enforcement discretion for those unauthorized products until August 2019 (so long as the product was on the market by August 2016 and the manufacturer submitted a PMTA by August 2018).[9]

b. **May 2017**: Approximately four months after President Trump first took office, and less than a week after President Trump's first FDA Commissioner was sworn in, the FDA extended its enforcement discretion period for unauthorized ENDS until November 2019 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by November 9, 2018).[10]

c. **July 2017**: As part of the FDA's new "comprehensive regulatory plan to shift [the] trajectory of tobacco-related disease [and] death," the agency announced that the enforcement discretion period for unauthorized ENDS would be extended until August 2023 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by August 9, 2022).[11]

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[9] *See* Deming 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, 81 Fed. Reg. 28,974, 29,011 (May 10, 2016).

[10] *See* Three Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability, 82 Fed. Reg. 22338 (May 15, 2017); (Exhibit C, FDA Guidance for Industry, Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule at 8 (May 2017)).

[11] (Exhibit D, FDA News Release, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 27, 2017); Exhibit E, FDA Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised) at 8 (Aug. 2017); Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability, 82 Fed. Reg. 37,459 (Aug. 10, 2017)).

d. **July 2019**: In response to a court ruling, the FDA shortened the enforcement discretion period for unauthorized ENDS to May 2021 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by May 9, 2020).[12]

e. **January 2020**: Largely in response to the popularity among youth of JUUL brand ENDS—an unauthorized "cartridge-based" ENDS that looked like a USB drive and was easy for youth to conceal from their teachers at school and from their parents at home—the FDA revised its enforcement discretion policy to target unauthorized cartridge-based ENDS that came in flavors other than tobacco or menthol.[13]

f. **April 2020**: As a result of the COVID-19 pandemic, the enforcement discretion period for other unauthorized ENDS was extended to September 2021 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by September 9, 2020).[14]

g. **September 2021**: Since September 2021, the FDA has exercised its enforcement discretion with respect to unauthorized ENDS on a "case-by-case" basis, citing its authority to do so under the Supreme Court's *Heckler v. Chaney* decision.[15] In exercising its enforcement discretion, the FDA says it "is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data," and that it "will take appropriate action regarding [ENDS] that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products."[16]

## G. Reynolds tries, but fails, to convince the FDA to revise its enforcement discretion policy.

55. In February 2023, RAI Services Company, an R.J. Reynolds affiliate, filed a Citizen Petition with the FDA requesting that the agency "adopt a new enforcement" policy

[12] *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019).
[13] (Exhibit F, FDA Guidance For Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Authorization (Revised) at 19 (April 2020)). The April 2020 Guidance made slight revisions to the January 2020 Guidance, such as extending the PMTA deadline to September 9, 2020. *See id.* at 31. Other changes made in the April 2020 version are not relevant here.
[14] (Exhibit F, at 31-22).
[15] (*Id.*at 9 n. 20 (citing *Heckler v. Chaney*, 470 U.S. 821, 835 (1985), for the proposition that the FDCA's "enforcement provisions commit broad discretion to the [FDA] to decide how and when they should be exercised")).
[16] *Id.* at 3.

because the FDA "was not [doing] enough" to prevent underage use of unauthorized ENDS. (*See* Exhibit G, Reynolds' Citizen Petition at 3 (Feb. 6, 2023)).

56. However, Reynolds' proposed policy excluded the company's own unauthorized ENDS from enforcement even though the latest CDC data showed that those ENDS were the second most popular ENDS among high school students and the third most popular ENDS among middle school students.[17]

57. Reynolds justified its proposal to exclude its own unauthorized ENDS from enforcement on the grounds that the products were on the market by August 8, 2016, the company submitted PMTAs for those products by September 9, 2020, and those PMTAs were still under review or were the subject of ongoing litigation against the FDA.

58. But Reynolds' justification for excluding its unauthorized ENDS products from enforcement was pretextual in that Reynolds' proposed policy would have offered no safe harbor for ENDS with non-tobacco-derived nicotine even if the product had a pending PMTA that had been timely filed when Congress made those products subject to the FDCA in April 2022. In other words, Reynolds' proposed enforcement policy was aimed at protecting the company's sales of its own cigarettes and unauthorized ENDS; it was not aimed at reducing youth usage of ENDS.

59. The FDA denied Reynolds' Citizen Petition in November 2023. (*See* Exhibit I, Letter from FDA to RAI Services Co. (Nov. 14, 2023)). In doing so, the FDA told Reynolds:

> [W]e do not agree that FDA has taken insufficient compliance and enforcement action against illegally marketed ENDS products . . . . To the contrary, we believe that FDA's comprehensive approach to

[17] (*See* Exhibit H, Maria Cooper, et al., *E-cigarette Use Among Middle and High School Students—United States, 2022*, 71 Morbidity and Mortality Weekly Report 1283, 1284 (Oct. 7, 2022) (stating that among high school students who had used an ENDS in the past 30 days, 23.8% used a Vuse brand ENDS; stating that among middle school students who had used an ENDS in the past 30 days, 20.9% had used a Vuse brand ENDS)).

> this matter demonstrates the Agency's robust commitment to implementing and enforcing the law with respect to such products (including restricting such unauthorized products from the lawful marketplace) and preventing their access to and promotion of use by youth.

(*Id.* at 3).

60. The FDA also provided Reynolds with a three-page, single-spaced summary of the various regulatory and enforcement actions the agency had taken to prevent youth usage of ENDS. (*See id.* at 5-7). The FDA concluded that "[g]iven all of [those] regulatory and enforcement actions," it was "clear that FDA has been taking critical compliance and enforcement efforts targeting [unauthorized] ENDS products." (*Id.* at 8). The FDA also assured Reynolds that the agency "is continuously evaluating new information and, in making enforcement decisions, taking into account data on youth use and other risk factors." (*Id.*).

**H. Reynolds tries, but fails, to convince the U.S. International Trade Commission to bar the importation of products identified in its Citizen Petition to the FDA.**

61. While its Citizen Petition to the FDA was pending, Reynolds also filed a complaint at the United States International Trade Commission ("ITC") asking the Commission to, *inter alia*, bar the importation of the same products that Reynolds asked the FDA to target via its Citizen Petition. *See Re: Complaint Filed by R.J. Reynolds Tobacco Co*., 2023 WL 11932250, *1 (U.S. Int'l Trade Comm'n Dec. 15, 2023).

62. After learning about Reynold's ITC complaint, the FDA filed a letter with the ITC urging it to reject Reynolds' attempt to use the Commission to enforce the FDCA. (Exhibit B). Citing 21 U.S.C. § 337(a), the FDA noted that Congress wants "decisions about the regulatory or compliance status of tobacco products and what products should be prioritized for enforcement [to] reflect the view of the agency charged with administering the FDCA." (*Id.* at 3). The FDA

also noted that 21 U.S.C. § 337(a) reflects congressional intent to have "uniform administration of the FDCA." (*Id.*).

63. Based in part on the FDA's letter, the ITC dismissed Reynolds' claim seeking to bar the importation of unauthorized ENDS. *See* 2023 WL 11932250, *1 (stating "the Commission agrees with FDA"). The ITC reasoned that "it would usurp the FDA's authority to enforce the FDCA and impermissibly grant a private right of action to enforce the FDCA if the Commission were to institute an investigation based on the Reynolds complaint." *Id.* at *2.

## I. The Wisconsin State Legislature adopts Reynolds' proposed enforcement policy for unauthorized ENDS.

64. The Wisconsin State Legislature passed S.B. 268 in November 2023, and the Governor signed S.B. 268 into law on December 6, 2023, as 2023 Wisconsin Act 73. (Exhibit A).

65. Section 64a of S.B. 268 was codified as Wisconsin Statutes § 995.15.[18]

66. Section 995.15 directs the Wisconsin Department of Revenue to do, in effect, what Reynolds asked the FDA to do via its March 2023 Citizen Petition and what Reynolds asked the International Trade Commission to do via its October 2023 complaint to the Commission—*i.e.*, take enforcement action against persons selling ENDS that have not been authorized by the FDA unless the product was on the market by August 8, 2016, and the product has a pending PMTA that was filed by September 9, 2020.

67. Section 995.15 establishes the following procedures by which the Department of Revenue will step into the FDA's role with respect to the enforcement of the FDCA's tobacco provisions:

[18] Section 995.15 was further amended by 2024 Wisconsin Act 146, which substituted "September 1, 2025," for "March 1, 2025" in subsections 9(a) and 9(b).

a. An ENDS manufacturer whose products are sold in Wisconsin, either directly by the manufacturer or through a distributor, wholesaler, or retailer, shall, on an annual basis, certify to the Department of Revenue that (1) those products have received marketing authorization from the FDA pursuant to the FDCA, 21 U.S.C. § 387j; or (2) the product was on the market by August 8, 2016, the manufacturer submitted a premarket tobacco application for the product to the FDA by September 9, 2020, and the application either remains under review by the FDA or "a final decision on the application has otherwise not taken effect." Wis. Stat. § 995.15(2)(a)-(b), (3), (4).

b. Beginning on September 1, 2025, the Department of Revenue shall publish (and update at least monthly) a directory listing all manufacturers that have provided certifications that comply with the statute and all products for which certifications have been submitted and approved. Wis. Stat. § 995.15(6)

c. Beginning on September 1, 2025, or on the date that the Department of Revenue first publishes the directory on its website, whichever is later, the Department of Revenue shall impose on each retailer who sells or offers for sale an ENDS product that is not included in the directory a forfeiture of $1,000 per day for each ENDS product offered for sale in violation of Section 995.15 until each such product is no longer offered for sale in Wisconsin or is properly listed on the directory. Wis. Stat. § 995.15(9)(a).

d. Beginning on the date that the Department of Revenue first publishes the directory on its website, the Department of Revenue shall impose on each manufacturer of an ENDS product that is not included in the directory a forfeiture of $1,000 per day for each ENDS product that is offered for sale in violation of Section 995.15 until each such product is no longer offered for sale in Wisconsin or is properly listed on the directory. Wis. Stat. § 995.15(9)(b).

e. Any ENDS products sold, offered for sale, or possessed for sale by retailers, distributors, wholesalers, or manufacturers in violation of the statute are deemed contraband and subject to seizure, and businesses who sell ENDS products not listed in the directory engage in an unfair and deceptive trade practice in violation of Wisconsin Stat. § 100.20. Wis. Stat. § 995.15(9)(c), (11)(a).

68. The Department of Revenue has indicated that it will publish the directory no later than September 1, 2025. (Exhibit J, Department of Revenue Publication 304, Cigarette, Tobacco, and Vapor Products Tax and Regulatory Information, at 12.)

**J. Section 995.15 also acts as a backdoor ban on non-nicotine vaporizer products, including federally legal hemp vaporizers.**

69. Section 995.15 also acts as a back-door ban on non-nicotine vaporizer products, including vaporizer products intended for use with federally legal hemp products.

70. Section 995.15 applies to "electronic vaping device[s]," which are defined as a "device that may be used to deliver any aerosolized or vaporized liquid *or other substance* for inhalation, regardless of whether the liquid or other substance contains nicotine," as well as "a component, part, or accessory of the device" and "a liquid or other substance that may be aerosolized or vaporized by such device, *regardless of whether the liquid or other substance contains nicotine*." Wis. Stat. §§ 995.15(1)(b), 134.65(1a)(b) (emphases added).

71. However, the FDA's jurisdiction only extends to "tobacco products," which means "any product made or derived from tobacco, or containing nicotine from any source . . . including any component, part, or accessory" thereof. *See* 21 U.S.C. § 387a(b); 21 C.F.R. 1100.1, 1100.3.

72. Thus, the FDCA's premarket authorization requirement established by 21 U.S.C. § 387j does not extend to non-nicotine and non-tobacco vaporizer products.

73. Because vaporizer products that aerosolize some "other substance," such as federally legal hemp, are not subject to the FDCA's premarket authorization requirement for tobacco products, they cannot qualify for listing in the Department of Revenue's directory and so their sale is necessarily banned by Section 995.15.

**K. The FDA announces that youth vaping has dropped to its lowest level in ten years.**

74. On September 5, 2024, the FDA announced that the latest CDC data shows that 500,000 "fewer U.S. youth reported current use of [ENDS] in 2024 compared to 2023." (Exhibit K, FDA Press Release dated Sept. 5, 2024, "Youth E-Cigarette Use Drops to Lowest Level in a

Decade"). This represented a drop to approximately one-third of the number of youth who reported using ENDS during the "peak" of youth usage in 2019. (*Id.*).

**COUNT I**

**Declaratory and Injunctive Relief on the Ground that Wisconsin Statutes § 995.15 Violates the Supremacy Clause of the United States Constitution**

75. Pursuant to Federal Rule of Civil Procedure 10(c), Plaintiffs adopt by reference paragraph 1- 74, above, as if fully set forth herein.

76. Under the Supremacy Clause of the United States Constitution, federal law impliedly preempts state law when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

77. Congress intended that the Federal Government have the sole authority to enforce the Federal Food, Drug, and Cosmetic Act's provisions on tobacco products. *See* 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States").

78. In other words, the FDCA's enforcement provisions "commit complete discretion to [the FDA] to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985).

79. Title 21 U.S.C. § 337(a) impliedly preempts state law when "the existence of [the FDCA]" is a "critical element" of the state law. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001). This includes state statutory law. *See*, *e.g.*, *Anthony v. Country Life Mfg., L.L.C.*, No. 02 C 1601, 2002 U.S. Dist. LEXIS 19445, at *9 (N.D. Ill. Oct. 7, 2002) (holding Illinois Consumer Fraud Act claim impliedly preempted).

80. 21 U.S.C. § 337(a) impliedly preempts Section 995.15.

a. Section 995.15 stands as an obstacle to Congress' intention that the Federal Government have the exclusive authority to enforce the FDCA in that Section 995.15 authorizes the Wisconsin Department of Revenue to enforce the FDCA's requirements regarding ENDS products.

b. The existence of the FDCA is a critical element to Section 995.15.

81. Section 995.15 injures one or more of Plaintiff WiscoFAST's members in that it forces them to stop possessing, offering for sale, or selling certain ENDS that currently lack premarket authorization (including, but not limited to, ENDS that contain non-tobacco-derived nicotine) in Wisconsin even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those particular products.

82. Section 995.15 injures Plaintiffs The Supply Plus, Johnny Vapes, and Nara Smoke in that it forces them to stop possessing, offering for sale, or selling certain ENDS products that currently lack premarket authorization (including, but not limited to, ENDS that contain non-tobacco-derived nicotine) even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

83. Section 995.15 injures Plaintiffs Distro Guys Wholesale and Wages and White Lion Investments, LLC in that it forces them to stop distributing certain ENDS products that currently lack premarket authorization (including, but not limited to, ENDS that contain non-tobacco-derived nicotine) to Wisconsin businesses even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

84. Section 995.15 injures Plaintiffs Wylie and Carmody in that, by forcing retailers to stop selling such products, it denies Plaintiffs Wylie and Carmody the ability to purchase and use certain ENDS products (including, but not limited to, unauthorized ENDS products containing non-tobacco-derived nicotine) that Plaintiffs Wylie and Carmody prefer even though

the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

**COUNT II**

**Declaratory and Injunctive Relief on the Ground that Section 995.15 Violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution**

85. Pursuant to Federal Rule of Civil Procedure 10(c), Plaintiffs adopt by reference paragraph 1 through 84, above, as if fully set forth herein.

86. The Equal Protection Clause of the Fourteenth Amendment provides that no State shall "deny any person within its jurisdiction the equal protection of the laws." U.S. Const. Art. XIV, § 1.

87. A State violates the Equal Protection Clause when it treats similarly situated persons differently and there is no "rational basis" for the differential treatment. *Nordlinger v. Hahn*, 505 U.S. 1, 11 (1992). A State's action fails this "rational basis test" when there is no "plausible policy reason for" the differential treatment or the differential treatment is "arbitrary" or "irrational." *Id.*

88. Wisconsin Statutes § 995.15 treats manufacturers and sellers of unauthorized ENDS containing tobacco-derived nicotine differently than it treats manufacturers and sellers of unauthorized ENDS containing non-tobacco-derived nicotine. Specifically, Section 995.15 allows for the sale of some unauthorized ENDS products containing tobacco-derived nicotine—those that were on the market as of August 2016 and for which a still-pending PMTA was filed by September 9, 2020—whereas Section 995.15 does not allow for the sale of any unauthorized ENDS containing non-tobacco-derived nicotine, including those for which a still-pending PMTA was timely filed.

89. Section 995.15 treats Wisconsin consumers of unauthorized ENDS containing tobacco-derived nicotine differently than it treats Wisconsin consumers of unauthorized ENDS containing non-tobacco-derived nicotine. Specifically, Section 995.15 has the effect of allowing consumers of some unauthorized ENDS containing tobacco-derived nicotine—that were on the market as of August 8, 2016, and for which a still-pending PMTA was filed by September 9, 2020—to continue purchasing and consuming their preferred products, whereas Section 995.15 does not allow consumers of unauthorized ENDS containing non-tobacco-derived nicotine, including those for which a still-pending PMTA was timely filed, to continue purchasing and consuming their preferred products.

90. Section 995.15's disparate treatment of manufacturers, sellers, and consumers of unauthorized ENDS with non-tobacco-derived nicotine fails the rational basis test. There is no plausible policy reason for treating the manufacturers, sellers, and consumers of ENDS containing non-tobacco-derived nicotine differently than the manufacturers, sellers, and consumers of ENDS containing tobacco-derived nicotine. The disparate treatment of the two categories of products is arbitrary and irrational.

91. The Federal Food, Drug, and Cosmetic Act makes no distinction between tobacco products containing tobacco-derived nicotine and tobacco products containing non-tobacco-derived nicotine. *See* 21 U.S.C. § 321(rr)(1) (defining "tobacco product" as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption").

92. Indeed, the arbitrariness and irrationality of Section 995.15's disparate treatment of ENDS containing tobacco-derived nicotine from ENDS containing non-tobacco-derived nicotine is underscored by the fact that tobacco-derived nicotine is likely to contain a higher

level of organic impurities than manufactured, non-tobacco-derived nicotine, yet, paradoxically, ENDS products containing tobacco-derived nicotine are treated preferentially under Section 995.15.

93. Section 995.15's violation of the Equal Protection Clause injures one or more of Plaintiff WiscoFAST's members in that it forces them to stop selling unauthorized ENDS products that contain non-tobacco-derived nicotine even though the FDA may decide to not exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

94. Section 995.15's violation of the Equal Protection Clause injures Plaintiffs The Supply Plus, Johnny Vapes, and Nara Smoke in that it forces them to stop possessing, offering for sale, and selling unauthorized ENDS products that contain non-tobacco-derived nicotine even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

95. Section 995.15's violation of the Equal Protection Clause injures Plaintiffs Distro Guys Wholesale and Wages and White Lion Investments, LLC, in that it forces them to stop distributing unauthorized ENDS products that contain non-tobacco-derived nicotine even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products and even though, in the case of Plaintiff Wages and White Lion Investments, LLC, it timely filed PMTAs for those non-tobacco-derived nicotine products with the FDA in May 2022 and those PMTAs remain pending before the agency.

96. Section 995.15's violation of the Equal Protection Clause injures Plaintiffs Wylie and Carmody in that, by forcing retailers to stop selling unauthorized ENDS products that contain non-tobacco-derived nicotine, it denies Plaintiffs Wylie and Carmody the ability to

purchase and consume those products that Plaintiffs Wylie and Carmody prefer even though the FDA may decide not to exercise its discretion to enforce the FDCA premarket authorization requirements for those products.

**REQUEST FOR RELIEF**

97. Plaintiffs respectfully requests that this Court enter a judgment in their favor that includes the following relief:

a. A declaration pursuant to 28 U.S.C. § 2201 that Wisconsin Statutes § 995.15 violates the Supremacy Clause of the United States Constitution;

b. A declaration pursuant to 28 U.S.C. § 2201 that Wisconsin Statutes § 995.15 violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

c. Preliminary and permanent orders enjoining the Secretary of the Wisconsin Department of Revenue from implementing and enforcing Wisconsin Statutes § 995.15;

d. An order awarding Plaintiffs their costs, expenses, and fees (including attorneys' fees); and

e. An order granting such further relief as is necessary and appropriate.

Dated: June 30, 2025

GODFREY & KAHN, S.C.

s/ *Kendall W. Harrison*

Kendall W. Harrison, SBN: 1023438
Jenna L. Riddle, SBN: 1129373
One East Main Street, Suite 500
Madison, Wisconsin 53703
Phone: 608-257-3911
Fax: 608-257-0609
kharrison@gklaw.com
jriddle@gklaw.com

THOMPSON HINE LLP
Eric N. Heyer (pro hac vice pending)
James Fraser (pro hac vice pending)

Joseph A. Smith (pro hac vice pending)
Anna Stressenger (pro hac vice pending)
1919 M Street, NW, Suite 700
Washington, DC 20036
T: (202) 331-8800
F: (202) 331-8330
Eric.Heyer@ThompsonHine.com
Joe.Smith@ThompsonHine.com
James.Fraser@ThompsonHine.com
Anna.Stressenger@ThompsonHine.com

*Counsel for Plaintiffs*

**VERIFICATION**

Tyler Hall, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint are true and correct based on his personal knowledge or documents with which he is familiar.

Tyler Hall, President

*Wisconsinites for Alternatives to Smoking & Tobacco, Inc.*

Tyler Hall, Managing Member

*Johnny Vapes, LLC*

**VERIFICATION**

David Beaupre, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint are true and correct based on his personal knowledge or documents with which he is familiar.

David Beaupre, President

*TruVibe, Inc. d/b/a The Supply Plus*

**VERIFICATION**

Pradeep Patel, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint are true and correct based on his personal knowledge or documents with which he is familiar.

Pradeep Patel, President

*Visfot Inc. d/b/a Nara Smoke Shop*

**VERIFICATION**

Todd Wages, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint are true and correct based on his personal knowledge or documents with which he is familiar.

Todd Wages, Managing Member

*Wages and White Lion Investments, LLC*

## VERIFICATION

Jamal Abujad, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint are true and correct based on his personal knowledge or documents with which he is familiar.

Jamal Abujad, Managing Member

*JHH 5 Brothers, LLC d/b/a*
*Distro Guys Wholesale*

**VERIFICATION**

Kurt Wylie, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint relating to him are true and correct based on his personal knowledge.

6-27-2

Kurt Wylie

**VERIFICATION**

Germaine Carmody, being first duly cautioned and sworn, deposes and says that the allegations contained in the Verified Complaint that relate to her are true and correct based on her personal knowledge.

Signed by:
Germaine Carmody
F0221547C731475...
Germaine Carmody