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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

R.J. REYNOLDS TOBACCO COMPANY; R.J. REYNOLDS VAPOR COMPANY; AMERICAN SNUFF COMPANY, LLC; SANTA FE NATURAL TOBACCO COMPANY, INC.; NEIGHBORHOOD MARKET ASSOCIATION, INC.; MORIJA, LLC dba Vapin' the 619; PHILIP MORRIS USA INC.; JOHN MIDDLETON CO.; U.S. SMOKELESS TOBACCO COMPANY LLC; and HELIX INNOVATIONS LLC,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Attorney General of California; and SUMMER STEPHAN, in her official capacity as District Attorney for the County of San Diego,

Defendants.

3:20-cv-01990-JLS-WVG

DEFENDANT ATTORNEY GENERAL BECERRA'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Date: December 10, 2020
Time: 1:30 p.m.
Courtroom: 4D
Judge: The Honorable Janis L. Sammartino
Trial Date:
Action Filed: 10/9/2020

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INTRODUCTION

Reflecting the increased recognition of flavors as a driver of tobacco initiation, localities around the country have enacted ordinances limiting or eliminating the lawful sale of flavored tobacco. *See generally* Am. Nonsmokers' Rights Found., Municipalities Prohibiting the Sale of Flavored Tobacco Products (2020), https://no-smoke.org/wp-content/uploads/pdf/flavored-tobacco-product-sales.pdf (cataloguing 207 such restrictions). With California's passage this year of S.B. 793, it stands poised to become the second state to enact statewide flavor restrictions. *See* Act of Aug. 28, 2020 ("S.B. 793"), 2020 Cal. Legis. Serv. ch. 34 (West) (to be codified at Cal. Health & Safety Code § 104559.5). S.B. 793 enacts statewide restrictions on the sale of flavored tobacco products, prohibiting their sale at retail effective January 1, 2021.

Plaintiffs' challenge to S.B. 793 is not unique. Across the country, plaintiffs—including several of the Plaintiffs and attorneys in this suit—have challenged these state and local "flavor bans," claiming them to be preempted by the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 15 U.S.C. §§ 1331–1340, 4401–4408; 21 U.S.C. §§ 387–387u). In every instance, the restrictions on the sale of flavored tobacco products have been found constitutional and consonant with the TCA. *See U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82–83 (1st Cir. 2013); *Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015); *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, CV 20-4880 DSF (KSx), 2020 WL 4390375, at *6 (C.D. Cal. July 13, 2020); *R.J. Reynolds Tobacco Co. v. City of Edina*, Case No. 20-CV-1402 (PJS/LIB), 2020 WL 5106853, at *9 (D. Minn. Aug. 31, 2020).

Plaintiffs here seek to preliminarily enjoin the enforcement of S.B. 793, relying again on the same consistently rejected preemption arguments. Those

arguments continue to lack any force: the TCA's robust and express preemption scheme specifically preserves states' authority to implement sales restrictions such as S.B. 793. And even if the legal question was colorable (which it is not), the importance of flavor restrictions in protecting the health and lives of California residents tilts the balance of equities in favor of allowing the law to take effect on January 1, 2021. Plaintiffs' Motion for Preliminary Injunction, ECF No. 6, against the enforcement of S.B. 793 should be denied.

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy . . . ." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). "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." *Id.* at 20. The Ninth Circuit uses a "sliding scale approach under which a preliminary injunction could issue where the likelihood of success is such that 'serious questions going to the merits were raised and the balance of the hardships tips sharply in [plaintiff's] favor.'" *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011) (quoting *Clear Channel Outdoor Inc. v. City of Los Angeles*, 340 F.3d 810, 813 (9th Cir. 2003)) (alteration in original). At the same time, if there is "no likelihood of success on the merits of their . . . claims, plaintiffs are not entitled to a preliminary injunction" and there is no need to address the balance of the hardships to each party. *Coal. for Econ. Equity v. Wilson*, 122 F.3d 692, 710 (9th Cir. 1997).

Where, as here, a plaintiff challenges a law based on an assertion that the state's action is preempted by operation of federal law, "[t]he purpose of Congress is the ultimate touchstone." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (alteration in original)). And "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)). This flows from the presumption "that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (alteration in original).

ARGUMENT

I. PLAINTIFFS HAVE NO LIKELIHOOD OF SUCCESS ON THE MERITS AND THEIR MOTION THUS FAILS AS A MATTER OF LAW

Plaintiffs' preemption arguments fail as a matter of law, and accordingly, Plaintiffs have no likelihood of success on the merits. For that reason alone, Plaintiffs' Motion for Preliminary Injunction should be denied.

A. The TCA's Preservation of State and Local Authority Sweeps Broadly and S.B. 793 is not Preempted

The TCA "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." *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 434 (1st Cir. 2013). Because S.B. 793 implements a retail sales regulation, it is not preempted, but instead within the broad authority preserved for the states.

1. S.B. 793 Implements a Retail Sales Restriction

S.B. 793 provides that "[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." S.B. 793, sec. 1, § 104559.5(b)(1). "Flavored tobacco products" are defined as "any tobacco product that contains a constituent that imparts a characterizing flavor." *Id.* sec. 1, § 104559.5(a)(4). And a "characterizing flavor" is in turn defined as "a distinguishable taste or aroma, or

both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product." *Id.* sec. 1, § 104559.5(a)(1).

S.B. 793 is on its face a sales restriction. It bans retail sales of a particular class of tobacco products—flavored tobacco products. It does not matter what or how an ingredient is added to a tobacco product that gives that product a characterizing flavor: "A tobacco product shall *not* be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information. Rather, it is the *presence* of a distinguishable taste or aroma, or both, . . . that constitutes a characterizing flavor." *Id.* (emphasis added).[1] But if the finished tobacco product, however manufactured, has a taste or aroma other than tobacco, it cannot be sold at retail.

2. The TCA Distinguishes Between Measures Relating to Sales and Manufacturing, Preserving the States' Authority Over Sales

"Where Congress enacts an express preemption provision," as it has in the TCA, courts "interpret the provision and 'identify the domain expressly pre-empted by that language.'" *Chae v. SLM Corp.*, 593 F.3d 936, 942 (9th Cir. 2010) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). In doing so, courts "use the text of the provision, the surrounding statutory framework, and Congress's stated purposes in enacting the statute to determine the proper scope of an express preemption provision." *Id.* (citing *Medtronic*, 518 U.S. at 485–86; *Cipollone*, 505 U.S. at 516). Here, the express statutory language and the surrounding framework demonstrate that Congress did not intend to preempt state flavored tobacco sales bans like S.B. 793.

[1] S.B. 793 also makes two clarifications by defining the "constituents" that can be said to impart a characterizing flavor and thus render a tobacco product unavailable for sale at retail. First, those "constituents" exclude tobacco and reconstituted tobacco, with the sole significance of ensuring that only flavors other than tobacco are included in the retail sales ban. *See* S.B. 793, sec. 1, § 104559.5(a)(2). Second, it does not matter how or at what point in the manufacturing process the non-tobacco flavor is added: "'Constituent' means any[thing] . . . added by the manufacturer to a tobacco product during the processing, manufacture, or packing of the tobacco product." *Id.*

Section 916 of the TCA, 21 U.S.C. § 387p, sets out the relationship between state and federal authority over tobacco products. It starts with the Preservation Clause, which sweeps broadly and preserves for the states and their localities virtually all regulatory authority over tobacco products except to set tobacco regulations less stringent than those imposed by the TCA. It includes the power "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" the TCA. *Id.* § 387p(a)(1). It goes on to provide examples of state authority. State authority includes, but is not limited to, "law[s], rule[s], regulation[s], or other measure[s] 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." *Id.*

The Preemption Clause follows, providing certain limited exceptions to the Preservation Clause. All of those exceptions address specific elements of the TCA that are of uniquely federal concern because they address the manufacture of tobacco products: "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, [and] modified risk tobacco products." *Id.* § 387p(a)(2)(A) (preempting "any requirement which is different from, or in addition to, any requirement under [the TCA] relating to" those eight topics). Together, preemption over these enumerated areas preserve from state interference a single federal regime for the manufacture and introduction into interstate commerce of tobacco products.

Finally,[2] the Savings Clause returns some authority relating to these eight categories to the states. That is, states and localities may implement restrictions "relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk

[2] Section 916(b) of the TCA, 21 U.S.C. § 387p(b), addresses state product liability law, and is not relevant here.

tobacco products," under certain circumstances. Relevant here, they can do so when the restriction is "relating to the sale . . . of[] tobacco products." *Id.* § 387p(a)(2)(B).

This three-part structure makes clear that the TCA distinguishes between measures related to manufacturing—which are preempted—and measures related to sales—which are not. The Second Circuit explained the different treatment of manufacturing standards and sales restrictions in *U.S. Smokeless* when it rejected arguments identical to those put forth by Plaintiffs here. By specifically enumerating restrictions "relating to the sale" of tobacco products in the Savings Clause, "§ 916 distinguishes between manufacturing and the retail sale of finished products." 708 F.3d at 434. Moreover, the distinction specifically contemplates complete bans on the sales of certain products, leaving such authority to the states. Indeed, if retail sales bans such as S.B. 793 were found preempted, it "would 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); *see also Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82 (1st Cir. 2013) (rejecting the plaintiffs' contention that bans of flavored tobacco products "impose a new product or manufacturing standard in violation of the preemption provision"); *Indeps. Gas & Serv. Stations Ass'ns, Inc. v. City of Chicago*, 112 F. Supp. 3d. 749, 754 (N.D. Ill. 2015) (finding a flavored tobacco product sales ban not preempted because it "regulates flavored tobacco products without regard for how they are manufactured").

This conclusion becomes even clearer when examining the purposes of the TCA as a whole. First, the TCA was written against historical state regulation of tobacco products. In 1998, forty-six states and four territories joined together to secure the tobacco Master Settlement Agreement ("MSA") with the major manufacturers. This "landmark agreement," *Lorillard Tobacco Co. v. Reilly*, 533

U.S. 525, 533 (2001), placed extensive restrictions on the manufacturers' sales and marketing practices, and provided for annual payments to the states in perpetuity.[3] States, bolstered by enforcement powers under the MSA and a public increasingly mindful of the dangers of tobacco products, passed a host of laws regulating the sale and use of cigarettes and tobacco products, placing restrictions on non-face-to-face tobacco sales, *see, e.g.*, Stop Tobacco Access to Kids Enforcement ("STAKE") Act of 2002, ch. 685, 2002 Cal. Stat. 4129 (codified at Cal. Bus. & Prof. Code § 22963); requiring licensing up and down the distribution chain, *see, e.g.*, Cigarette and Tobacco Products Licensing Act of 2003, ch. 890, 2003 Cal. Stat. 6496 (codified at Cal. Bus. & Prof. Code §§ 22970–22995); and even regulating, in the absence of federal standards, the manufacture of tobacco products, *see, e.g.*, California Cigarette Fire Safety and Firefighter Protection Act of 2005, ch. 633, 2005 Cal. Stat. 4830 (codified at Cal. Health & Safety Code §§ 14950–14960).

It was against this accumulated backdrop of state regulation that Congress passed and the President signed the Tobacco Control Act. Thus, as explained above, Congress specifically preserved state authority, and reserved to the FDA only those novel manufacturing regulations introduced by the TCA—product standards, premarket review, adulteration, misbranding, registration, good manufacturing practices, and modified risk tobacco products—or previously already reserved to the federal government—labeling, *see* 21 U.S.C. § 387p(a)(2)(A). Even then, the TCA enabled the states to maintain authority over tobacco product manufacturing where they had already acted. For example, the TCA preserved the already extant state regulation of fire-safe cigarettes, despite being a regulation of tobacco product manufacturing. *See id.* § 387p(a)(2)(B) (saving from preemption all measures "relating to fire safety standards for tobacco products").

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[3] The text of the MSA can be found at http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf.

Second, Congress made its intent explicit in its findings, stating it was concerned with "national standards controlling the *manufacture* of tobacco products and the identity, public disclosure, and amount of ingredients used in such products." 21 U.S.C. § 387 note (emphasis added).

Finally, all of the preempted areas address manufacture of tobacco products and the related issue of their introduction into the United States. For example, under section 901 of the TCA, a tobacco product is "adulterated" if, among other things, "it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." *Id.* § 387b(2). Similarly, premarket review requires an analysis of "the components, ingredients, additives, and properties, and of the principle or principles of operation, of [new] tobacco product[s]," as well as "the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, [new] tobacco product[s]." *Id.* § 387j(b)(1). Indeed, even "registration" is directed at "person[s] who own[] or operate[] any establishment . . . engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products." *Id.* § 387e(b); *see also id.* § 387e(c) (new owners/operators); *id.* § 387e(d) (new establishments); *id.* § 387e(h) (foreign establishments).

Thus it is clear, as the Second Circuit concluded, that the TCA "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*, 708 F.3d at 434.

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3. Plaintiffs Ignore the TCA as a Whole, and Instead Rely on Selective Readings of Both the TCA and Caselaw to Argue in Favor of Preemption

Plaintiffs do not engage with the holistic analysis required to determine the scope of the TCA's preemptive effect, but instead rely on selective readings of both the TCA and caselaw to reach their desired conclusion.

a. Statutory Language

Plaintiffs selectively isolate portions of the TCA to claim that S.B. 793 sets a tobacco product standard and thus preempted. Looking to section 907 of the TCA, 21 U.S.C. § 387g, which addresses tobacco product standards, Plaintiffs claim that "'tobacco product standards' cover more than just manufacturing" because "the [TCA] explicitly lists 'labeling' relating to 'the proper use of the tobacco product' as an example." Mem. P. & A. Supp. Pls.' Mot. Prelim. Inj. ("Pls.' Mot. Prelim. Inj.") 12, ECF No. 6-1 (quoting 21 U.S.C. § 387g(a)(4)(C)). But labeling is itself a component of manufacturing—a tobacco product includes its packaging. *See* 21 C.F.R. § 1140.3 (defining "manufacturer" as including one who "labels a finished tobacco product"); *id.* § 1143.3(a)(1) ("For . . . tobacco products other than cigars, it is unlawful for any person to *manufacture* . . . such product unless the tobacco product package bears the . . . required warning statement on the package label . . . ." (emphasis added)). Additionally, if the inclusion of "labeling" in section 907 is construed to expand the definition of "tobacco product standard" and thus the Preemption Clause's reach, then the separate inclusion of "labeling" in the Preemption Clause is made superfluous. *See United States v. Wenner*, 351 F.3d 969, 975 (9th Cir. 2003) ("It is a fundamental canon of statutory construction that a statute should not be construed so as to render any of its provisions mere surplusage."). It is true that a tobacco product standard may *also* include "a provision requiring that the sale and distribution of the tobacco product be restricted." 21 U.S.C. § 387g(a)(4)(B)(v). But that does not render every sales

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restriction a tobacco product standard, especially in light of the different treatment of the two in section 916.

Plaintiffs also point to one of two "special rules" in section 907 of the TCA—that is, one of two congressionally established tobacco product standards—to claim S.B. 793 is a preempted tobacco product standard. Pls.' Mot. Prelim. Inj. 9–10. That "Special rule for cigarettes" sets a manufacturing standard—cigarettes "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," 21 U.S.C. § 387g(a)(1)(A) (emphasis added)—by regulating the contents of cigarettes. The tobacco product standard the special rule imposes does not prohibit the retail sale of flavored cigarettes; it prohibits cigarettes from containing specific ingredients, and renders any cigarette containing those prohibited ingredients "adulterated." *Id.* § 387b(5); *see also id.* § 331(a), (g) (prohibiting adulterated tobacco products from being "manufacture[d]" or "introduce[ed] or deliver[ed] for introduction into interstate commerce"). The second "special rule" reinforces the focus on manufacturing, proscribing the amount of pesticide residue allowed on the tobacco used to make tobacco products. *See id.* § 387g(a)(1)(B).

Not only does Plaintiffs' selective approach collapse under its own weight, the full text of section 907 and its legislative history remove any doubt that "tobacco product standards" must be concerned with the manufacture of tobacco products. Tobacco product standards are expressly defined as manufacturing regulations aimed at reducing the presence of nicotine and other harmful constituents in tobacco products.

Section 907(a)(3), entitled "Tobacco product standards," describes such standards as "requir[ing] the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the [FDA] has found that the additive, constituent, or other component is or may be harmful." *Id.* § 387g(a)(3)(B)(ii). Thus, they are aimed directly at reducing harm

caused by ingredients themselves. Section 907(a)(4), entitled "Content of Tobacco Product Standards," is written in light of that express definition. It first reiterates that tobacco standards regulate the ingredients of tobacco products, addressing "nicotine yields," *id.* § 387g(a)(4)(A)(i), and "the reduction or elimination of other constituents, including smoke constituents, or harmful components," *id.* § 387g(a)(4)(A)(ii). The section then refers to section 907(a)(4)(B) to describe what may be included in such a standard. *See id.* § 387g(A)(4)(A)(iii). Accordingly, in order to reduce the nicotine or other harmful substances found in tobacco products, the FDA may regulate aspects such as "the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product," *id.* § 387g(a)(4)(B)(i), and how testing and measurement need be performed to show compliance, *see id.* § 387g(a)(4)(B)(ii)–(iv). Finally, if reduction or elimination of particular harmful constituents require sales restrictions to be reasonably effectuated, tobacco product standards can include them. *See id.* § 387g(a)(4)(B)(v).

And in adopting section 907 of the TCA, Congress cited its express purpose in enabling the FDA to enact tobacco product standards as giving the FDA "authority to establish product standards regarding the testing and measurement of products, nicotine yields, constituents, construction, components, ingredients, additives, and all other properties of the tobacco product." H.R. Rep. No. 111-58, pt. 1 at 39–40 (2009), *as reprinted in* 2009 U.S.C.C.A.N. 468, 488.[4] From top to bottom, Congress made clear that tobacco product standards regulate the manufacture of tobacco products to reduce the instance of nicotine or other harmful substances.

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[4] Section 907 of the TCA also allows for two other kinds of tobacco product standards: (1) those setting "labeling for the proper use of the tobacco product," 21 U.S.C. § 387g(a)(4)(C), which is part of manufacturing; and (2) those "requir[ing] tobacco products containing foreign-grown tobacco . . . meet the same standards applicable to tobacco products containing domestically grown tobacco," *id.* § 387g(a)(4)(D), another aspect of manufacturing.

Taken together with section 916, the TCA establishes a clear distinction between manufacturing restrictions and sales restrictions. Manufacturing restrictions are the exclusive province of the federal government, while states are free to enact restrictions on the sale of any tobacco product.

b. Caselaw

As noted above, courts interpreting these preemption provisions of the Tobacco Control Act have consistently reached the conclusion that state sales-based restrictions on tobacco products are permitted under the Act. The First Circuit, Second Circuit, Northern District of Illinois, District of Minnesota, and Central District of California have all addressed the claims Plaintiffs pose here and all have all found that the states have authority under the TCA to ban the sales of flavored tobacco products. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82–83; *U.S. Smokeless*, 708 F.3d at 436; *Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago*, 112 F. Supp. 3d at 754; *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, CV 20-4880 DSF (KSx), 2020 WL 4390375, at *6 (C.D. Cal. July 13, 2020); *R.J. Reynolds Tobacco Co. v. City of Edina*, Case No. 20-CV-1402 (PJS/LIB), 2020 WL 5106853, at *9 (D. Minn. Aug. 31, 2020).

Largely avoiding these cases that address preemption under the TCA, the cases cited by Plaintiffs address wholly different statutes establishing wholly different preemption regimes. For example, Plaintiffs point to *Engine Manufacturers Association v. South Coast Air Quality Management District*, 541 U.S. 246 (2004), for the broad proposition that "a standard is a standard even when not enforced through manufacturer-directed regulation," Pls.' Mot. Prelim. Inj. 12 (quoting *Engine Mfrs. Ass'n*, 541 U.S. at 254). But the Clean Air Act preemption clause at issue bears no resemblance to the TCA's, and the Court's analysis flowed directly from the statutory text of the Clean Air Act, not the TCA. *See Engine Mfrs.*, 541 U.S. at 252 ("Statutory construction must begin with the language employed by Congress . . . ."). That clause provided:

> No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No State shall require certification, inspection, or any other approval relating to the control of emissions . . . as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.

42 U.S.C. § 7543(a). Congress did not separate out product standards and sales restrictions for different preemptive treatment in the Clean Air Act as it did in the TCA. Instead, it broadened the preemption of measures relating to standards to sweep up not only standards themselves, but also any "attempt to enforce" standards that differ from the federal ones. The statute's text made clear that "Congress contemplated the enforcement of emission standards through purchase requirements," and the defendant implemented a purchase requirement related to emissions standards. *Engine Mfrs. Ass'n*, 541 U.S. at 254. These purchase restrictions were thus preempted as an "attempt to enforce" an emission standard. *See id.* This is not the approach Congress took regarding the TCA. Instead, it limited preemption specifically to "establish[ing] or continu[ing] in effect" only "requirement[s] . . . relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A). S.B. 793 does not establish—or continue in effect—any tobacco product standard.

National Meat Association v. Harris, 565 U.S. 452 (2012), similarly addressed a preemption clause bearing little resemblance to the statute at issue here. Regardless, Plaintiffs cite it for the broad proposition that sales restrictions are preempted because a "'sales . . . ban functions as a command to [manufacturers] to structure their operations' in a particular way by imposing a 'ban on the sale of [a product] produced in whatever way the State disapproved." Pls.' Mot. Prelim. Inj. 13 (quoting *Nat'l Meat*, 565 U.S. at 464 (alterations in original)). First, the preemption clause of the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§ 601–695, at issue did not set out different treatment for sales restrictions, *see id.* § 678, as does the TCA. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82 (finding

National Meat "easily distinguishe[d]" from the TCA because the FMIA "did not contain a savings clause that expressly exempted regulations 'relating to the sale' of the product from preemption").

Second, the state statute at issue there functioned in a fundamentally different way than the sales ban at issue here. *National Meat* addressed a California law prohibiting slaughterhouses from buying or selling nonambulatory animals or their meat, as well as the processing of such animals. *See Nat'l Meat*, 565 U.S. at 458–59. The prohibition on the sale of meat derived from nonambulatory animals was preempted not because, as Plaintiffs contend, sales restrictions *per se* place restrictions on a manufacturer's operations, but because of the specific operation of the statute itself. The sales ban "operate[d] within [the state statute] as a whole . . . to help implement and enforce each of the [statute's] other regulations—its prohibition of receipt and purchase, its bar on butchering and processing, and its mandate of immediate euthanasia." *Nat'l Meat*, 565 U.S. at 463–64. Moreover, in *National Meat*, as the Central District of California recognized in finding the case inapplicable to Los Angeles County's ban on the sale of flavored tobacco, "the *only* way to determine whether a product was banned was to consider how it was manufactured." *R.J. Reynolds v. County of Los Angeles*, 2020 WL 4390375, at *5.

Plaintiffs next claim "the Preemption Clause would be rendered a nullity" if states "could simply work around the preemption clause by framing its law a sales ban." Pls.' Mot. Prelim. Inj. 14. But that is not the case here. Whether a tobacco product is flavored is determinable only by examination of the finished product and does not intrude on what is preempted by the TCA, i.e., how tobacco products are made; ingredients and processes. *Cf. Nat'l Meat*, 565 U.S. at 467. By its text and operation, S.B. 793 does not prohibit any specific additives or otherwise place any restrictions on the contents of any particular tobacco product. Nor does it demand the tobacco products be made in any particular way. But if any combination of the ingredients and processes used in manufacture results in a flavored tobacco product,

that product cannot be sold at retail in California. *See R.J. Reynolds v. County of Los Angeles*, 2020 WL 4390375, at *5 ("Here, banned products can be identified based on how they are marketed and sold.").

4. S.B. 793 Escapes Preemption Even Under a Broad Reading of "Relating to Tobacco Product Standards"

As noted above, every court to address bans on the sale of flavored tobacco products have found them to be within the states' authority under the TCA. Moreover, all but one has found that such bans are not "relating to tobacco product standards" at all and thus not subject to the Preemption Clause. *See City of Edina*, 2020 WL 5106853, at *3 (applying the Preemption Clause despite "[o]ther courts . . . holding . . . that a *sales* regulation is not a tobacco-product standard unless it is a de facto manufacturing regulation"). And even that court agreed that flavored tobacco sales bans are not preempted. Accordingly, under either analysis, S.B. 793 is not preempted.

In one respect, the Minnesota District Court departed from other courts, concluding that a retail sales ban on flavored tobacco products is "a provision respecting a 'propert[y]'" of tobacco products, and thus "relating to tobacco product standards." *Id.* at *4 (quoting 21 U.S.C. § 387g(a)(4)) (alteration in original). It also concluded that "[t]here 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." *Id.* (citing *Nat'l Meat*, 565 U.S. at 464). As explained above, that analysis is incorrect. *See supra*, subsection I.A.3.a, at pp. 9–12 (explaining statutory distinction between sales restrictions and manufacturing restrictions); *supra*, subsection I.A.3.b, at pp. 12–15 (explaining distinction between sales restrictions that act as manufacturing restrictions and those that do not).

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But even under its analysis, the Minnesota District Court maintained section 916's distinction between tobacco manufacture and sales: "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.'" *Id.* at *4 (quoting 21 U.S.C. § 387p(a)(2)(B)) (alterations in original). That is, the difference between *City of Edina*'s analysis and that of other courts' that have addressed flavored tobacco sales bans, is superficial and all of them reach the same conclusion. Sales bans are expressly not preempted because of the TCA's different treatment of measures "relating to sales," which requires a different result for measures aimed at the manufacture of tobacco products and those aimed at the sales of tobacco products. Whether construed as outside the scope of the Preemption Clause or saved by the Savings Clause, S.B. 793 is not preempted. Congress expressly preserved the authority of states to enact sales restrictions, and S.B. 793 is exactly that.

5. S.B. 793 Escapes Preemption Whether or Not It Is Properly Construed as a Prohibition

As noted above, the Savings Clause of the TCA operates to return to the states certain authority otherwise preempted by the Preemption Clause. To succeed on this motion then, Plaintiffs must answer not one issue but two—it is not enough to say that the flavor ban is preempted by the Preemption Clause; they must also show that it is not then saved by the Savings Clause.

The Savings Clause specifically reserves to the states authority to establish "requirements relating to the sale of . . . tobacco products." 21 U.S.C. § 387p(a)(3). As S.B. 793 literally establishes the conditions under which the sale of certain tobacco products can or cannot proceed, the plain meaning of this provision is satisfied, irrespective of one's reading of the Preemption Clause. So concluded the district court in *City of Edina*. *See* 2020 WL 5106853, at *4.

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Attempting to avoid the obvious, Plaintiffs argue that because S.B. 793 is a "prohibition" on retail sales of flavored tobacco products, it falls outside of the Savings Clause's preservation of state authority for "requirements relating to the sale of . . . tobacco products"—that is, Plaintiffs argue that a prohibition is not a "requirement." Pls.' Mot. Prelim. Inj. 17. Even assuming S.B. 793's restrictions on retail sales of flavored tobacco products is properly construed as a "prohibition," Plaintiffs' arguments fall flat. Plaintiffs claim that because the Preservation Clause mentions measures "relating to" requirements set by the TCA as well as measures "prohibiting the sale" of tobacco products, those two concepts are distinct. Thus, they continue, "Congress excluded sales prohibitions from the class of non-preempted laws in the Savings Clause." *Id.* But Plaintiffs fail to carry their logic to its natural conclusion. If a prohibition is not a "requirement," then yes, under Plaintiffs' reading it is not saved by the Savings Clause. But it is also not preempted by the Preemption Clause, as it, too, only addresses "requirements." *See City of Edina*, 2020 WL 5106853, at *6 ("If a prohibition is a 'requirement' . . . then the Ordinance is preempted under the preemption clause . . . , but it is saved by the saving clause . . . . If a prohibition is not a 'requirement' . . . then the Ordinance is not preempted under the preemption clause and the saving clause is irrelevant.").

Without support, Plaintiffs claim that the Preemption Clause refers to "'requirements' writ large" and therefore includes prohibitions. Pls.' Mot. Prelim. Inj. 19 n.13. But Plaintiffs give no reason for their conclusion that "requirements" in the Savings Clause do not also include "'requirements' writ large" and thus prohibitions. The argument contradicts itself. Even accepting the premises that S.B. 793 is a "prohibition" and that it is "relating to tobacco product standards," Plaintiffs give no reason why such a prohibition is not also "relating to the sale" of tobacco products. Nor could they. *See Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 933 F.3d 1088, 1095 (9th Cir. 2019) ("[I]t is a well-established principle of statutory construction that the same words or phrases are presumed to have the

same meaning when used in different parts of a statute." (quoting *Prieto-Romero v. Clark*, 534 F.3d 1053, 1061 n.7 (9th Cir. 2008)) (alteration in original)). Instead, and as explained above, because S.B. 793 is directed specifically at sales, it is more closely "relating to the sale" of tobacco products than it is "relating to tobacco product standards," if it is at all.

Finally, as explained above, if a prohibition of the sale of tobacco products establishes a preempted tobacco product standard, then the preservation of state authority to establish such prohibitions would be a nullity. *See U.S. Smokeless*, 708 F.3d at 434; *supra* subsection I.A.2, p. 6.

6. State Regulation Is Not Limited to Age-Based Restrictions

Plaintiffs lastly argue that the phrase "by individuals of any age" in the Savings Clause "limits the scope of the Savings Clause to age-based requirements." Pls.' Mot. Prelim. Inj. 19. This argument makes little sense and has been rejected by both courts that have considered it. "[P]laintiffs' interpretation turns the plain meaning of this phrase on its head." *City of Edina*, 2020 WL 5106853, at *4. Rather, "[t]he plain meaning of that phrase is the opposite of what Plaintiffs suggest—states and localities are free to enact requirements regardless of age." *R.J. Reynolds v. County of Los Angeles*, 2020 WL 4390375, at *5 n.7.

B. S.B. 793 Is Not Impliedly Preempted

Plaintiffs' arguments that S.B. 793 is impliedly preempted start from a faulty premise. Implied preemption occurs only when it is "the clear and manifest purpose of Congress." *Altria Grp.*, 555 U.S. at 77 (quoting *Santa Fe Elevator Corp.*, 331 U.S. at 230). Moreover, the presumption against preemption "applies with particular force when Congress has legislated in a field traditionally occupied by the States," *id.*, such as tobacco sales. That presumption also applies with particular force when Congress specifically legislated to maintain state authority as it did with the TCA. *See Cipollone*, 505 U.S. at 517 ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach

are not pre-empted."). As explained above, the TCA was carefully crafted to maintain the states' traditional role as tobacco regulators.

1. That the FDA Need Follow a Specified Process to Ban Certain Products Nationally Does Not Usurp the States' Power to Ban Sales of Certain Products Within Their Borders

Plaintiffs argue that if the FDA chooses not to take action against a particular product, it affirmatively intends for that product to remain on the market. Indeed, Plaintiffs make this argument twice: once as to menthol cigarettes, *see* Pls.' Mot. Prelim. Inj. 21–22, and once as to flavored electronic nicotine delivery systems ("ENDS"), *see id.* at 22. But 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 as "prov[ing] too much" 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"). That the FDA may not yet have gathered sufficient evidence to meet the strict standard Congress set for the FDA to ban menthol cigarettes, *see* Pls.' Mot. Prelim. Inj. 21–22 (quoting 21 U.S.C. § 387g(a)(3), (b)(2)), does not mean that it has exercised its scientific expertise to determine that keeping menthol cigarettes in the U.S. market benefits the public health.

With regard to ENDS, Plaintiffs stand on even shakier ground, ascribing broad preemptive effect to non-binding guidance used "to prioritize [the FDA's] enforcement resources." FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) 2 (Apr. 2020) [hereinafter, Guidance], https://www.fda.gov/media/133880/download. Such enforcement guidance does not have the effect of law, let alone the power to broaden the scope of Congress's explicit choice to limit the TCA's preemptive reach.

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Like all tobacco products, ENDS are subject to the TCA's premarket authorization provisions. *See* Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,102 (May 3, 2016) (expanding the TCA's regulatory scheme to cover ENDS, among other products). As of the date of this filing, no ENDS product has received premarket authorization. *See* FDA, *Premarket Tobacco Product Authorization Orders* (Jan. 21, 2020), https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders. Accordingly, no ENDS product can lawfully be sold in the United States. *See* Guidance, *supra*, at 3 ("This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization.").

The FDA's limited enforcement resources, however, have resulted in a policy of non-enforcement toward certain ENDS despite their unlawful status under the TCA and the notice-and-comment-promulgated Deeming Rule. But this discretionary allocation of enforcement priorities, even if read as a decision made "expressly [to keep] certain menthol-flavored ENDS products on the market," Pls.' Mot. Prelim. Inj. 22, can hardly be read as expanding the preemptive scope of the TCA, especially in the face of the broad Preservation and Savings Clauses. The FDA's enforcement priorities are no substitute for Congress's express intent. *See Cipollone*, 505 U.S. at 516 ("[T]he purpose of Congress is the ultimate touchstone." (quoting *White Motor Corp.*, 435 U.S. at 504)). Indeed, FDA non-enforcement policies of the kind Plaintiffs rely on have been found contrary to the TCA itself. *See Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 494 (D. Md. 2019) ("[T]he decision here, not to enforce the premarket review requirements against any manufacturers, . . . is inconsistent with the Tobacco Control Act and in excess of [the FDA's] statutory authority, and it cannot stand."). Moreover, given that no ENDS product has lawful status, California's decision to prohibit a subset of

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those products can hardly be said to "actually conflict[] with federal law." Pls.' Mot. Prelim. Inj. 20 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).[5]

2. Congress Specifically Retained States' Authority to Ban Tobacco Products and Such Bans Are Not Impliedly Preempted

Plaintiffs also argue that S.B. 793 amounts to a "regulatory assessment" of new tobacco products, and thus conflicts with the premarket authorization process of the TCA. Pls.' Mot. Prelim. Inj. 23. That process requires tobacco products "not commercially marketed in the United States as of February 15, 2007," receive premarket authorization from the FDA prior to being marketed in the United States. 21 U.S.C. § 387j(a). Applicants must provide detailed information to the FDA, including "full reports of all information . . . concerning investigations which have been made to show the health risks of [the] tobacco product," 21 U.S.C. § 387j(b)(1)(A), "a full statement of the components, ingredients, additives, and properties . . . of [the] tobacco product," *id.* § 387j(b)(1)(B), and exemplars of both the product and its labeling, *id.* § 387j(b)(1)(E)–(F). The FDA must then conduct a particularized inquiry into the tobacco product in question and determine whether its introduction "would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). S.B. 793 requires no such assessment, creates no new "review processes," Pls.' Mot. Prelim. Inj. 23, and is instead fully consonant with the TCA.

Plaintiffs' arguments otherwise prove too much. S.B. 793 simply bans the retail sale of a specific category of product. If S.B. 793's "regulatory assessment"—is the product flavored or not?—is impliedly preempted then no state sales prohibition could escape preemption, making a nullity of the TCA's explicit

[5] Ultimately, Plaintiffs resort to a policy argument, contending that unless Senate Bill 793 is preempted, "state laws could prohibit all flavored tobacco products no matter how compelling the scientific evidence that such bans could backfire and undermine health claims." Pls.' Mot. Prelim. Inj. 22. Plaintiffs' fears, however, are no substitute for Congress's explicit preservation of state authority, and the California Legislature's exercise of that authority. Moreover, there is no compelling evidence that flavored tobacco products—menthol or otherwise—are beneficial to the public health. Should such evidence emerge, both Congress and the California Legislature retain the authority to revisit the law to account for it.

preservation of the states' powers of "prohibiting the sale, distribution, [or] possession . . . of tobacco products." 21 U.S.C. § 387p(a)(1). Moreover, the legislative history shows a conscious decision by Congress to allow states to ban tobacco sales, either fully or as to certain products, if they wished. *See U.S. Smokeless*, 708 F.3d at 433 n.1 ("Earlier versions of § 907 would have expressly reserved to the federal government authority to ban the sale of entire categories of tobacco products. These draft versions . . . were eventually rewritten to deny such power only to the FDA . . . ." (citations omitted)); *Berger v. Philip Morris USA, Inc.*, 185 F. Supp. 3d 1324, 1340 (M.D. Fla. 2016) ("Congress thus made plain what one would otherwise presume: that the states retained broad authority to regulate cigarettes, and specifically, to ban their sale, distribution, possession, or use outright."). S.B. 793 implements a retail restriction on a discrete class of tobacco products, and the only "regulatory assessment" required is identification of those tobacco products.

II. THE BALANCE OF THE EQUITIES DOES NOT SUPPORT THE EXTRAORDINARY REMEDY OF ISSUING A PRELIMINARY INJUNCTION

As noted above, every preemption challenge to state or local flavored tobacco sales bans has failed as legally deficient. Moreover, in every instance where the plaintiffs sought preliminary injunctions, their challenges failed to "demonstrate[] serious questions going to, or a likelihood of success on, the merits of their . . . preemption claim[s]," and there was no need to address the balance of equities. *R.J. Reynolds v. Los Angeles County*, 2020 WL 4390375, at *6, *7; *see also U.S. Smokeless Mfg. Co. v. City of New York*, 703 F. Supp. 2d 329, 348 (S.D.N.Y. 2010) ("[T]he Court does not reach the question of whether plaintiffs have established irreparable injury."); *City of Edina*, 2020 WL 5106853, at *9 (denying a motion for preliminary injunction solely because the flavored tobacco sales ban was "neither expressly nor impliedly preempted"). Here, there is also no

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need to address the balance of the equities—S.B. 793 clearly is not preempted and Plaintiffs have no likelihood of success on the merits.

But even balancing the equities, Plaintiffs' motion should be denied. In arguing they will suffer irreparable harm, Plaintiffs rely primarily on their claim that S.B. 793 is unconstitutional. *See* Pls.' Mot. Prelim. Inj. 24 ("Being forced to comply with an unconstitutional law is by definition irreparable harm."). But as demonstrated above, S.B. 793 is not unconstitutional. *See Ass'n des Éleveurs de Canards et d'Oies du Québec v. Harris*, 2:12-cv-05735-SVW-RZ, 2012 WL 12842942, at *11 (C.D. Cal. Sept. 28, 2012) ("[G]iven that Plaintiffs are unlikely to succeed on the merits, Plaintiffs' argument that it is '"in the public interest to terminate the unconstitutional application" of a statute' is inapplicable.").

Plaintiffs next claim they will endure "substantial financial losses," Pls.' Mot. Prelim. Inj. 24, without entry of a preliminary injunction. But California is just one market and nothing in S.B. 793 prevents the manufacturer Plaintiffs from making or marketing exactly the same products they currently make and market or from selling their non-flavored products in California. Indeed, tobacco products are routinely manufactured and sold only in certain markets for certain periods, whether in response to shifts in consumer tastes or market regulation, and halting sales of flavored products to California is no different.

Similarly, nothing in S.B. 793 keeps the retailer Plaintiffs from selling any of the myriad non-flavored tobacco products to their customers. Even if irreparable due to the state's sovereign immunity, marginal lost sales is not a compelling interest that can meet the high standard necessary for issuance of a preliminary injunction. *See All. for the Wild Rockies*, 632 F.3d at 1135 (requiring the plaintiff show "the balance of hardships tips *sharply* in [plaintiff's] favor" to grant a motion for preliminary injunction (alteration in original) (emphasis added)). Indeed, when challenging other flavored tobacco sales bans, some of the very same parties that are also Plaintiffs in this action did not find their interest in flavored tobacco sales

sufficient to file suit until after the bans already went into effect. *See R.J. Reynolds v. County of Los Angeles*, 2020 WL 4390375, at *1 (R.J. Reynold Tobacco Co.; American Snuff Co., LLC; and Santa Fe Natural Tobacco Co.); *U.S. Smokeless*, 703 F. Supp. 2d at 332 (U.S. Smokeless Manufacturing Co.); *Neighborhood Market Ass'n v. County of San Diego*, Case No. 3:20-cv-01124-JLS-WVG (S.D. Cal. filed June 19, 2020) (Neighborhood Market Ass'n and Vapin' the 619)

On the other side of the scale rests the state's interest in the public health, *see Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) ("When the government is a party, [the balance of the equities and the public interest] factors merge."), an undoubtedly compelling interest, *see Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905) ("The safety and the health of the people . . . are, in the first instance, for th[e states] to guard and protect."). Plaintiffs argue that "the state will suffer little or no harm from a preliminary injunction because it would merely maintain the status quo temporarily." Pls.' Mot. Prelim. Inj. 8. Plaintiffs do not, however, describe the status quo. Currently, smoking is "responsible for more than 480,000 deaths per year in the United States" constituting "about one in five deaths annually." Ctrs. for Disease Control, Smoking & Tobacco Use: Fast Facts, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (last updated May 21, 2020). Moreover, the total economic cost in the United States is "more than $300 billion a year." *Id.* And "[e]ach day, about 2000 people younger than 18 years smoke their first cigarette." *Id.* Thousands more try other tobacco products like ENDS for the first time, placing them on the path to addiction.

Many of those underage users' first tobacco product is a flavored one. The vast majority of youth who begin smoking start with a flavored product, including 81.0% of ENDS users and 50.1% of cigarette users. Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12–17 Years, 2013–2014*, 314 J. Am. Med. Ass'n 1871, 1872 (2015). Indeed, in 2019, 86.4% of California high school students who used tobacco reported that they used a flavored product.

Cal. Dep't of Pub. Health, California Tobacco Facts and Figures 2019, at 12 (May 2019), https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/FactsandFigures/CATobaccoFactsandFigures2019.pdf. Enjoining enforcement of S.B. 793 would only risk additional Californians, especially younger Californians, contracting a life-long addiction to nicotine.

CONCLUSION

For the reasons provided above, Plaintiffs' Motion for Preliminary Injunction, ECF No. 6, should be denied. S.B. 793 represents an exercise of state authority specifically preserved by the Tobacco Control Act, and is not preempted. Moreover, the state's interest in the health of its residents outweigh the potential marginal lost sales that might result from enforcement of S.B. 793, and the Court should not enjoin it from coming into effect on January 1, 2021.

Dated: November 12, 2020

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