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., d/b/a Vernon BP; and LANG'S AUTOMOTIVE SERVICE INC., d/b/a Lang's One Stop Market,	Case No. 20-CV-1402 (PJS/LIB)
Plaintiffs,	ORDER
v.	
CITY OF EDINA; EDINA CITY COUNCIL; and SCOTT NEAL, in his official capacity as City Manager of the City of Edina,	
Defendants.	

Christian G. Vergonis, Lisa L. Beane, and Ryan J. Watson, JONES DAY, for plaintiffs.

David S. Kendall and Shana N. Conklin, CAMPBELL KNUTSON P.A., for defendants.

Defendant City of Edina ("the City") recently adopted an ordinance banning the sale of "flavored tobacco products." Plaintiffs—a group of tobacco-product manufacturers and retailers—bring this action for declaratory and injunctive relief, alleging that the ordinance is expressly and impliedly preempted by federal law.

This matter is before the Court on the City's motion to dismiss and plaintiffs' motion for a preliminary injunction. For the reasons that follow, the Court grants the City's motion, denies plaintiffs' motion, and dismisses this action.[1]

A. Standard of Review

In reviewing a motion for a preliminary injunction, a court must consider four factors: (1) the movant's likelihood of success on the merits; (2) the threat of irreparable harm to the movant if the injunction is not granted; (3) the balance between that harm and the harm that granting the injunction will inflict on the other parties; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981).

In reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *York v. Wellmark, Inc.*, 965 F.3d 633, 638 (8th Cir. 2020). Although the factual allegations need not be detailed, they must be sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must "state a claim to relief that is plausible on its face." *Id.* at 570.

[1]In addition to suing the City, plaintiffs also sued the city council and the city manager in their official capacities. At oral argument, however, plaintiffs conceded that their claims against those defendants are redundant. The Court accordingly dismisses those claims without prejudice.

Even though the parties' motions are subject to different standards of review, the parties agree that this case turns on pure questions of law and that, regardless of how the Court resolves the parties' motions, the case is ripe for resolution and entry of judgment. *See* Fed. R. Civ. P. 65(a)(2) (permitting a court to consolidate a preliminary-injunction hearing with the trial on the merits).

B. The Ordinance

On June 16, 2020, the City adopted Ordinance No. 2020–08 ("the Ordinance"), which provides that "[n]o person shall sell or offer for sale any flavored tobacco products." Compl. Ex. C. The Ordinance defines "flavored tobacco product" as follows:

> *Flavored tobacco product* means any 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, including, but not limited to, any taste or smell relating to menthol, mint, wintergreen, chocolate, cocoa, vanilla, honey, fruit, or any candy, dessert, alcoholic beverage, herb or spice. A public statement or claim, whether express or implied, made or disseminated by a manufacturer of the product or device, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such products, that a product has or produces a taste or smell other than tobacco will constitute presumptive evidence that the product is a flavored tobacco product.

Id. The Ordinance takes effect on September 1, 2020. *Id.*

Plaintiffs argue that the Ordinance is both expressly and impliedly preempted. The Court considers each argument in turn.

C. Express Preemption

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("the Act"), Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009), which grants the Food and Drug Administration ("FDA") authority to regulate tobacco products. The Act contains several provisions that expressly address the extent of state and local authority to regulate tobacco products. Specifically, 21 U.S.C. § 387p—entitled "Preservation of State and local authority"—contains a preservation clause (§ 387p(a)(1)), a preemption clause (§ 387p(a)(2)(A)), and a saving clause (§ 387p(a)(2)(B)).

The preservation clause (§ 387p(a)(1)) provides as follows:

> Except as provided in paragraph (2)(A) [the preemption clause], nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit

> or otherwise affect any State, tribal, or local taxation of tobacco products.

The preemption clause (§ 387p(a)(2)(A)) provides as follows:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

And finally the saving clause (§ 387p(a)(2)(B)) provides as follows:

> Subparagraph (A) [the preemption clause] does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. . . .

The parties first dispute whether the Ordinance falls within the scope of the preemption clause. Specifically, they dispute whether the Ordinance qualifies as a "requirement . . . relating to tobacco product standards . . . ." (The Court adopts the parties' shorthand convention of referring to such requirements as "tobacco product standards.") The City argues that the Ordinance does not establish a "tobacco product standard"—and thus is not within the preemption clause—because it regulates the sale of finished products and does not dictate anything about the manufacturing process or about what ingredients tobacco products may contain.

Other courts have agreed with this distinction, holding that a tobacco-product standard is a *manufacturing* regulation, and thus that a *sales* regulation is not a tobacco-product standard unless it is a de facto manufacturing regulation—that is, unless it "clearly infringe[s] on the FDA's authority to determine what chemicals and processes may be used in making tobacco products." *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 434–35 (2d Cir. 2013) (holding that a sales restriction was not a "tobacco product standard" because "[w]hether a product is governed by Administrative Code § 17–715 depends on its characteristics as an end product, and not on whether it was manufactured in a particular way or with particular ingredients"); *CA Smoke & Vape Ass'n, Inc. v. Cty. of Los Angeles*, No. 20-4065, 2020 WL 4390384, at *5 (C.D. Cal. June 9, 2020) ("a sales ordinance that does not direct manufacturers as to which ingredients they may or may not include is not a preempted tobacco product standard" (footnote omitted)); *see also Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82–83 & n.11 (1st Cir. 2013) (holding that sales regulations are not tobacco-product standards and stating that "whether those regulations have an impact on manufacturing is irrelevant").

Unfortunately, however, the courts that have embraced this manufacturing/sales distinction have provided little in the way of justification—and, indeed, have sometimes

provided little more than ipse dixit. In this Court's view, the distinction is insupportable in light of the statutory text.

While the Act does not expressly define "tobacco product standards," it does prescribe the content of such standards. Section 387g(a)(4) provides that a tobacco-product standard "shall include provisions that are appropriate for the protection of the public health . . . ." Section 387g(a)(4) goes on to describe specific types of provisions that may be included "where appropriate," including "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product"; provisions for nicotine yields; testing provisions; provisions for measurement of tobacco-product characteristics; provisions prescribing the form and content of labeling; and "a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title."[2]

In addition to prescribing the content of tobacco-product standards, the Act also includes two provisions that the Act itself labels as "tobacco product standards." *See* 21 U.S.C. § 387g(a)(3). One of those tobacco-product standards concerns the flavor of

[2]Section 387f(d) requires the FDA to take into account certain factors in determining whether a sales or distribution restriction would be "appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1).

cigarettes. *See* 21 U.S.C. § 387g(a)(1)(A) ("a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice . . . that is a characterizing flavor of the tobacco product or tobacco smoke").

Clearly, then, "tobacco product standards" are not limited to provisions that relate to manufacturing processes and components; they also include "provisions respecting the . . . properties" of the tobacco product and restrictions on the "*sale and distribution* of the tobacco product." 21 U.S.C. § 387g(a)(4) (emphasis added). The Ordinance is, of course, both a provision respecting a property—specifically, the flavor—of tobacco products and a restriction on the sale of tobacco products. Thus, the Ordinance fits comfortably within the description of tobacco-product standards found in § 387g(a)(1)(A).

The City disagrees. According to the City, § 387g(a)(1)(A) envisions that a tobacco-product standard must directly regulate the ingredients that a tobacco product may contain. The Ordinance is not such a provision, the City argues, because it bans the sale of certain tobacco products—specifically, tobacco products "that contain[] a taste or smell, other than the taste or smell of tobacco"—no matter how those tobacco products are manufactured.

Again, however, tobacco-product standards include "provisions respecting the . . . properties" of tobacco products, and there can be no dispute that a provision respecting the flavor of a tobacco product is a provision respecting a "propert[y]" of that product. Moreover, even if it were necessary to show a direct ban on ingredients (as opposed to flavors), the Ordinance is in effect such a ban. There is little difference between the government telling a manufacturer that it may not add an ingredient that imparts a flavor to a tobacco product and the government telling a manufacturer that it may not sell a tobacco product if it has added an ingredient that imparts a flavor. *Cf. Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 464 (2012) ("if the sales ban were to avoid the FMIA's preemption clause, then any State could impose any regulation on slaughterhouses just by framing it as a ban on the sale of meat produced in whatever way the State disapproved"); *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 254–55 (2004) (rejecting argument that a purchase restriction on vehicles with particular emission characteristics was not a "standard" and explaining that "a standard is a standard even when not enforced through manufacturer-directed regulation").

The Court therefore agrees with plaintiffs that the Ordinance is a "requirement . . . relating to tobacco product standards" within the meaning of the preemption clause. The Ordinance is therefore expressly preempted unless it is "saved" by the saving clause. *See U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 433 ("pursuant to

the saving clause, local laws that would otherwise fall within the preemption clause are exempted" if they come within the saving clause).

On its face, the Ordinance falls within the scope of the saving clause, as it is a "requirement[] relating to the sale . . . of . . . tobacco products by individuals of any age . . . ." 21 U.S.C. § 387p(a)(2)(B). Plaintiffs nevertheless argue that the saving clause does not apply.

Plaintiffs first argue that the phrase "by individuals of any age" means that the saving clause exempts only age-related requirements from the scope of the preemption clause.[3] As other courts have noted, plaintiffs' interpretation turns the plain meaning of this phrase on its head. *See R.J. Reynolds Tobacco Co. v. Cty. of Los Angeles*, No. 20-4880, 2020 WL 4390375, at *5 n.7 (C.D. Cal. July 13, 2020) ("The plain meaning of that phrase is the opposite of what Plaintiffs suggest—states and localities are free to enact requirements regardless of age.").

[3]The saving clause's list of exempted regulations include those directed at the activities of retailers and merchants (including the "sale," "distribution," "information reporting to the State," "advertising," and "promotion" of tobacco products), as well as those directed at the activities of consumers (including the "possession," "exposure to," "access to," and "use" of tobacco products). It is difficult to believe that Congress meant the modifier "*by* individuals of any age" to apply to every item on the list—i.e., that the phrase was meant to apply not only to those who use tobacco, but to those who advertise it or report information about it to the government. One way to resolve this oddity would be to interpret "by individuals of any age" to apply only to "use of" tobacco products (the last item in the list). The City did not press this argument, however, and as plaintiffs' interpretation is wrong even if "by individuals of any age" modifies the entire list (including "sale"), the Court need not address this issue further.

Plaintiffs argue that this interpretation renders the phrase surplusage, as deleting it would not change the meaning of the statute. That is true—although the same thing can often be said about the use of "all," "every," or "any" in a statute. A statute that says that "drivers must be licensed" has the same meaning as a statute that says that "all drivers must be licensed" or "every driver must be licensed." Terms such as "all," "every," and "any"—although technically surplusage—are commonly used to emphasize the universal application of the provisions in which they appear. The fact remains that there is no reasonable way to construe language that authorizes regulations governing activities "by individuals of *any* age" to authorize only regulations governing individuals of *particular* ages.

Moreover, the inclusion of "by individuals of any age" makes sense in the broader context of the Act, which was partly a response to the FDA's earlier unsuccessful attempt to assert jurisdiction over tobacco products in order to enact age-specific tobacco regulations. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125–26 (2000) (holding that FDA, which had promulgated regulations to reduce tobacco use among children and adolescents, lacked statutory authority to regulate tobacco products); *see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 703 F. Supp. 2d 329, 336–37 (S.D.N.Y. 2010) (recounting background of the Act).

This history is also reflected in the congressional findings memorialized in the Act, which highlight the problem of tobacco use by children and adolescents. 21 U.S.C. § 387 note. Against this backdrop, Congress would have reason to emphasize that, although the Act grew out of concerns over tobacco use by minors, state and local governments are not limited to enacting age-related restrictions. *See U.S. Smokeless Tobacco Mfg. Co.*, 703 F. Supp. 2d at 348 (noting that, given the background of the Act, the reference to "'individuals of any age' was Congress' way of saying that the carve-outs for state prerogative would not be limited to enacting laws aimed only at minors").

Plaintiffs next argue that the saving clause only exempts "requirements" and that a prohibition is not a "requirement." Plaintiffs contrast the language of the preservation clause (which preserves authority to enact regulations "relating to *or prohibiting* the sale" of tobacco products) with the language of the saving clause (which permits "requirements relating to the sale" of tobacco products but does not explicitly refer to prohibitions). Plaintiffs also point out that, while the saving clause concerns only state and local authority, the preservation clause also refers to the authority of federal agencies and Indian tribes. Plaintiffs argue that if these clauses are read together to give effect to each phrase, it is apparent that Congress intended to preempt state and local prohibitions on sales while preserving the authority of federal agencies and Indian tribes to prohibit sales. As a result, plaintiffs argue, state and local governments cannot

prohibit sales of tobacco products; they may only regulate the time, place, and manner of sales and distribution.

The Court disagrees. The preservation clause explicitly protects the authority of state and local governments to prohibit the sale of tobacco products "[e]xcept as provided in" the preemption clause. The preemption clause then carves out of the preservation clause—and thus preempts—certain "requirements" enacted by state and local governments. If, as plaintiffs argue, a prohibition is not a "requirement," then the preemption clause leaves untouched the preservation clause's protection of the authority of state and local governments to prohibit the sale of tobacco products. In other words, if the Ordinance is a prohibition[4]—and a prohibition is not a "requirement"—then the Ordinance is not preempted under the preemption clause, and it does not matter what the saving clause says. *See U.S. Smokeless Tobacco Mfg. Co v. City of New York*, No. 09-10511, 2011 WL 5569431, at *7 (S.D.N.Y. Nov. 15, 2011) ("Plaintiffs

[4]The Court notes that it is not clear that the Ordinance *is* a prohibition. Nearly any regulation can be characterized as a "prohibition," including the "time, place, and manner" restrictions that plaintiffs contend are within the meaning of the word "requirement." For example, the regulation at issue in *U.S. Smokeless Tobacco* prohibited the sale of certain tobacco products at anything other than a tobacco bar. It does not take much creativity to frame this regulation as a "prohibition" on sales at gas stations and convenience stores. Similarly, an ordinance that permitted sales of tobacco products only between 10:00 pm and 6:00 am could easily be characterized as a "prohibition" on sales between 6:00 am and 10:00 pm. Thus, another problem with plaintiffs' theory is that it would be nearly impossible to distinguish a permissible "restriction" from an impermissible "prohibition."

try to find meaning in the fact that the Preservation Clause purports to reach both sales restrictions 'and prohibitions,' while the Saving Clause reaches only sales restrictions. . . . But as the Preemption Clause is itself silent regarding sales prohibitions, it seems far more likely that prohibitions are preserved and never preempted, and therefore need never be saved."), *aff'd*, 708 F.3d 428 (2d Cir. 2013).

In short, the problem with plaintiffs' argument is that it ignores the fact that the preemption clause, like the saving clause, uses the term "requirement" and does not explicitly refer to prohibitions. "Requirement" must mean the same thing in the two clauses. If a prohibition is a "requirement"—and if the Ordinance is a prohibition—then the Ordinance is preempted under the preemption clause (because, as the Court has held, the Ordinance relates to tobacco-product standards), but it is saved by the saving clause (because it relates to the sale of tobacco products). If a prohibition is not a "requirement"—and if the Ordinance is a prohibition—then the Ordinance is not preempted under the preemption clause and the saving clause is irrelevant. Either way, the Ordinance is not expressly preempted.

Finally, plaintiffs argue that, if the Ordinance is not expressly preempted, then states and municipalities can regulate tobacco-product standards by simply casting such regulations in the form of sales regulations. For example, a municipality could establish conflicting requirements concerning nicotine levels, premarket review

processes, and other matters simply by banning the sale of products that do not meet these requirements. In the Court's view, this is not really an argument about how to interpret the language of the saving clause, which, as discussed above, the Court has already construed to encompass the Ordinance. Instead, this argument raises a concern that may be addressed by the application of ordinary principles of implied preemption, to which the Court now turns. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (an express preemption provision does not, by itself, foreclose application of principles of implied preemption).

D. Implied Preemption

Plaintiffs argue that the Ordinance is impliedly preempted under the doctrine of obstacle preemption, which is a type of conflict preemption. Pursuant to that doctrine, a state law is preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (citations and quotation marks omitted)). Determining whether obstacle preemption applies "is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects . . . ." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). At the same time, however, "[i]mplied preemption analysis does not justify a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives; such an

endeavor would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation and quotation marks omitted). Plaintiffs bear the burden to show that the Ordinance is impliedly preempted. *Paris Limousine of Okla., LLC v. Exec. Coach Builders, Inc.*, 867 F.3d 871, 874 (8th Cir. 2017).

Plaintiffs first argue that the Ordinance acts as an obstacle to Congress's goal of establishing uniform national manufacturing standards for tobacco products, including standards governing the ingredients used in such products. The Court disagrees for the simple reason that the Ordinance does not impose any manufacturing requirements; it is a ban on the sale of certain types of finished tobacco products. The Ordinance will not cause any manufacturer to change anything about the ingredients that it uses or anything else about the way that it manufactures its products. The Ordinance may have the effect of reducing the sales of certain products, but that is not the same as subjecting manufacturers to varying requirements about how to produce those products.

It is true that, if every municipality in the United States adopted a similar ordinance, that would as a practical matter amount to a nationwide ban on the use of certain ingredients, because it would become impossible for manufacturers to sell a product that contained those ingredients. As discussed above, that is one reason why

the Court agrees with plaintiffs' argument that the Ordinance qualifies as a "tobacco product standard." *See Engine Mfrs. Ass'n*, 541 U.S. at 255 ("[I]f one State or political subdivision may enact such rules, then so may any other; and the end result would undo Congress's carefully calibrated regulatory scheme.").

But *Engine Manufacturers* was an express-preemption case. To find implied preemption, the conflict must be more than speculative. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) (rejecting a hypothetical factual scenario as "simply too speculative a basis on which to rest a finding of pre-emption"and stating that "[t]he Court has observed repeatedly that pre-emption is ordinarily not to be implied absent an actual conflict" (citation and quotation marks omitted)); *see also Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute."). It is theoretically possible that thousands of municipalities could ban the sale of flavored tobacco products, but the remote possibility of such a de facto nationwide ban is an insufficient basis on which to find an actual conflict.

Plaintiffs next argue that the Ordinance undermines Congress's and the FDA's judgment that certain flavored tobacco products—including menthol cigarettes and menthol electronic nicotine delivery systems ("ENDS") products—should remain on the market. Plaintiffs point out that Congress exempted menthol cigarettes from its ban on

flavored cigarettes. 21 U.S.C. § 387g(a)(1)(A). Plaintiffs further point out that Congress empowered the FDA to determine whether to ban menthol cigarettes or other types of flavored tobacco products and specifically instructed the FDA to study the impact of menthol cigarettes on public health. *Id.* § 387g(a)(1)(A), (e). Since then, the FDA has twice sought input with respect to regulatory actions that it might take regarding flavored tobacco products: once specifically with respect to menthol in cigarettes and other tobacco products, *see* Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44,484 (July 24, 2013), and once concerning flavored tobacco products in general (including whether and how they may help adult smokers reduce cigarette use), *see* Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018). In both cases, the agency did not adopt a final rule.

Contrary to plaintiffs' argument, none of this represents a decision by Congress that menthol cigarettes or any other flavored tobacco products should remain on the market. To the contrary, Congress explicitly gave the FDA authority to regulate menthol and other flavors in tobacco products. 21 U.S.C. § 387g(a)(1)(A). It is true that the FDA decided not to take action after twice soliciting comments about flavored tobacco products. But the decision of a federal agency not to issue a *nationwide* regulation is not the same thing as a decision by Congress (or even by that agency) that *state and local governments* should not be able to regulate. The federal government

has—through inaction—left countless matters to be regulated by state and local governments.

Plaintiffs also point to various FDA press releases, policy proposals, and other documents discussing the role that flavored ENDS products may play in helping adult smokers transition away from smoking. These documents reflect that, in determining its enforcement priorities, the FDA balanced this consideration against the appeal that such products have for minors. Most of this commentary appears to be related to decisions that the FDA made about its enforcement priorities in the wake of its 2016 rule deeming most products meeting the statutory definition of "tobacco product" to be subject to its regulatory authority. *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973 (May 10, 2016) ["Deeming Rule"].

The Deeming Rule brought "approximately 25,000 new tobacco products, including various cigars, e-cigarettes, pipe tobacco products, and hookah within the purview of the Act." *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 470 (D. Md. 2019), *appeal dismissed in part and dismissed as moot in part sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). This meant, among other things, that thousands of new products became subject to premarket review requirements. *See generally* 21 U.S.C. § 387j. Ordinarily, if a product requires premarket authorization, and if the

product has not received that authorization, the product is considered adulterated and may not be introduced into interstate commerce. 21 U.S.C. § 387b(6); 21 U.S.C. § 331(a). To manage the flood of applications, however, the Deeming Rule adopted staggered compliance periods based on the level of premarket review that various categories of products required. During these periods, certain products that were technically "adulterated" would not be the subject of enforcement actions. Deeming Rule, 81 Fed. Reg. at 29,011.

Since then, the FDA has extended these timelines on several occasions[5] and has continued to prioritize its enforcement efforts. For example, in its current Guidance, the FDA announced that it would prioritize enforcement against, among other products, ENDS products *other than* tobacco and menthol flavors. FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (April 2020), *available at* https://www.fda.gov/media/133880/download (last visited Aug. 31, 2020) ["Guidance"]. The FDA noted that menthol appears to be less popular among young users and that there is some evidence to suggest that flavored ENDS products may help addicted adults transition away from smoking. Guidance at 14–15, 20, 24. In light of these

[5]A detailed history of these extensions—at least one of which became the subject of litigation, *see American Academy of Pediatrics*, 379 F. Supp. 3d at 468–69—is not necessary here.

considerations, the FDA explained, its decision to prioritize enforcement against flavored ENDS products other than 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 products." Guidance at 20. The FDA has made similar statements on other occasions.

Clearly, then, the FDA has—through its enforcement priorities—demonstrated a preference for avoiding the removal of certain flavored ENDS products from the market. But these priorities represent nothing more than a nonbinding exercise in resource allocation that "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." Guidance at 2–3. The fact that, in preparing to process a large influx of applications for premarket approval, the FDA has decided to focus on those products that present the greatest threat of enticing minors simply reflects the fact that enforcement resources are finite and that there will inevitably be delays in reviewing and approving products.

Notably, the FDA's enforcement priorities have shifted in the face of new evidence and changing trends in youth tobacco use.[6] Obviously, then, the conclusions

[6] *See* Guidance at 20 (explaining that the FDA "reconsider[ed] its approach" regarding mint-flavored ENDS products in light of new data showing the popularity of mint and a recent surge in youth use of ENDS products); *FDA Regulation of Electronic*

(continued...)

supporting the current version of its Guidance are tentative. Indeed, the Guidance begins by stating that it "represents the current thinking of the [FDA] on this topic" and "does not establish any rights for any person and is not binding on FDA or the public." Guidance at 2. Under the circumstances, and in light of the fact that the Act expressly contemplates a role for state and local regulation, the tension between the Ordinance and these discretionary, provisional enforcement decisions does not represent "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp.*, 514 U.S. at 287 (citation and quotation marks omitted).

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[6](...continued)
Nicotine Delivery Systems and Investigation of Vaping Illnesses Before H. Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce (Sept. 25, 2019) (testimony of Norman Sharpless, M.D., Acting FDA Commissioner), *available at* https://www.hhs.gov/about/agencies/asl/testimony/2019-09/fda-regulation-of-electronic-nicotine-delivery-systems-and-investigation-of-vaping-illnesses.html (last visited Aug. 31, 2020) ("FDA intends to finalize a compliance policy in the coming weeks that would prioritize the Agency's enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, *including mint- and menthol-flavored products*." (emphasis added)); Statement from FDA Commissioner Scott Gottlieb, M.D. (Nov. 15, 2018), *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access (last visited Aug. 31, 2020) (announcing new proposals, including new enforcement priorities, in light of recent increase in youth use of ENDS products); Statement from FDA Commissioner Scott Gottlieb, M.D. (Sept. 11, 2018), *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use (last visited Aug. 31, 2020) (noting that "in view of the accelerating use among youth, we're actively considering whether we will enforce the premarket review provision earlier, when it is apparent that these products are now subject to widespread youth use" and that "we may take steps to curtail the marketing and selling of flavored products").

Finally, plaintiffs argue that allowing states and municipalities to prohibit the sale of certain tobacco products threatens to subject manufacturers to multiple approval processes instead of the single, detailed, uniform process set forth in § 387j. As noted, § 387j subjects new products to a premarket approval process. 21 U.S.C. § 387j(a)(2). The statute sets forth various pathways to gaining approval as well as exceptions to the requirement. *See generally Cigar Ass'n of Am. v. FDA*, No. 16-CV-1460, 2020 WL 4816459, at *1–2 (D.D.C. Aug. 19, 2020) (describing the Act's approval requirements and process). The statute also prescribes the contents of an application for approval and standards for approving or denying an application. 21 U.S.C. § 387j(b), (c).

This argument fails for the same reason that plaintiffs' argument regarding manufacturing standards fails. Simply put, the Ordinance does not impose any kind of premarket approval process that could conflict with the detailed regime set forth in § 387j. Plaintiffs go on to argue that the Ordinance interferes with the FDA's judgment (rendered through the Act's approval process) that a given product may be marketed to the public. This is simply a reiteration of plaintiffs' argument that the Ordinance interferes with the goal of uniform national regulation. The Court has already explained why it is unpersuaded by that argument.

The Court therefore agrees with the City that the Ordinance is neither expressly nor impliedly preempted by federal law. Consequently, the Court grants the City's motion to dismiss and denies plaintiffs' motion for a preliminary injunction.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Plaintiffs' motion for a preliminary injunction [ECF No. 25] is DENIED.

2. Defendants' motion to dismiss [ECF No. 34] is GRANTED as follows:

   a. The motion is GRANTED as to plaintiffs' claims against defendants Edina City Council and Scott Neal and those claims are DISMISSED WITHOUT PREJUDICE.

   b. The motion is GRANTED as to plaintiffs' claims against defendant City of Edina and those claims are DISMISSED WITH PREJUDICE AND ON THE MERITS.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: August 31, 2020

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge