1 2 3 4 5 6 7 8 UNITED STATES DISTRICT COURT 9 SOUTHERN DISTRICT OF CALIFORNIA 10 11 R.J. REYNOLDS TOBACCO Case No.: 20-CV-1290 JLS (WVG) COMPANY.; R.J. REYNOLDS VAPOR 12 **ORDER (1) DENYING PLAINTIFFS'** COMPANY.; SANTA FE NATURAL 13 TOBACCO COMPANY., INC.; MOTION FOR PRELIMINARY AMERICAN SNUFF COMPANY, LLC; **INJUNCTION AND (2) GRANTING** 14 **DEFENDANTS' MOTION TO** and MODORAL BRANDS INC., 15 **DISMISS** Plaintiffs, 16 v. (ECF Nos. 6, 26) 17 COUNTY OF SAN DIEGO; and HELEN N. ROBBINS-MEYER, in her official 18 capacity as the County of San Diego's 19 Chief Administrative Officer, 20 Defendants. 21 22

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This Order addresses the constitutionality of two county ordinances that permanently ban the sale of various flavored tobacco products in San Diego County. Specifically before the Court are Plaintiffs R.J. Reynolds Tobacco Company; R.J. Reynolds Vapor Company; Santa Fe Natural Tobacco Company, Inc.; American Snuff Co., LLC; and Modoral Brands Inc.'s (collectively, "Plaintiffs") Motion for Preliminary Injunction ("Mot.," ECF No. 6-1) and Defendants County of San Diego and Helen N. Robbins-Meyer's (collectively, "Defendants") Motion to Dismiss Plaintiffs' Complaint ("MTD," ECF No. 26). Also

before the Court is the brief of Medical and Public Health *Amici Curiae* filed in Opposition to Plaintiffs' Motion for Preliminary Injunction ("*Amici* Br.," ECF No. 21). The Court took these matters under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). *See* ECF No. 36. Having carefully considered the Parties' pleadings, evidence, arguments, and the applicable law, the Court **DENIES** Plaintiffs' Motion for Preliminary Injunction and **GRANTS** Defendants' Motion to Dismiss, as follows.

BACKGROUND

On January 28, 2020, the San Diego County Board of Supervisors adopted Regulatory Code Ordinance Number 10647 (the "Ordinance"), which was enacted on February 27, 2020 and became effective on July 1, 2020. *See generally* San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8.8, §§ 32.871–32.895 (2020). The Ordinance (1) permanently prohibits the sale or distribution of flavored smoking products within San Diego County and (2) temporarily prohibits the sale or distribution of electronic smoking devices within San Diego County for a period of one year. *See generally id.* Plaintiffs seek to enjoin the County from enforcing the sales ban on flavored smoking products. *See generally* Mot.

First, the Ordinance prohibits the sale of certain tobacco products. The Ordinance bans "the sale or distribution of all flavored smoking products . . . in the unincorporated area of the County." San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8.8, § 32.883(a) (2020). A "flavored smoking product" is defined as:

[A] product containing, made, or derived from tobacco or nicotine that is intended for smoking, and that emits a taste or smell, other than the taste or smell of tobacco, including, but not limited to, any taste or smell relating to fruit, menthol, mint, wintergreen, chocolate, cocoa, vanilla, honey, candy, dessert, alcoholic beverage, herb, or spice.

Id. § 32.882(b). The ban exempts shisha, which is "a flavored smoking product that is traditionally mixed with molasses, honey, fruit pulp, or dried fruits and is sold for use in a water pipe known as a hookah." *Id.* § 32.872(b). Additionally, the prohibition on the sale

of flavored smoking products does not apply to "a product that has been approved by the Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes, where the product is marketed and sold solely for such an approved purpose." *Id.* § 32.883(c).

The Ordinance was enacted to combat the health risks associated with youth tobacco consumption. *See generally id.* § 32.881(a)–(g). The 2019 National Youth Tobacco Survey conducted by the Centers for Disease Control and Prevention ("CDC") and the Food and Drug Administration ("FDA") "showed that more than 5 million U.S. middle and high school students reported current e-cigarette use . . . [and] 27.5 percent of high school students reported current e-cigarette use, a percentage that has increased dramatically since 2018." *Id.* § 32.881(c). The County found that "[f]lavors, such as fruit, menthol, mint, candy, or dessert, hide the harshness of nicotine, making initiation of nicotine use easier among youth." *Id.* § 32.881(d). The County also was concerned with underage purchasers having access to tobacco products. The 2018 Young Adult Tobacco Purchase Survey "showed that tobacco and vape shops made sales to underage decoys 49.8 percent of the time, twice the rate of any other category of retailer." *Id.* § 32.881(g).

Second, the Ordinance temporarily banned, for a period of one year, the "sale or distribution of an electronic smoking device" *Id.* § 32.893(a). An "Electronic Smoking Device" is defined as:

[A]n electronic and/or battery-operated device, which can be used to deliver an inhaled dose of nicotine or other substances whether manufactured, distributed, marketed, or sold as an electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, or any other product name or descriptor.

Id. § 32.892(b). Like the flavored smoking products sales ban, the temporary prohibition on the sale of electronic smoking devices does not apply to "any product that the Food and Drug Administration has either granted premarket approval, or approved for use as a tobacco cessation product or for other therapeutic purposes where the product is marketed

and sold solely for such an approved purpose." *Id.* The ban on the sale of electronic smoking devices expired on February 28, 2021. *Id.* § 32.893(a).

The San Diego County Board of Supervisors was motivated to adopt the temporary ban on electronic smoking devices because the "long-term health consequences of electronic smoking devices are unclear, but evidence is mounting that there are serious risks." *Id.* § 32.891(d). Among the suspected health risks is an illness called e-cigarette or vaping product use-associated lung injury ("EVALI"), which "has led to hospitalizations and deaths nationwide There have been 41 confirmed or probable EVALI cases in San Diego County as of December 18, 2019." *Id.* § 32.892(g). The County was particularly concerned with youth use of electronic smoking devices, which has increased since 2018. *Id.* § 32.892(f). Additionally, the FDA has not approved e-cigarettes as an aid to quit smoking, and "[s]tudies indicate no evidence of definitive long-term efficacy of e-cigarettes as a cessation aid" *Id.* § 32.891(c).

On December 8, 2020, the San Diego County Board of Supervisors adopted Ordinance No. 10699, (the "New Ordinance," the Ordinance and the New Ordinance collectively the "ordinances"), which repealed and added provisions in the San Diego County Code regarding the sale of tobacco products in the unincorporated area of San Diego County. See generally San Diego County, Cal., Code of Regulatory Ordinances, tit. 2, div. 1, ch. 26, §§ 21.2601–21.2610 (2021). As of July 1, 2021, the New Ordinance will repeal the Ordinance's current ban on flavored smoking products and replace it with a ban on the sale of flavored tobacco products. Compare San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8.8, § 32.883 (2020) with San Diego County, Cal., Code of Regulatory Ordinances, tit. 2, div. 1, ch. 26, § 21.2604 (2021). The New Ordinance does not reinstate a ban on the sale of electronic smoking devices. See generally San Diego County, Cal., Code of Regulatory Ordinances, tit. 2, div. 1, ch. 26 (2021). Specifically, the New Ordinance provides, "A tobacco retailer, or any of the tobacco retailer's agents or employees, shall not sell, offer for sale, or possess with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer." Id.

§ 21.2604(a). A "flavored tobacco product" is defined as:

[A]ny tobacco product 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 the consumption of the product, including, but not limited to, any taste or smell relating to chocolate, cocoa, menthol, mint, wintergreen, vanilla, honey, fruit or any candy, dessert, alcoholic beverage, herb or spice.

Id. § 21.2602(i). The New Ordinance has exemptions for shisha products, loose leaf pipe tobacco, and premium cigars. *Id.* § 21.2604(c)–(d). The practical effect of the change from flavored smoking products to flavored tobacco products is that the New Ordinance prohibits the sale of more types of products, not just those related to smoking.

Plaintiffs are corporations that develop, manufacture, market, and distribute flavored smoking products, flavored tobacco products, flavored electronic smoking devices, and menthol cigarettes. Complaint ("Compl.") ¶¶ 9–11, ECF No. 1; Supplemental Complaint ("Suppl. Compl.") ¶ 3, ECF No. 39. Plaintiffs contend they will suffer "substantial financial losses" due to the ordinances. Mot. at 21 (citing Declaration of Lamar W. Huckabee ("Huckabee Decl.") ¶ 8, ECF No. 6-4; Declaration of Christy L. Canary-Garner ("Canary-Garner Decl.") ¶ 6, ECF No. 6-3).

PROCEDURAL HISTORY

On July 9, 2020, Plaintiffs filed their Complaint seeking declaratory and injunctive relief against Defendants. *See generally* Compl. On July 16, 2020, Plaintiffs filed their Motion for a Preliminary Injunction or Summary Judgment. *See generally* Mot. Defendants filed their Response in Opposition to Plaintiffs' Motion ("Opp'n," ECF. No. 15), and Plaintiffs filed a Reply in support of their Motion ("Reply," ECF No. 16). On September 15, 2020, Defendants filed their Motion to Dismiss for Failure to State a Claim. *See generally* MTD. Plaintiffs filed a Response in Opposition to Defendants' Motion to Dismiss, ECF. No. 28, and Defendants filed a Reply in support of their Motion, ECF No. 30.

This action was originally assigned to the Honorable Roger T. Benitez, but the action was transferred pursuant to the low-number rule to the Honorable Marilyn L. Huff on July 15, 2020 as related to *Neighborhood Market Association, Inc. v. County of San Diego*, Case No. 3:20-cv-01124-JLS-WVG. *See generally* ECF No. 5. Both actions were reassigned to this Court on August 4, 2020, when Judge Huff recused herself. *See* ECF No. 18.

On March 3, 2021, Plaintiffs requested leave to file a Supplemental Complaint, ECF No. 37, which the Court granted, ECF No. 38. Plaintiffs added two new claims that the New Ordinance is expressly and impliedly preempted by federal law. *See generally* Suppl. Compl. At the Order of the Court, ECF No. 38, the Parties filed supplemental briefs addressing the effect of the pending motions on Plaintiffs' Supplemental Complaint, *see* ECF Nos. 41, 42.

On August 28, 2020, California Governor Gavin Newsom approved California Senate Bill 793 ("S.B. 793"), which prohibits the sale of flavored tobacco products or tobacco product flavor enhancers in California. *See generally* S.B. 793, Act of Aug. 28, 2020, 2020 Cal. Legis. Serv. ch. 34 (to be codified at Cal. Health & Safety Code § 104559.5). A referendum challenging S.B. 793 has suspended the operation of the statewide flavored tobacco products sales ban unless and until it is approved by a majority of voters in the November 8, 2022 election. *See* Cal. Sec. of State, Nov. 8, 2022 Qualified Statewide Ballot Measures, at https://www.sos.ca.gov/elections/ballot-measures/qualified-ballot-measures (last visited Mar. 19, 2021). Because S.B. 793 is not currently in effect, the Court will not examine the effect of the state statute on the present action.

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MOTION FOR PRELIMINARY INJUNCTION¹

Plaintiffs request that the Court preliminarily enjoin Defendants from enforcing the San Diego County ordinances, which ban the sale of flavored tobacco products. Mot. at 3. Plaintiffs argue the ordinances are unconstitutional because they are expressly and impliedly preempted by the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"). Mot. at 6.

I. Legal Standard

A preliminary injunction is an equitable remedy aimed at preserving the status quo and preventing the occurrence of irreparable harm during the course of litigation. *See* Fed. R. Civ. P. 65. "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 20 (2008). "A preliminary injunction is an extraordinary remedy never awarded as a matter of right." *Id.* at 24. Although a plaintiff seeking a preliminary injunction must make a showing on each factor, the Ninth Circuit employs a "version of the sliding scale" approach where "a stronger showing of one element may offset a weaker showing of another." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131–35 (9th Cir. 2011). "[W]hen a plaintiff has failed to show the likelihood of success on the merits, we 'need not consider the remaining three [*Winter* elements]." *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (en

¹ On a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may take into account the Parties' pleadings, any documents physically attached to those pleadings or incorporated by reference therein, and any documents properly subject to judicial notice. *See, e.g., Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (judicial notice and incorporation by reference); *Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007) (Rule 12(b)(6) motion). "Nonetheless, in deciding a motion for preliminary injunction—unlike a motion to dismiss—the Court is not limited solely to the pleadings and may consider affidavits or declarations along with other evidence submitted by the parties." *Walker v. Woodford*, 454 F. Supp. 2d 1007, 1024 (S.D. Cal. 2006) (citing Fed. R. Civ. P. 65; *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *Flynt Distrib. Co. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984)), *aff'd*, 393 F. App'x 513 (9th Cir. 2010). The Court is guided by these legal principles in its Analysis, *infra* Section II.

banc) (alterations in original) (quoting *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 944 (9th Cir. 2013)).

II. Analysis

Plaintiffs argue that the flavored tobacco and flavored smoking products sales bans violate the Supremacy Clause because the ordinances are expressly and impliedly preempted by the FSPTCA, 21 U.S.C. §§ 387–387u. *See generally* Mot. The Court will address Plaintiffs' express and implied preemption arguments in turn.

A. Express Preemption

In determining whether the ordinances are expressly preempted by the FSPTCA, Congress's intent "is the ultimate touchstone." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). "Where the federal statute contains an express preemption clause, we must determine the substance and scope of the clause." *Ass'n des Éleveurs de Canards et d'Oies du Quebec v. Becerra*, 870 F.3d 1140, 1146 (9th Cir. 2017). In so doing, the court assumes "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc.*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). And finally, "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors preemption." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

With these principles in mind, the Court begins its analysis with the plain language of the statute. The FSPTCA amends the Federal Food, Drug, and Cosmetic Act ("FDCA") to grant the FDA "the authority to regulate tobacco products." H.R. Rep. No. 111–58, pt. 1, at 2 (2009) (the "FSPTCA Report"). The FSPTCA defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)," provided that such product is not "an article that is a drug under [21 U.S.C. § 321](g)(1), a

device under [21 U.S.C. § 321](h), or a combination product described in [21 U.S.C. § 353](g)." 21 U.S.C. § 321(rr)(1)–(2).²

The FSPTCA grants the FDA "the authority to regulate the sale, distribution, advertising, promotion, and use of tobacco products if such actions would be in the interest of the public health," FSPTCA Report at 26, but prohibits the FDA from "banning a class" of nicotine products, such as all cigarettes, or reducing the nicotine level [of such products] to zero," id. at 2. The Act also "requires the [FDA] to establish tobacco product standards to protect the public health." *Id*.

Section 916 of the FSPTCA, entitled "Preservation of State and Local Authority," contains three clauses that address the power of state and local governments to enact laws relating to tobacco products: a preservation clause, a preemption clause, and a savings clause. See 21 U.S.C. § 387p(a). The interaction of these three clauses governs whether the ordinances are expressly preempted. First, the Preservation Clause explains that the FSPTCA preserves state and local authority to enact 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.

Id. § 387p(a)(1). The broad authority preserved for the state and local governments is limited only to the extent that a local law contravenes one of the specific prohibitions enumerated in the Preemption Clause. The Preemption Clause expressly preempts:

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² On May 10, 2016, the FDA exercised the authority Congress conferred upon it in 21 U.S.C. § 387a(b) to deem electronic cigarettes, the type at issue in the Ordinance, to be "tobacco products" subject to the FSPTCA. Deeming Rule, 81 Fed. Reg. at 28,976 ("Products that meet the statutory definition of 'tobacco products' include . . . ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) ").

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.

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Id. § 387p(a)(2)(A). However, state and local laws that would otherwise fall within the Preemption Clause are exempted if they fall within the Savings Clause, which clarifies that the Preemption Clause:

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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.

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Id. $\S 387p(a)(2)(B)$.

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The Second Circuit has held that when these three clauses are read in conjunction, the FSPTCA "distinguishes between manufacturing and the retail sale of finished products; it reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry in the absence of conflicting federal regulation." U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428, 434 (2d Cir. 2013).

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Plaintiffs argue that the flavored smoking and tobacco products sales bans are impermissible tobacco products standards, such that the ordinances would fall within the FSPTCA's Preemption Clause. See Mot. 6–11. Plaintiffs contend that they are likely to succeed on the merits of their claim because the ordinances "establish[] a local

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requirement that is 'different from' and 'in addition to' federal requirements related to

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tobacco product standards," and therefore the ordinances are expressly preempted. *Id.* at

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Plaintiffs maintain that under the FSPTCA, tobacco product standards include "provisions respecting the . . . additives [and] properties of the tobacco product." *Id.* at 7

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(alterations in original) (quoting 21 U.S.C. § 387g(a)(4)(B)(i)). Because additives include

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"substances intended for use as flavorings," 21 U.S.C. § 387(1), Plaintiffs argue that "a

ban on the sale of flavored smoking products qualifies as a tobacco product standard because the ban regulates additives," Mot. at 7. Plaintiffs further argue that the Savings Clause does not save the ordinances. *Id.* at 11–16.

Defendants maintain that because the ordinances are sales bans and not tobacco product standards, there is no conflict with the FSPTCA. Opp'n at 14. Even if the Court were to find the sales bans are tobacco product standards, Defendants argue that the Savings Clause acts to save the ordinances because it contains "requirements relating to the sale" of tobacco products. *Id.* at 19; *see* 21 U.S.C. § 387p(a)(2)(B).

To determine whether the ordinances are expressly preempted, the Court must first determine whether a sales ban on flavored smoking or tobacco products constitutes a tobacco product standard within the meaning of the FSPTCA. Generally, section 387g governs tobacco product standards, although the term "tobacco product standards" is not expressly defined in the FSPTCA. See generally 21 U.S.C. § 387g. The FSPTCA describes the tobacco product standards as including "provisions that are appropriate for the protection of the public health." *Id.* § 387g(a)(4). Tobacco product standards include "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product"; testing provisions; provisions for nicotine yields; provisions for measurement of tobacco-product characteristics; provisions related to 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." *Id.* § 387g(a)(4). Section 387f(d) states that the sale and distribution of a tobacco product may be restricted by regulation if the Secretary determines that such regulation would be appropriate "for the protection of the public health." *Id.* § 387f(d).

The FSPTCA sets out two tobacco product standard "[s]pecial rules" and gives the FDA authority to revise those rules as well as adopt additional tobacco standards. *Id*.

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§ 387g(a)(3). The "[s]pecial rule for cigarettes" concerns the flavor of cigarettes. The rule prohibits cigarettes from:

contain[ing], as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.

Id. § 387g(a)(1)(A) (the "Special Rule"). The Special Rule "is intended to prohibit the manufacture and sale of cigarettes with certain 'characterizing flavors' that appeal to youth." FSPTCA Report at 37.

Referring to the Special Rule, Plaintiffs argue that "[i]f a ban on all flavored cigarettes except menthol is a tobacco product standard—indeed, the paradigmatic example of a tobacco product standard—then a state law or local ordinance that bans all flavored smoking products *including* menthol is a tobacco product standard as well." Mot. at 8 (emphasis in original). However, the Second Circuit has held that a tobacco product standard is a manufacturing regulation, and therefore a sales regulation like the one at issue here is not a tobacco product standard 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.*, 708 F.3d at 434–35; *see also R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, 471 F. Supp. 3d 1010, 1015 (C.D. Cal. 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."). The ordinances do not "direct manufacturers as to which ingredients they may or may not include in their products." *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 435.

Plaintiffs present two alternate theories in an attempt to classify the ordinances' sales bans as tobacco product standards. First, Plaintiffs argue that the sales ban regulates ///

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additives of tobacco products, and second that it regulates properties of tobacco products. Neither of these arguments is persuasive to the Court, for the following reasons.

First, Plaintiffs contend that because "additives" include "substances intended for use as a flavoring," 21 U.S.C. § 387(1), "a 'tobacco product standard' includes any provision respecting the substances intended for use as a tobacco-product flavoring," Mot. at 7. This argument is misplaced because the ordinances do not regulate additives. The Ordinance bans the sale or distribution "of all flavored smoking products" San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8.8, § 32.883(a) (2020). Flavored smoking products are defined as products that "emit[] a taste or smell, other than the taste or smell of tobacco." *Id.* § 32.882(b). Similarly, the New Ordinance bans the sale of "a flavored tobacco product or a tobacco product flavor enhancer." San Diego County, Cal., Code of Regulatory Ordinances, tit. 2, div. 1, ch. 26, § 21.2604(a) (2021). A "flavored tobacco product" is defined as "any tobacco product 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 the consumption of the product." Id. § 21.2602(i). Neither of the ordinances specifies permitted or banned ingredients. These are sales bans directed at what end products are available to consumers, not a directive to manufacturers about what materials are permitted to make tobacco products. The latter would be a tobacco product standard falling within the Preemption Clause, but the former is explicitly contemplated by the FSPTCA and permitted. Therefore, the ordinances' sales bans do not regulate additives and cannot be considered tobacco product standards. This result is required by the express terms of the FSPTCA, which state that the Act is not to be "construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any . . . measure . . . prohibiting the sale . . . of tobacco products." 21 U.S.C. § 387p(a)(1).

Some courts have held that a sales ban could be considered a tobacco product standard if the sales ban is a de facto manufacturing regulation. *See U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 435 n.2. An example of such a de facto manufacturing

regulation can be found in the law at issue in *National Meat Association v. Harris*, 565 U.S. 452 (2012). In *National Meat Association*, a California law prohibited slaughterhouses from buying, processing, or selling nonambulatory animals or their meat. *See id.* at 458–59. The prohibition on the sale of meat derived from nonambulatory animals was preempted by the Federal Meat Inspection Act because the "idea – and the inevitable effect – of the provision is to make sure that slaughterhouses remove nonambulatory pigs from the production process." *Id.* at 464. Therefore, the sales ban in *National Meat Association* was preempted because the law "serves to regulate how slaughterhouses must deal with non-ambulatory pigs on their premises." *Id.* The only way to determine whether a product was banned under the law in *National Meat Association* was to consider how it was manufactured. This is not analogous to the present regulation, which does not regulate how tobacco manufacturers manufacture products, but instead determines what end products are allowed on retail shelves based on identifiable end product characteristics.

The Honorable Dale S. Fischer of the U.S. District Court for the Central District of California examined a similar flavored tobacco products sales ban in Los Angeles County. See generally Cnty. of Los Angeles, 471 F. Supp. 3d 1010. The Central District court concluded that the Los Angeles County sales ban on flavored tobacco products is not a de facto manufacturing regulation because the ordinance banned the sale of "products [that] can be identified based on how they are marketed and sold." Id. Similarly, the San Diego County ordinances at issue here identify banned products based on whether they "emit[] a taste or smell, other than the taste or smell of tobacco" San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8.8, § 32.882(b) (2020); see also San Diego County, Cal., Code of Regulatory Ordinances, tit. 2, div. 1, ch. 26, § 21.2602(i) (2021) (defining "flavored tobacco product" as "any tobacco product that contains a taste or smell, other than the taste or smell of tobacco"). Therefore, the ingredients or additives used by the manufacturer are irrelevant because the banned products are identifiable at the consumer stage if the product emits or contains a smell or taste other than tobacco.

Second, Plaintiffs argue that the term "properties" encompasses "flavors," and because the ordinances "regulate[]" flavors, they create tobacco product standards. Mot. at 8 (citing 21 U.S.C. § 387g(a)(4)(B)(i)). To support this argument, Plaintiffs rely on a proposed rule that purports to interpret the statutory language of the FSPTCA. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566–637 (proposed Sept. 25, 2019) ("If the product does not have a listed product property, such as . . . characterizing flavor, the application must state 'none' for that property."). Plaintiffs argue that because the proposed rule considers a tobacco product's "characterizing flavor" to be a "product property," the Court should apply the same interpretation to the FSPTCA's tobacco product standards. *See* Mot. at 8. In the Ninth Circuit, "proposed regulations carry no more weight than a position advanced on brief." *Tedori v. United States*, 211 F.3d 488, 492 (9th Cir. 2000) (citation omitted). If the proposed rule were to become final, it would be entitled to deference by this Court under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), but such is not the case here.

Only one court that examined the constitutionality of a flavored tobacco product sales ban agreed with Plaintiffs' present argument and held that the ban fell within the FSPTCA's definition of tobacco product standards. *See R.J. Reynolds Tobacco Co. v. City of Edina*, No. 20-CV-1402 (PJS/LIB), 2020 WL 5106853, at *4 (D. Minn. Aug. 31, 2020). The *Edina* court found that "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." *Id.* (quoting 21 U.S.C. § 387g(a)(4)). This made no difference in the outcome of the case, however, because the *Edina* court found that, "[o]n its face, the Ordinance falls within the scope of the Savings Clause, as it is a 'requirement[] relating to the sale ... of ... tobacco products by individuals of any age" *Id.* (quoting 21 U.S.C. § 387p(a)(2)(B)) (alterations in original). However, this Court follows the Second Circuit, which held that this reading of the Preemption Clause is overly broad. *See U.S.*

Smokeless Tobacco Mfg. Co., 708 F.3d at 434. If the Court found that a retail sales ban on end products is a preempted tobacco product standard, it "would render superfluous § 916's three-part structure . . . [and] vitiate the preservation clause's instruction that the Act not be 'construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any . . . measure . . . prohibiting the sale . . . of tobacco products." Id. (quoting 21 U.S.C. § 387p(a)(1)) (alterations in original). If possible, statutes should be construed to give effect to every clause and word. See, e.g., Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687, 698 (1995) (describing the Court's "reluctance to treat statutory terms as surplusage"). Accordingly, Plaintiffs' "properties" argument is similarly unavailing.

Other courts that have addressed whether similar local ordinances banning or restricting access to flavored tobacco products were preempted by the FSPTCA have uniformly held that they were not. See, e.g., Nat'l Ass'n of Tobacco Outlets v. City of *Providence*, 731 F.3d 71, 82–83, 85 & n.11 (1st Cir. 2013) (holding that tobacco product sales regulations are not tobacco product standards preempted by the FSPTCA and stating that "whether those regulations have an impact on manufacturing is irrelevant"); U.S. Smokeless Tobacco Mfg. Co., 708 F.3d at 436 (holding an ordinance that banned the sale of flavored tobacco products was not preempted by the FSPTCA); Cnty. of Los Angeles, 471 F. Supp. 3d at 1018 (same); *Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015) (holding that ordinance that restricted sale of flavored tobacco near schools was not preempted by the FSPTCA); City of Edina, 2020 WL 5106853, at *3 (holding a ban on the sale of flavored tobacco products was a tobacco product standard that falls within the Savings Clause and is therefore not preempted by the FSPTCA). While not binding on this Court, the findings of these courts are persuasive. Accordingly, the Court finds that the ordinances' sales bans on flavored smoking and tobacco products are not tobacco product standards and therefore are not expressly preempted by the FSPTCA.

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In the absence of Ninth Circuit authority, this Court follows the First and Second Circuits and concludes that the sales regulations in the ordinances do not "clearly infringe on the FDA's authority to determine what chemicals and processes may be used in making tobacco products." *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434; *see also Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 85. Therefore, the ordinances do not constitute a tobacco product standard, and Plaintiffs are unlikely to succeed on the merits of their express preemption claim.

B. Implied Preemption

Next, Plaintiffs argue that the ordinances are impliedly preempted "because [they] 'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Mot. at 16 (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000)). Plaintiffs contend that the sales bans (1) undermine the ability of the FDA to set national standards for the manufacturing of tobacco products, (2) undermine Congress and the FDA's judgment that certain flavored smoking and tobacco products should remain on the market, and (3) interfere with the regulatory process chosen by Congress to effectuate its objective. *Id.* at 16–21. In response, Defendants argue that the FSPTCA's Preemption Clause expressly "'defin[es] the pre-emptive reach' of the Act on State and local regulation of tobacco sales." Opp'n at 21 (quoting *Ass'n des Éleveurs de Canards et d'Oies du Quebec v. Becerra*, 870 F.3d 1140, 1149 (9th Cir. 2017)). Defendants contend that "matters beyond that reach are not pre-empted." *Id.* (quoting *Ass'n des Éleveurs de Canards et d'Oies du Quebec*, 870 F.3d at 1149).

In analyzing implied preemption, "[a]s with express preemption, courts assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." *Ass'n des Éleveurs de Canards et d'Oies du Quebec*, 870 F.3d at 1149. "Implied 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 Commerce of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (quoting *Gade*)

v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 111 (1992)). The language of the FSPTCA's Preemption Clause "implies that matters beyond that reach are not pre-empted." Ass'n des Éleveurs de Canards et d'Oies du Quebec, 870 F.3d at 1149 (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 517 (1992)); see Graham v. R.J. Reynolds Tobacco Co., 857 F.3d 1169, 1186 (11th Cir. 2017) ("Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it.").

First, Plaintiffs argue that the ordinances are impliedly preempted because Congress adopted the FSPTCA to "set national standards controlling the manufacture of tobacco products and the . . . amount of ingredients used in such products." Mot. at 14 (citing 21) U.S.C. § 387 note). This argument is unavailing because the Court concluded that the ordinances do not set manufacturing standards or regulate the ingredients used in tobacco products. See supra Section II.A. Generally, a ban on certain finished tobacco products will not cause manufacturers to change the ingredients they use or the way that they manufacture products; however, it is conceivable that a large enough sales ban on certain products could change manufacturing behavior. See City of Edina, 2020 WL 5106853, at *6 ("[I]f 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."). However, this Court already determined that the ordinances do not regulate the ingredients or additives used in products because the ordinances regulate the sale of end products based on characterizing smells and tastes. The "clear and manifest purpose of Congress," Ass'n des Éleveurs de Canards et d'Oies du Quebec, 870 F.3d at 1149, was to preserve state and local authority to enact such sales bans, as evidenced by the Preservation Clause. The ordinances classify end products based on characterizing flavors or smells; therefore, the ordinances do not infringe on the FSPTCA's authority to regulate the ingredients used in tobacco products.

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Second, Plaintiffs contend that the ordinances undermine Congress and the FDA's "judgment that certain flavored smoking [and tobacco] products—including menthol cigarettes and menthol-flavored [electronic nicotine delivery system ("]ENDS[")] products—should remain on the market." Mot. at 17; see also ECF No. 42 at 6. This argument ignores that the FSPTCA expressly gives states and local governments the power to prohibit the sale of tobacco products, even if those sales bans are stricter than the federal ban, so long as the regulation is not covered by the Preemption Clause. See U.S. Smokeless Tobacco Mfg. Co., 708 F.3d at 433 ("While § 907(d)(3) prohibits the FDA from banning entire categories of tobacco products throughout the country, 21 U.S.C. § 387g(d)(3), the FSPTCA nowhere extends that prohibition to state and local governments. To the contrary, the preservation clause of § 916 expressly preserves localities' traditional power to adopt any 'measure relating to or prohibiting the sale' of tobacco products." (footnote omitted)); see also Berger v. Philip Morris USA, Inc., 185 F. Supp. 3d 1324, 1340–41 (M.D. Fla. 2016), aff'd sub nom. Cote v. R.J. Reynolds Tobacco Co., 909 F.3d 1094 (11th Cir. 2018) ("[S]tate-law prohibitions on cigarette sales can stand side-by-side with the fact that Congress has tolerated cigarettes and purposefully refrained from banning them."). By the very language of the FSPTCA, a stricter sales ban can stand side-by-side with federal regulations.

Plaintiffs argue that if Congress chooses not to act against a particular product, like menthol-flavored ENDS products, Congress affirmatively intends for that product to remain on the market. *See* Mot. at 18. However, failure to take active steps to prohibit a product is not equivalent to an affirmative decision that the product should remain on the national market. *Cf. Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) (rejecting the defendant's argument that "the FDA's failure to issue specific regulations on [use of the word 'natural'] is tantamount to a conscious decision by the agency to permit any use of this term a manufacturer sees fit").

Finally, Plaintiffs argue that the ordinances "interfere[] with 'the method chosen by Congress to effectuate [its] objective." Mot. at 19 (quoting *McDaniel v. Wells Fargo*

Invs., LLC, 717 F.3d 668, 674 (9th Cir. 2013)). Plaintiffs contend that in the FSPTCA, Congress "created a detailed regulatory process as the sole method for evaluating the design and sale of new tobacco products . . . , [and] Congress intended to subject each new tobacco product to one regulatory assessment conducted by FDA, not multiple rounds of assessments by states and localities." Id. As the Court has already determined, the FSPTCA "reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry in the absence of conflicting federal regulation." U.S. Smokeless Tobacco Mfg. Co., 708 F.3d at 434. Thus, the Court disagrees with Plaintiffs' characterization of Congress' objective in enacting the FSPTCA.

Accordingly, the Court finds the ordinances do not stand as obstacles to the objectives of the FSPTCA, and Plaintiffs have not shown a likelihood of success on the merits of their implied preemption claim. The Court need not address the remaining factors necessary for injunctive relief because Plaintiffs have failed to establish any chance of success on the merits of their express preemption or implied preemption claims. *See Garcia*, 786 F.3d at 740. Therefore, the Court **DENIES** Plaintiffs' Motion for Preliminary Injunction. *See, e.g., Sports Form, Inc. v. United Press Int'l, Inc.*, 686 F.2d 750, 753 (9th Cir. 1982) (affirming district court's denial of preliminary injunction where the plaintiff "had failed to show any chance of success on the merits," which "made a determination of potential injury or a balancing of hardships unnecessary").

MOTION TO DISMISS

Federal Rule of Civil Procedure 12(b)(6) permits a party to raise by motion the defense that the complaint "fail[s] to state a claim upon which relief can be granted," generally referred to as a motion to dismiss. The Court evaluates whether a complaint states a cognizable legal theory and sufficient facts in light of Federal Rule of Civil Procedure 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Although Rule 8 "does not require 'detailed factual allegations,' . . . it [does] demand more than an unadorned, the-defendant-unlawfully-

harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A complaint will not suffice "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement." *Iqbal*, 556 U.S. at 677 (citing *Twombly*, 550 U.S. at 557).

To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Id.* (quoting *Twombly*, 550 U.S. at 570); *see also* Fed. R. Civ. P. 12(b)(6). A claim is facially plausible when the facts pled "allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 677 (citing *Twombly*, 550 U.S. at 556). That is not to say that the claim must be probable, but there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Facts "merely consistent with' a defendant's liability" fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). This review requires context-specific analysis involving the Court's "judicial experience and common sense." *Id.* at 678 (citation omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief." *Id.*

Where a complaint does not survive 12(b)(6) analysis, the Court will grant leave to amend unless it determines that no modified contention "consistent with the challenged pleading . . . [will] cure the deficiency." *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (quoting *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

Defendants seek to have Plaintiffs' Complaint and Supplemental Complaint dismissed for failure to state a claim because there is no plausible argument that the ordinances are expressly or impliedly preempted. *See generally* MTD; *see also* ECF No.

41 at 2–3. Defendants argue that "Plaintiffs cannot establish that the Act expressly or impliedly preempts the Ordinance . . . [and] these defects cannot possibly be cured by amendment" *Id.* at 11. Plaintiffs bring only the claims for express and implied preemption. *See generally* Compl.; Suppl. Compl. The Court already examined the merit of these claims *supra* at Sections II.A–II.B and found that Plaintiffs have not proven a likelihood of success on the merits of their express and implied preemption claims.

Therefore, the Court **GRANTS** Defendants' Motion to Dismiss Plaintiffs' Complaint and Supplemental Complaint, as the Court does not find Plaintiffs' preemption claims plausible in light of the plain statutory language of the ordinances and the FSPTCA. *See Angelotti Chiropractic, Inc. v. Baker*, 791 F.3d 1075, 1088 (9th Cir. 2015) (reversing district court's grant of preliminary injunction where there was no "serious question" going to the merits of the claim and, consequently, reversing district court's denial of motion to dismiss as to that claim); *Kelley v. Mortg. Elec. Registration Sys., Inc.*, 642 F. Supp. 2d 1048, 1059 (N.D. Cal. 2009) (granting motions to dismiss and therefore denying motion for preliminary injunction for failure to show likelihood of success on the merits); *Washington v. O'Dell*, No. 3:17-CV-1615-MMA-PCL, 2018 WL 1942372, at *10 (S.D. Cal. Apr. 25, 2018) (denying preliminary injunction when granting motion to dismiss); *Physician's Surrogacy, Inc. v. German*, No. 17CV718-MMA (WVG), 2018 WL 638229, at *11 (S.D. Cal. Jan. 31, 2018) (same); *Wallace v. Sosa*, No. 16-CV-01501-BAS-BGS, 2017 WL 469140, at *4–5 (S.D. Cal. Feb. 3, 2017) (same); *Ananiev v. Aurora Loan Servs., LLC*, No. C 12-2275 SI, 2012 WL 2838689, at *8 (N.D. Cal. July 10, 2012) (same).

CONCLUSION

For the reasons discussed above, the Court **DENIES** Plaintiffs' Motion for Preliminary Injunction (ECF No. 6) and **GRANTS** Defendants' Motion to Dismiss (ECF No. 26). Plaintiffs' Complaint and Supplemental Complaint are **DISMISSED**

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WITHOUT PREJUDICE. Plaintiffs may file an amended complaint within thirty (30) days of the date on which this Order is electronically docketed. IT IS SO ORDERED. Dated: March 29, 2021 United States District Judge