

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

R.J. REYNOLDS TOBACCO
COMPANY, R.J. REYNOLDS VAPOR
COMPANY, AMERICAN SNUFF
COMPANY, LLC, SANTA FE
NATURAL TOBACCO COMPANY,
INC., COUSINS II INC. dba VERNON
BP, and LANG'S AUTOMOTIVE
SERVICE INC. dba LANG'S ONE STOP
MARKET,

Case No.

COMPLAINT

Plaintiffs,

v.

CITY OF EDINA, EDINA CITY
COUNCIL, and SCOTT NEAL, IN HIS
OFFICIAL CAPACITY AS CITY
MANAGER OF THE CITY OF EDINA,

Defendants.

Plaintiffs R.J. Reynolds Tobacco Company ("RJRT"), R.J. Reynolds Vapor Company ("RJR"), American Snuff Company, LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("Santa Fe"), Cousins II Inc. dba Vernon BP ("Vernon BP"), and Lang's Automotive Service Inc. dba Lang's One Stop Market ("Lang's One Stop Market") bring this action for declaratory and injunctive relief against the City of Edina, the City Council, and the City Manager, Scott Neal, in his official capacity.

INTRODUCTION

1. In an overbroad reaction to legitimate public-health concerns about youth vaping, the City of Edina (“the City” or “Edina”) recently enacted one of the most draconian bans on tobacco products of any municipality in the nation. The City is rightly concerned with the recent rise in youth use of vaping products. The increase in youth vaping over the past two years, and serious health issues from illicit products, are now at the heart of a national discussion. But Edina’s ordinance strikes far broader than that, unnecessarily banning menthol-flavored vapor products and myriad non-vapor products manufactured and sold by Plaintiffs R.J. Reynolds Tobacco Company, R.J. Reynolds Vapor Company, American Snuff Company, and Santa Fe Natural Tobacco Company (collectively, “Reynolds”), and sold by Plaintiffs Vernon BP and Lang’s One Stop Market (collectively, the “Retailers”).

2. Reynolds is committed to keeping tobacco products out of the hands of youth. Reynolds has rigorous standards to ensure its marketing is accurate and responsibly directed to adult tobacco consumers aged twenty-one and over. Reynolds also has strict compliance policies for retailers who sell its products in order to prevent youth from purchasing tobacco products, and it supports programs that train retailers to comply with age restrictions.

3. The federal Food and Drug Administration shares Reynolds’ goal, and, earlier this year, effectively banned the sale of flavored cartridge-based electronic nicotine

delivery system (“ENDS”) products (other than tobacco- or menthol-flavored cartridge-based ENDS products). FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and other Deemed Products on the Market Without Premarket Authorization* 19 (May 2020) (“*Enforcement Priorities*”), at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>.

4. The City of Edina could have supplemented these efforts by targeting youth usage of vapor products through increased enforcement of age restrictions or public-education campaigns. Instead, the City’s Ordinance No. 2020-08 bans sales to adult tobacco consumers and, moreover, indiscriminately extends the ban to every conceivable flavored tobacco product, from menthol cigarettes and smokeless tobacco to flavored vapor products and flavored modern oral products. This categorical ban is unjustified.

5. For one, Congress has already banned all characterizing flavors in cigarettes other than tobacco or menthol. 21 U.S.C. § 387g(a)(1)(A). And as to menthol, Congress left it to FDA to determine whether that flavor should be banned when it comes to cigarettes. To date, even though FDA has studied the issue, FDA has chosen not to ban menthol in cigarettes.

6. Moreover, Edina’s ordinance could have adverse public health consequences. FDA’s Director of the Center for Tobacco Products has asserted that “[d]ramatically and precipitously reducing availability of [ENDS] could present a serious

risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products.” *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883, Dkt. 120-1, at ¶ 15 (D. Md. filed June 12, 2019) (Decl. of Director of FDA’s Center for Tobacco Products Mitchell Zeller) (“Zeller Decl.”). This risk of migration is especially pronounced for menthol-flavored products. When FDA previously considered restrictions on flavored ENDS products, FDA declined to impose restrictions on menthol-flavored ENDS products precisely because adults who used those products “may be at risk of migrating back to cigarettes, which continue to be available in menthol flavor, in the absence of access to mint- and menthol-flavored ENDS products.” *See FDA, Modifications to Compliance Policy for Certain Deemed Tobacco Products* 19 (Mar. 2019), available at <https://tinyurl.com/yyyywgoat>.

7. But not only is Edina’s ordinance misguided, the sweeping ban is also preempted by federal law and therefore unconstitutional under the U.S. Constitution’s Supremacy Clause.

8. *First*, federal law expressly preempts the City of Edina’s categorical ban on flavored tobacco products. The manufacture of tobacco products is subject to intensive regulation by the federal government. In striking a balance between federal authority and state and local authority over the regulation of tobacco products, Congress expressly denied states and local units of government the ability to promulgate standards that are different from or in addition to federal tobacco product standards. The City’s ban on flavored

tobacco products, however, is a product standard because it regulates the ingredients and additives in, and the properties of, those products. The City's ban is thus expressly preempted by federal law.

9. *Second*, federal law also impliedly preempts the ordinance because the City of Edina's ban stands as an obstacle to the purposes of federal law. Congress authorized FDA to promulgate tobacco product standards that, in appropriate circumstances, can establish uniform, national standards for the manufacture of tobacco products and the ingredients used in such products. Congress and FDA have made the judgment that certain tobacco products, particularly menthol cigarettes and menthol-flavored ENDS products, should remain available to adult users of tobacco products. The City's ordinance, however, conflicts with those federal goals and must give way.

10. The City has no legitimate interest in enforcing its unconstitutional law. The Court should thus grant injunctive and declaratory relief in Plaintiffs' favor and prevent the City from violating the U.S. Constitution's Supremacy Clause.

PARTIES

11. Plaintiff RJRT is a North Carolina corporation headquartered in Winston-Salem, North Carolina. RJRT develops, manufactures, markets, and distributes a variety of flavored tobacco products under a variety of brand names, including menthol cigarettes under the brand names Newport and Camel, among others, and flavored smokeless tobacco products under the brand name Camel SNUS.

12. Plaintiff RJRV is a North Carolina corporation headquartered in Winston-Salem, North Carolina. RJRV develops, manufactures, markets, distributes, and sells menthol-flavored electronic delivery devices under the brand name “VUSE” and a variety of flavored modern oral products under the brand name VELO.

13. Plaintiff ASC is a North Carolina corporation headquartered in Winston-Salem, North Carolina. ASC develops, manufactures, markets, and distributes a variety of flavored smokeless tobacco products, including under the brand name “Grizzly.”

14. Plaintiff Santa Fe is a New Mexico corporation headquartered in Oxford, North Carolina. Santa Fe develops, manufactures, markets, and distributes menthol cigarettes under the brand name Natural American Spirit.

15. All of Plaintiffs’ aforementioned flavored products qualify as “flavored tobacco products” that are prohibited under the City of Edina’s Ordinance.

16. Plaintiff Vernon BP is a Minnesota corporation headquartered in Minneapolis, Minnesota. Vernon BP operates a gas station and convenience store on Vernon Avenue South in Edina, Minnesota. At its Edina location, Vernon BP sells a variety of “flavored tobacco products” that are prohibited under the City of Edina’s Ordinance, including menthol cigarettes, flavored smokeless tobacco products, and flavored modern oral products. Some of those products are manufactured by Reynolds.

17. Plaintiff Lang’s One Stop Market is a Minnesota corporation headquartered in Edina, Minnesota. Lang’s One Stop Market operates a gas station and convenience store

on Edina Industrial Boulevard in Edina, Minnesota. At its Edina location, Lang’s One Stop Market sells a variety of “flavored tobacco products” that are prohibited under the City of Edina’s Ordinance, including menthol cigarettes, menthol-flavored vapor products, flavored smokeless products, and flavored modern oral products. Some of those products are manufactured by Reynolds.

18. Defendant City of Edina is a “statutory city” that exercises “municipal government” authority under Minnesota law. *See* Minn. Stat. §§ 412.015–412.016. The City operates under the “Optional Plan B” format under Minnesota law, also known as the “council-manager plan.” *See Nelson v. City of Eden Prairie*, 2011 WL 5767433, at *1 (Minn. Ct. App. Dec. 27, 2011).

19. Defendant Edina City Council constitutes the City’s official governing body. By law, the City Council “exercise[s] the legislative power of the city and determine[s] all matters of policy.” Minn. Stat. § 412.611; *see id.* § 412.631 (noting the council under Plan B is composed of “a mayor and four or six council members”). The City Council acts under color of law.

20. Defendant Scott Neal is the Edina City Manager. By law, the City Manager is “the head of the administrative branch of the government” and is “responsible to the council for the proper administration of all affairs relating to the city.” Minn. Stat. § 412.611; *see id.* § 412.631. Mr. Neal acts under color of law and is sued in his official capacity.

JURISDICTION AND VENUE

21. The Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the Constitution and laws of the United States.

22. This Court also has authority to grant relief under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*

23. This judicial district is the proper venue under 28 U.S.C. § 1391(b) because it is where the City of Edina lies, where Defendants perform their official duties, and where a substantial part of the events giving rise to the claims occurred.

BACKGROUND

The Tobacco Control Act and Federal Regulation of Tobacco Products

24. The Family Smoking Prevention and Tobacco Control Act of 2009, Public Law 111-31, 123 Stat. 1776 (June 22, 2009), amended the Federal Food, Drug, and Cosmetic Act and established the U.S. Food and Drug Administration as “the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products.” *Id.* § 3(1), 123 Stat. at 1781 (codified at 21 U.S.C. § 387 note). The Tobacco Control Act applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products, as well as to any other tobacco products that FDA by regulation deems subject to the Act. 21 U.S.C. § 387a(b). The Act defines “tobacco product” as “any product made or derived from tobacco that is intended for human consumption.” 21 U.S.C. § 321(rr)(1).

25. In 2016, FDA exercised its “deeming authority, 21 U.S.C. § 387a(b), to bring within its regulatory authority all products meeting the statutory definition of a tobacco product, including vapor products and modern oral products, both of which utilize nicotine derived from tobacco. *See 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*, 81 Fed. Reg. 28,974 (May 10, 2016).

26. Congress passed the Tobacco Control Act to, *inter alia*, “authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the . . . amount of ingredients used in such products.” Tobacco Control Act § 3(3), 123 Stat. at 1781 (codified at 21 U.S.C. § 387 note). To that end, the Act empowers FDA to adopt “tobacco product standards,” 21 U.S.C. § 387g, including “provisions respecting the . . . additives . . . [and] properties of the tobacco product,” *id.* § 387g(a)(4)(B)(i). The term “additives” includes “substances intended for use as a flavoring.” *Id.* § 387(1).

27. The Act also directly created tobacco product standards such as a “Special Rule for Cigarettes.” The Special Rule for Cigarettes bans the use in cigarettes of “characterizing flavors” “other than tobacco or menthol.” 21 U.S.C. § 387g(a)(1)(A). But the Act expressly reserves “menthol cigarettes” to FDA’s regulatory authority. *See id.* (noting “the Secretary’s authority to take action . . . applicable to menthol”). To date, FDA has chosen not to ban the use of menthol in cigarettes.

28. In fact, FDA has issued advance notices of proposed rulemaking (“ANPRMs”) contemplating the adoption of “tobacco product standard[s]” banning various flavored tobacco products, including menthol cigarettes and flavored vapor products. *See, e.g., Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018). But it has never banned menthol in cigarettes or smokeless tobacco. And studies have shown that menthol cigarettes do not adversely affect initiation of or progression to smoking, and there is no clear association between menthol use and decreased smoking cessation. *See RAI Services Company, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors in Tobacco Products* (July 18, 2018), available at <https://www.regulations.gov/document?D=FDA-2017-N-6565-18265>.

29. The Tobacco Control Act expressly preempts state or local regulations that set forth requirements “different from, or in addition to,” any of the Tobacco Control Act’s or FDA’s requirements relating to federal “tobacco product standards.” *Id.* § 387p(a)(2)(A) (“Tobacco Preemption Clause”). The Tobacco Preemption Clause ensures that tobacco product manufacturers will have to comply with just one set of product specifications nationwide—rather than having to grapple with potentially hundreds of different requirements set by different states and local jurisdictions governing the same products. *See Tobacco Control Act* § 3(3), 123 Stat. 1782 (codified at 21 U.S.C. § 387 note).

30. The Tobacco Control Act also contains a narrow saving clause, which provides that the Tobacco Preemption Clause “does not apply to requirements relating to the sale [and] distribution . . . of . . . tobacco products by individuals of any age.” *Id.* § 387p(a)(2)(B). But the saving clause narrows the category of permissible state and local requirements to those that turn on the “age” of the “individuals” buying or using the regulated tobacco products. *See id.* And even if the saving clause applies beyond age-based requirements, the clause does not protect state and local laws that prohibit a product’s sale and distribution altogether, but rather only more limited laws that regulate the time, place, and manner of the product’s sale and distribution. *Compare id., with id.* § 387p(a)(1).

Reynolds and FDA Work To Keep Tobacco Products Out of the Hands of Youth

31. The catalyst for Edina’s ordinance was the rise in youth use of vaping products. Both Reynolds and FDA have been active in combatting that rise and are committed to keeping tobacco products out of the hands of youth.

32. Reynolds has taken active steps to prevent youth access to its products. Reynolds is an original sponsor and lead participant in the We Card program. Reynolds requires its contracted retailers to commit to participating in We Card. Since this partnership began in 1995, We Card has trained nearly half a million storeowners, managers, and frontline employees to help prevent youth access to tobacco products. Reynolds has expanded those efforts, including through use of We Card’s “mystery

shopper” program, which also will provide additional retailers with further education and training on verifying legal age of purchasers.

33. In 2018, RJRV took targeted action to ensure youth were not obtaining its vapor products. The company instituted a contract-based tiered compliance program that involves penalties on retailers that are found to have illegally sold VUSE products to youth. In conjunction with this program, RJRV also has its trade marketing representatives discussing the issue of underage youth access with each of RJRV’s contracted retailers on an ongoing basis. The company intends to provide access to additional materials and resources on preventing youth access to tobacco products via its online customer portal, EngageTradePartners.com.

34. FDA also has specifically addressed the rise in youth vaping. In a recent guidance for industry, FDA states that it “intends to prioritize enforcement for lack of marketing authorization against any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product) that is offered for sale in the United States without regard to whether or when premarket application for such product has been submitted.” FDA, *Enforcement Priorities* 19. By way of background, when FDA promulgated its Deeming Rule, it brought ENDS products within its regulatory umbrella—meaning before the products were sold, they needed FDA authorization. 81 Fed. Reg. 28,974. At the time, FDA said it would use its enforcement discretion and allow the products to stay on the market for some time even if they had not received FDA

authorization. *Id.* at 28,977–78. FDA has now changed course with regard to flavored, cartridge-based ENDS products (other than those that are tobacco- or menthol-flavored). *Id.* The upshot of the new policy is that flavored, cartridge-based ENDS products (other than those that are tobacco- or menthol-flavored) can no longer be sold, unless and until FDA grants authorization for such products.

35. In addition, as part of the same guidance referred to above, FDA stated that it would prioritize enforcement against ENDS products for which the manufacturer has failed to take adequate measures to prevent minors’ access. FDA, *Enforcement Priorities* 3. And FDA will make enforcement a priority with respect to ENDS products that are “targeted to minors or whose marketing is likely to promote use of ENDS by minors.” *Id.*

36. In addition, FDA has issued numerous warning letters to entities that are improperly marketing or selling “unauthorized, flavored, cartridge-based ENDS products” and other ENDS products that are being marketed or sold in ways that are appealing to youth. *See, e.g.*, FDA News Release, *FDA Warns Manufacturers and Retailers to Remove Certain E-cigarette Products Targeted to Youth from the Market* (Apr. 27, 2020), at <https://www.fda.gov/news-events/press-announcements/fda-warns-manufacturers-and-retailers-remove-certain-e-cigarette-products-targeted-youth-market> (announcing warning letters).

37. Importantly, however, FDA has decided to allow the sale of menthol-flavored ENDS products. That is, in part, to allow menthol cigarette smokers to transition

to other “potentially less harmful” menthol-flavored products and also because “[d]ata shows that . . . menthol-flavored ENDS products are not as appealing to minors as other flavored ENDS products.” FDA, *Enforcement Priorities* 23–24, 39. In FDA’s view, “[t]his approach”—effectively banning flavors except for menthol and tobacco—“strikes an appropriate balance between restricting youth access to such products, while maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted [tobacco- and menthol-flavored] tobacco products.” *Id.* at 20.

The City’s Categorical Ban on Flavored Tobacco Products

38. In December 2019, in response to concerns about reported increases in youth vaping, the Edina Community Health Commission recommended that the City Council revise the City Code “to reduce vaping by youth in the city by banning the sale of flavored vapor products.” City of Edina, Memorandum from the Community Health Commission to the Mayor and City Council (Dec. 3, 2019), *reprinted in Agenda & Report and Recommendation to City Council* (June 2, 2020), Exhibit A.

39. Two weeks later, however, Edina city staff took hold of the matter and effectively overruled the Commission’s narrower recommendation. Jeff Brown, Edina’s Community Health Administrator, wrote in a memorandum to the City Council that while he “support[ed] the Community Health Commission’s recommendation,” “[he] believe[d] the ban should include the sale of *all* flavored tobacco products in addition to flavored

vaping products.” *Id.*, Memorandum from Jeff Brown, Community Health Administrator, to the Mayor and City Council (Dec. 17, 2019) (emphasis added), Exhibit A.

40. That broader recommendation eventually made its way before the City Council. In April 2020, the Edina City Council formally noticed its intent to “substantially amend the City of Edina Code related to the sale of tobacco products.” *See* City of Edina, Notice of Amendment of Local Ordinance Regarding Tobacco (Apr. 24, 2020), Exhibit B. The Notice stated, “The ordinance will prohibit sale of any flavored tobacco products in the City of Edina.” *Id.*

41. On June 2, the Council unanimously approved a first reading of the Ordinance. Despite having recently held a public hearing with the opportunity for community members to testify regarding the tobacco ordinance that raised the minimum purchase age to twenty-one, the Council decided to forgo that same process for the proposed ordinance banning all flavored tobacco products. In fact, when a trade representative attempted to speak against the proposed ban during the public-comment period, the Mayor cut her off and would not permit her to finish making her statement.

42. Then at nearly midnight on June 16, the Council unanimously approved a second reading of that Ordinance, with little discussion. The Council therefore adopted the Ordinance. *See* City of Edina, Ordinance No. 2020-08 (to be codified at Edina City Code, c. 12, §§ 12-189, 12-257) (June 16, 2020), Exhibit C.

43. Despite the Council's prior focus on raising the minimum age for which to purchase tobacco products to twenty-one, the Ordinance it adopted strikes far broader. The Ordinance makes it illegal for *any* "person" to "sell or offer for sale *any* flavored products." *Id.* § 2 (emphasis added), Exhibit C.

44. Under the Ordinance, a "*flavored tobacco product*" is "[a]ny tobacco, tobacco-related product, or tobacco-related device that contains a taste or smell, other than the taste or smell of tobacco, that is distinguishable by an ordinary consumer either prior to or during consumption or use of the product or device." *Id.* § 1 (to be codified at Edina City Code § 12-189). Menthol is among the flavors specified in the ordinance. *See id.*

45. "*Tobacco or tobacco-related product* means cigarettes and any product containing, made, or derived from tobacco that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed or ingested by any other means, or component, part or accessory of a tobacco product." Edina City Code § 12-189. "*Tobacco-related device* means any tobacco product as well as a pipe, rolling papers or other device intentionally designed or intended to be used in a manner which enables the chewing, sniffing, smoking, or the inhalation of vapors of tobacco or tobacco-related products," including "electronic delivery devices." *Id.* And "*electronic delivery device*," or "*e-cigarette*," "mean[s] any product" (or a "any component part of a product") "containing or delivering nicotine, lobelia, or any other substance intended for human consumption that

can be used by a person to simulate smoking in the delivery of nicotine or any other substance through inhalation of vapor from the product.” *Id.*

46. In short, the Ordinance bans any kind of flavored tobacco product, including the sale of all menthol cigarettes and other menthol-flavored products.

47. The ban on flavored tobacco products is effective September 1, 2020. *See* Ordinance No. 2020-08, § 3, Exhibit C.

Plaintiffs’ Products

48. Plaintiffs RJRT, RJRV, ASC, and Santa Fe collectively manufacture numerous “flavored tobacco product[s],” *i.e.*, “tobacco, tobacco-related product[s], or tobacco-related device[s],” which are subject to the Ordinance’s prohibition on flavored tobacco products and which Plaintiffs would continue distributing for resale in the City of Edina but for the Ordinance.

49. RJRT manufactures and sells various “tobacco or tobacco-related product[s]”—including products with characterizing flavors, such as menthol cigarettes, as well as cigarettes that do not have characterizing flavors—under a variety of brand names, including Newport and Camel. RJRT also sells other tobacco-related products, including flavored smokeless tobacco products, under the brand name Camel SNUS.

50. RJRV manufactures and sells “tobacco-related device[s].” Those include menthol- and tobacco-flavored vaping products, under the brand name VUSE, as well as a variety of flavored modern oral products under the brand name VELO.

51. ASC markets and sells various smokeless “tobacco or tobacco-related product[s]”—including products with and without characterizing flavors—under the brand name “Grizzly.”

52. Santa Fe markets and sells various “tobacco or tobacco-related product[s]”—including products with characterizing flavors, such as menthol cigarettes, as well as cigarettes that do not have characterizing flavors—under the brand name Natural American Spirit.

53. RJRT, RJRV, ASC, and Santa Fe each desires to continue distributing for resale banned “flavored tobacco product[s]” for resale within the City of Edina. In addition, RJRV desires to continue selling its products online to consumers in the City of Edina.

54. Plaintiffs Vernon BP and Lang’s One Stop Market collectively sell numerous “flavored tobacco product[s],” which are subject to the Ordinance’s prohibition on flavored tobacco products and which Plaintiffs would continue selling in the City of Edina but for the Ordinance.

55. Vernon BP sells menthol cigarettes, flavored smokeless tobacco products, and flavored modern oral products, including products manufactured by Reynolds.

56. Lang’s One Stop Market sells menthol cigarettes, menthol-flavored vapor products, flavored smokeless tobacco products, and flavored modern oral products, including products manufactured by Reynolds.

57. Vernon BP and Lang's One Stop Market each desires to continue selling banned "flavored tobacco product[s]" within the City of Edina.

58. The Act's categorical ban on "flavored tobacco product[s]" harms RJRT, RJRV, ASC, Santa Fe, Vernon BP, and Lang's One Stop Market because it severely restricts their ability to market and sell such products to customers in the City of Edina.

CLAIMS FOR RELIEF

COUNT I

Express Preemption

59. The preceding paragraphs are incorporated and re-alleged here.

60. The Supremacy Clause of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, state laws and local ordinances that conflict with federal law are "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

61. As of the effective date of the City of Edina Tobacco Ordinance, Plaintiffs' "flavored products" can no longer be "s[old] or offer[ed] for sale," as such products are defined to include "[a]ny tobacco, tobacco-related product[s], or tobacco-related device[s] that contain[] a taste or smell, other than the taste or smell of tobacco, that is distinguishable by an ordinary consumer either prior to or during the consumption or use of the product or device." Ordinance No. 2020-08, §§ 1–2 (to be codified at Edina City Code §§ 12-189, 12-257).

62. Any violation can result in civil penalties and misdemeanor prosecution. *See, e.g.,* Edina City Code §§ 12-280, 12-282.

63. Under the Tobacco Control Act’s preemption clause, the City of Edina is prohibited from enacting and enforcing ordinances that are “different from, or in addition to,” any of the Tobacco Control Act’s or FDA’s requirements relating to federal “tobacco product standards.” 29 U.S.C. § 387p(a)(2)(A). The City’s categorical ban on flavored tobacco products is “different from, or in addition to,” the requirements of federal law, and is thus preempted.

64. Accordingly, the Tobacco Control Act preempts the City of Edina’s categorical ban on flavored tobacco products, rendering it invalid and unenforceable.

COUNT II

Implied Preemption

65. The preceding paragraphs are incorporated and re-alleged here.

66. “Obstacle preemption” occurs when a state law or local ordinance “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

67. One purpose of the Tobacco Control Act is “to authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the ... amount of ingredients used in such products.” Tobacco Control Act § 3(3), 123 Stat. at 1781 (codified at 21 U.S.C. § 387 note).

68. The City of Edina’s categorical ban on flavored tobacco products directly undermines the Act’s purpose of establishing national standards.

69. Another purpose of the Tobacco Control Act is “to continue to permit the sale of tobacco products to adults” while making them inaccessible to minors. *Id.* § 3(7), 123 Stat. at 1782 (codified at 21 U.S.C. § 387 note). To that end, FDA has elected to allow menthol cigarettes to stay on the market. *See id.* § 387g(a)(1)(A). Menthol cigarettes thus must remain available on the market unless and until FDA properly determines that they must be removed from the market. *See id.*

70. Consistent with its federal authority, FDA has been exploring regulation of flavors in tobacco products, particularly menthol cigarettes. *See, e.g., Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018). In addition, FDA is currently engaged in efforts to address concerns about youth use of flavored vapor products. Indeed, in a recent guidance for industry, FDA states that it “intends to prioritize enforcement for lack of marketing authorization against any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product).” FDA, *Enforcement Priorities* 19. In other words, flavored, cartridge-based ENDS products (other than those that are tobacco- or menthol-flavored) can no longer be sold, unless and until FDA grants authorization for such products. In issuing its guidance,

FDA made the specific judgment that menthol-flavored ENDS products could remain on the market.

71. Edina's ordinance also interferes with the method that Congress chose to effectuate the goals of the Tobacco Control Act. Congress created a detailed regulatory process as the sole method for evaluating the design and sale of new tobacco products such as ENDS. *See* 21 U.S.C. § 387j. By creating that singular channel, Congress intended to subject each new tobacco product to one regulatory assessment conducted by FDA, not multiple rounds of assessments by states and localities. FDA is thus the sole entity charged with striking "an appropriate balance of complex and competing public health and agency resource considerations," including the benefits of innovation and the risk that former smokers would revert "from potentially less harmful ENDS products back to combustible tobacco products." Zeller Decl. ¶¶ 11–12.

72. By creating a holistic regulatory process for the evaluation of new tobacco products, Congress clearly signaled that it did not intend for states and localities to interfere with FDA's evaluation. But that is precisely what Edina's ordinance threatens to do. If the ordinance stands, then every state and locality could create its own standards and review processes, upending the pathway Congress designated as the sole path for evaluating new tobacco products.

73. In sum, the City of Edina's categorical ban on flavored tobacco products directly conflicts with the federal government's ongoing and active efforts to address

flavors in tobacco products. It also frustrates the method Congress chose for the evaluation of new tobacco products. Edina's ban is thus preempted.

74. Accordingly, the Tobacco Control Act preempts the City's ordinance, rendering it invalid and unenforceable.

REQUEST FOR RELIEF

Plaintiffs request that this Court grant the following relief:

75. Pursuant to 28 U.S.C. § 2201, declare that under the Supremacy Clause of the United States Constitution, the Tobacco Control Act preempts the City of Edina Tobacco Ordinance's ban on flavored tobacco products, rendering it invalid and unenforceable;

76. Under Federal Rule of Civil Procedure 65, preliminarily enjoin Defendants from enforcement or implementation of the City of Edina's ban on all flavored tobacco products;

77. Permanently enjoin Defendants from enforcement or implementation of the City of Edina's ban on all flavored tobacco products;

78. Award Plaintiffs their costs and disbursements associated with this litigation under 28 U.S.C. § 2412 and other applicable authority; and

79. Provide such other relief as the Court deems appropriate.

Respectfully submitted,

Dated: June 17, 2020

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**Motion for admission pro hac vice pending*