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10 IN THE UNITED STATES DISTRICT COURT  
 11 FOR THE SOUTHERN DISTRICT OF CALIFORNIA

13  
 14 **R.J. REYNOLDS TOBACCO**  
**COMPANY; R.J. REYNOLDS**  
 15 **VAPOR COMPANY; AMERICAN**  
**SNUFF COMPANY, LLC; SANTA**  
 16 **FE NATURAL TOBACCO**  
**COMPANY, INC.;**  
 17 **NEIGHBORHOOD MARKET**  
**ASSOCIATION, INC.; MORIJA,**  
 18 **LLC dba Vapin' the 619; PHILIP**  
**MORRIS USA INC.; JOHN**  
 19 **MIDDLETON CO.; U.S.**  
**SMOKELESS TOBACCO**  
 20 **COMPANY LLC; and HELIX**  
**INNOVATIONS LLC,**

21 Plaintiffs,

22 v.

23  
 24 **XAVIER BECERRA, in his official**  
**capacity as Attorney General of**  
 25 **California; and SUMMER**  
**STEPHAN, in her official capacity as**  
 26 **District Attorney for the County of**  
**San Diego,**

27 Defendants.  
 28

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

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

13 Plaintiffs’ challenge to S.B. 793 is not unique. Across the country, plaintiffs—  
14 including several of the Plaintiffs and attorneys in this suit—have challenged these  
15 state and local “flavor bans,” claiming them to be preempted by the Family  
16 Smoking Prevention and Tobacco Control Act of 2009 (“Tobacco Control Act” or  
17 “TCA”), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 15 U.S.C. §§ 1331–  
18 1340, 4401–4408; 21 U.S.C. §§ 387–387u). In every instance, the restrictions on  
19 the sale of flavored tobacco products have been found constitutional and consonant  
20 with the TCA. *See U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d  
21 428, 436 (2d Cir. 2013); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*,  
22 731 F.3d 71, 82–83 (1st Cir. 2013); *Indeps. Gas & Serv. Stations Ass’ns v. City of*  
23 *Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015); *R.J. Reynolds Tobacco Co. v.*  
24 *County of Los Angeles*, CV 20-4880 DSF (KSx), 2020 WL 4390375, at \*6 (C.D.  
25 Cal. July 13, 2020); *R.J. Reynolds Tobacco Co. v. City of Edina*, Case No. 20-CV-  
26 1402 (PJS/LIB), 2020 WL 5106853, at \*9 (D. Minn. Aug. 31, 2020).

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

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

### 8 LEGAL STANDARD

9 “A preliminary injunction is an extraordinary remedy . . . .” *Winter v. Nat.*  
10 *Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). “A plaintiff seeking a preliminary  
11 injunction must establish that he is likely to succeed on the merits, that he is likely  
12 to suffer irreparable harm in the absence of preliminary relief, that the balance of  
13 equities tips in his favor, and that an injunction is in the public interest.” *Id.* at 20.  
14 The Ninth Circuit uses a “sliding scale approach under which a preliminary  
15 injunction could issue where the likelihood of success is such that ‘serious  
16 questions going to the merits were raised and the balance of the hardships tips  
17 sharply in [plaintiff’s] favor.’” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127,  
18 1131 (9th Cir. 2011) (quoting *Clear Channel Outdoor Inc. v. City of Los Angeles*,  
19 340 F.3d 810, 813 (9th Cir. 2003)) (alteration in original). At the same time, if there  
20 is “no likelihood of success on the merits of their . . . claims, plaintiffs are not  
21 entitled to a preliminary injunction” and there is no need to address the balance of  
22 the hardships to each party. *Coal. for Econ. Equity v. Wilson*, 122 F.3d 692, 710  
23 (9th Cir. 1997).

24 Where, as here, a plaintiff challenges a law based on an assertion that the  
25 state’s action is preempted by operation of federal law, “[t]he purpose of Congress  
26 is the ultimate touchstone.” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516  
27 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (alteration  
28 in original)). And “when the text of a pre-emption clause is susceptible of more



1 than one plausible reading, courts ordinarily ‘accept the reading that disfavors  
 2 preemption.’” *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Bates v.*  
 3 *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). This flows from the  
 4 presumption “that the historic police powers of the States [are] not to be superseded  
 5 by the Federal Act unless that was the clear and manifest purpose of Congress.” *Id.*  
 6 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (alteration in  
 7 original).

## 8 ARGUMENT

### 9 I. PLAINTIFFS HAVE NO LIKELIHOOD OF SUCCESS ON THE MERITS AND 10 THEIR MOTION THUS FAILS AS A MATTER OF LAW

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

#### 14 A. The TCA’s Preservation of State and Local Authority Sweeps 15 Broadly and S.B. 793 is not Preempted

16 The TCA “reserves regulation at the manufacturing stage exclusively to the  
 17 federal government, but allows states and localities to continue to regulate sales and  
 18 other consumer-related aspects of the industry.” *U.S. Smokeless Tobacco Mfg. Co.*  
 19 *v. City of New York*, 708 F.3d 428, 434 (1st Cir. 2013). Because S.B. 793  
 20 implements a retail sales regulation, it is not preempted, but instead within the  
 21 broad authority preserved for the states.

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

23 S.B. 793 provides that “[a] tobacco retailer, or any of the tobacco retailer’s  
 24 agents or employees, shall not sell, offer for sale, or possess with the intent to sell  
 25 or offer for sale, a flavored tobacco product.” S.B. 793, sec. 1, § 104559.5(b)(1).  
 26 “Flavored tobacco products” are defined as “any tobacco product that contains a  
 27 constituent that imparts a characterizing flavor.” *Id.* sec. 1, § 104559.5(a)(4). And a  
 28 “characterizing flavor” is in turn defined as “a distinguishable taste or aroma, or

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

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

## 12 2. The TCA Distinguishes Between Measures Relating to 13 Sales and Manufacturing, Preserving the States’ Authority Over Sales

14 “Where Congress enacts an express preemption provision,” as it has in the  
15 TCA, courts “interpret the provision and ‘identify the domain expressly pre-empted  
16 by that language.’” *Chae v. SLM Corp.*, 593 F.3d 936, 942 (9th Cir. 2010) (quoting  
17 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). In doing so, courts “use the text  
18 of the provision, the surrounding statutory framework, and Congress’s stated  
19 purposes in enacting the statute to determine the proper scope of an express  
20 preemption provision.” *Id.* (citing *Medtronic*, 518 U.S. at 485–86; *Cipollone*,  
21 505 U.S. at 516). Here, the express statutory language and the surrounding  
22 framework demonstrate that Congress did not intend to preempt state flavored  
23 tobacco sales bans like S.B. 793.

24 <sup>1</sup> S.B. 793 also makes two clarifications by defining the “constituents” that  
25 can be said to impart a characterizing flavor and thus render a tobacco product  
26 unavailable for sale at retail. First, those “constituents” exclude tobacco and  
27 reconstituted tobacco, with the sole significance of ensuring that only flavors other  
28 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.*

1 Section 916 of the TCA, 21 U.S.C. § 387p, sets out the relationship between  
2 state and federal authority over tobacco products. It starts with the Preservation  
3 Clause, which sweeps broadly and preserves for the states and their localities  
4 virtually all regulatory authority over tobacco products except to set tobacco  
5 regulations less stringent than those imposed by the TCA. It includes the power “to  
6 enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure  
7 with respect to tobacco products that is in addition to, or more stringent than,  
8 requirements established under” the TCA. *Id.* § 387p(a)(1). It goes on to provide  
9 examples of state authority. State authority includes, but is not limited to, “law[s],  
10 rule[s], regulation[s], or other measure[s] relating to or prohibiting the sale,  
11 distribution, possession, exposure to, access to, advertising and promotion of, or use  
12 of tobacco products by individuals of any age.” *Id.*

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

23 Finally,<sup>2</sup> the Savings Clause returns some authority relating to these eight  
24 categories to the states. That is, states and localities may implement restrictions  
25 “relating to tobacco product standards, premarket review, adulteration,  
26 misbranding, labeling, registration, good manufacturing standards, or modified risk

27 <sup>2</sup> Section 916(b) of the TCA, 21 U.S.C. § 387p(b), addresses state product  
28 liability law, and is not relevant here.

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

3 This three-part structure makes clear that the TCA distinguishes between  
4 measures related to manufacturing—which are preempted—and measures related to  
5 sales—which are not. The Second Circuit explained the different treatment of  
6 manufacturing standards and sales restrictions in *U.S. Smokeless* when it rejected  
7 arguments identical to those put forth by Plaintiffs here. By specifically  
8 enumerating restrictions “relating to the sale” of tobacco products in the Savings  
9 Clause, “§ 916 distinguishes between manufacturing and the retail sale of finished  
10 products.” 708 F.3d at 434. Moreover, the distinction specifically contemplates  
11 complete bans on the sales of certain products, leaving such authority to the states.  
12 Indeed, if retail sales bans such as S.B. 793 were found preempted, it “would vitiate  
13 the preservation clause’s instruction that the Act not be ‘construed to limit the  
14 authority of . . . a State or political subdivision of a State . . . to enact . . . and  
15 enforce any . . . measure . . . prohibiting the sale . . . of tobacco products.’” *Id.*  
16 (quoting 21 U.S.C. § 387p(a)(1)) (alterations in original); *see also Nat’l Ass’n of*  
17 *Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82 (1st Cir. 2013)  
18 (rejecting the plaintiffs’ contention that bans of flavored tobacco products “impose  
19 a new product or manufacturing standard in violation of the preemption  
20 provision”); *Indeps. Gas & Serv. Stations Ass’ns, Inc. v. City of Chicago*, 112 F.  
21 Supp. 3d. 749, 754 (N.D. Ill. 2015) (finding a flavored tobacco product sales ban  
22 not preempted because it “regulates flavored tobacco products without regard for  
23 how they are manufactured”).

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

1 U.S. 525, 533 (2001), placed extensive restrictions on the manufacturers’ sales and  
2 marketing practices, and provided for annual payments to the states in perpetuity.<sup>3</sup>  
3 States, bolstered by enforcement powers under the MSA and a public increasingly  
4 mindful of the dangers of tobacco products, passed a host of laws regulating the  
5 sale and use of cigarettes and tobacco products, placing restrictions on non-face-to-  
6 face tobacco sales, *see, e.g.*, Stop Tobacco Access to Kids Enforcement (“STAKE”)  
7 Act of 2002, ch. 685, 2002 Cal. Stat. 4129 (codified at Cal. Bus. & Prof. Code  
8 § 22963); requiring licensing up and down the distribution chain, *see, e.g.*,  
9 Cigarette and Tobacco Products Licensing Act of 2003, ch. 890, 2003 Cal. Stat.  
10 6496 (codified at Cal. Bus. & Prof. Code §§ 22970–22995); and even regulating, in  
11 the absence of federal standards, the manufacture of tobacco products, *see, e.g.*,  
12 California Cigarette Fire Safety and Firefighter Protection Act of 2005, ch. 633,  
13 2005 Cal. Stat. 4830 (codified at Cal. Health & Safety Code §§ 14950–14960).

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

26 ///

27 <sup>3</sup> The text of the MSA can be found at [http://www.naag.org/assets/redesign](http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf)  
28 [/files/msa-tobacco/MSA.pdf](http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf).

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

5           Finally, all of the preempted areas address manufacture of tobacco products  
6 and the related issue of their introduction into the United States. For example, under  
7 section 901 of the TCA, a tobacco product is “adulterated” if, among other things,  
8 “it has been prepared, packed, or held under insanitary conditions whereby it may  
9 have been contaminated with filth, or whereby it may have been rendered injurious  
10 to health.” *Id.* § 387b(2). Similarly, premarket review requires an analysis of “the  
11 components, ingredients, additives, and properties, and of the principle or principles  
12 of operation, of [new] tobacco product[s],” as well as “the methods used in, and the  
13 facilities and controls used for, the manufacture, processing, and, when relevant,  
14 packing and installation of, [new] tobacco product[s].” *Id.* § 387j(b)(1). Indeed,  
15 even “registration” is directed at “person[s] who own[] or operate[] any  
16 establishment . . . engaged in the manufacture, preparation, compounding, or  
17 processing of a tobacco product or tobacco products.” *Id.* § 387e(b); *see also id.*  
18 § 387e(c) (new owners/operators); *id.* § 387e(d) (new establishments); *id.* § 387e(h)  
19 (foreign establishments).

20           Thus it is clear, as the Second Circuit concluded, that the TCA “reserves  
21 regulation at the manufacturing stage exclusively to the federal government, but  
22 allows states and localities to continue to regulate sales and other consumer-related  
23 aspects of the industry in the absence of conflicting federal regulation.” *U.S.*  
24 *Smokeless*, 708 F.3d at 434.

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

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

7                   **a. Statutory Language**

8                   Plaintiffs selectively isolate portions of the TCA to claim that S.B. 793 sets a  
9                   tobacco product standard and thus preempted. Looking to section 907 of the TCA,  
10                  21 U.S.C. § 387g, which addresses tobacco product standards, Plaintiffs claim that  
11                  “‘tobacco product standards’ cover more than just manufacturing” because “the  
12                  [TCA] explicitly lists ‘labeling’ relating to ‘the proper use of the tobacco product’  
13                  as an example.” Mem. P. & A. Supp. Pls.’ Mot. Prelim. Inj. (“Pls.’ Mot. Prelim.  
14                  Inj.”) 12, ECF No. 6-1 (quoting 21 U.S.C. § 387g(a)(4)(C)). But labeling is itself a  
15                  component of manufacturing—a tobacco product includes its packaging. *See*  
16                  21 C.F.R. § 1140.3 (defining “manufacturer” as including one who “labels a  
17                  finished tobacco product”); *id.* § 1143.3(a)(1) (“For . . . tobacco products other than  
18                  cigars, it is unlawful for any person to *manufacture* . . . such product unless the  
19                  tobacco product package bears the . . . required warning statement on the package  
20                  label . . . .” (emphasis added)). Additionally, if the inclusion of “labeling” in section  
21                  907 is construed to expand the definition of “tobacco product standard” and thus the  
22                  Preemption Clause’s reach, then the separate inclusion of “labeling” in the  
23                  Preemption Clause is made superfluous. *See United States v. Wenner*, 351 F.3d  
24                  969, 975 (9th Cir. 2003) (“It is a fundamental canon of statutory construction that a  
25                  statute should not be construed so as to render any of its provisions mere  
26                  surplusage.”). It is true that a tobacco product standard may *also* include “a  
27                  provision requiring that the sale and distribution of the tobacco product be  
28                  restricted.” 21 U.S.C. § 387g(a)(4)(B)(v). But that does not render every sales

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

3 Plaintiffs also point to one of two “special rules” in section 907 of the TCA—  
4 that is, one of two congressionally established tobacco product standards—to claim  
5 S.B. 793 is a preempted tobacco product standard. Pls.’ Mot. Prelim. Inj. 9–10.  
6 That “Special rule for cigarettes” sets a manufacturing standard—cigarettes “shall  
7 not *contain*, as a constituent (including a smoke constituent) or additive, an  
8 artificial or natural flavor (other than tobacco or menthol) or an herb or spice,”  
9 21 U.S.C. § 387g(a)(1)(A) (emphasis added)—by regulating the contents of  
10 cigarettes. The tobacco product standard the special rule imposes does not prohibit  
11 the retail sale of flavored cigarettes; it prohibits cigarettes from containing specific  
12 ingredients, and renders any cigarette containing those prohibited ingredients  
13 “adulterated.” *Id.* § 387b(5); *see also id.* § 331(a), (g) (prohibiting adulterated  
14 tobacco products from being “manufacture[d]” or “introduce[ed] or deliver[ed] for  
15 introduction into interstate commerce”). The second “special rule” reinforces the  
16 focus on manufacturing, proscribing the amount of pesticide residue allowed on the  
17 tobacco used to make tobacco products. *See id.* § 387g(a)(1)(B).

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

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



1 caused by ingredients themselves. Section 907(a)(4), entitled “Content of Tobacco  
2 Product Standards,” is written in light of that express definition. It first reiterates  
3 that tobacco standards regulate the ingredients of tobacco products, addressing  
4 “nicotine yields,” *id.* § 387g(a)(4)(A)(i), and “the reduction or elimination of other  
5 constituents, including smoke constituents, or harmful components,” *id.*  
6 § 387g(a)(4)(A)(ii). The section then refers to section 907(a)(4)(B) to describe what  
7 may be included in such a standard. *See id.* § 387g(A)(4)(A)(iii). Accordingly, in  
8 order to reduce the nicotine or other harmful substances found in tobacco products,  
9 the FDA may regulate aspects such as “the construction, components, ingredients,  
10 additives, constituents, including smoke constituents, and properties of the tobacco  
11 product,” *id.* § 387g(a)(4)(B)(i), and how testing and measurement need be  
12 performed to show compliance, *see id.* § 387g(a)(4)(B)(ii)–(iv). Finally, if  
13 reduction or elimination of particular harmful constituents require sales restrictions  
14 to be reasonably effectuated, tobacco product standards can include them. *See id.*  
15 § 387g(a)(4)(B)(v).

16 And in adopting section 907 of the TCA, Congress cited its express purpose in  
17 enabling the FDA to enact tobacco product standards as giving the FDA “authority  
18 to establish product standards regarding the testing and measurement of products,  
19 nicotine yields, constituents, construction, components, ingredients, additives, and  
20 all other properties of the tobacco product.” H.R. Rep. No. 111-58, pt. 1 at 39–40  
21 (2009), *as reprinted in* 2009 U.S.C.C.A.N. 468, 488.<sup>4</sup> From top to bottom,  
22 Congress made clear that tobacco product standards regulate the manufacture of  
23 tobacco products to reduce the instance of nicotine or other harmful substances.

24 ///

25 <sup>4</sup> Section 907 of the TCA also allows for two other kinds of tobacco product  
26 standards: (1) those setting “labeling for the proper use of the tobacco product,”  
27 21 U.S.C. § 387g(a)(4)(C), which is part of manufacturing; and (2) those  
28 “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.

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

5 **b. Caselaw**

6 As noted above, courts interpreting these preemption provisions of the  
7 Tobacco Control Act have consistently reached the conclusion that state sales-based  
8 restrictions on tobacco products are permitted under the Act. The First Circuit,  
9 Second Circuit, Northern District of Illinois, District of Minnesota, and Central  
10 District of California have all addressed the claims Plaintiffs pose here and all have  
11 all found that the states have authority under the TCA to ban the sales of flavored  
12 tobacco products. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82–83; *U.S.*  
13 *Smokeless*, 708 F.3d at 436; *Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago*,  
14 112 F. Supp. 3d at 754; *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, CV  
15 20-4880 DSF (KSx), 2020 WL 4390375, at \*6 (C.D. Cal. July 13, 2020); *R.J.*  
16 *Reynolds Tobacco Co. v. City of Edina*, Case No. 20-CV-1402 (PJS/LIB), 2020 WL  
17 5106853, at \*9 (D. Minn. Aug. 31, 2020).

18 Largely avoiding these cases that address preemption under the TCA, the  
19 cases cited by Plaintiffs address wholly different statutes establishing wholly  
20 different preemption regimes. For example, Plaintiffs point to *Engine*  
21 *Manufacturers Association v. South Coast Air Quality Management District*,  
22 541 U.S. 246 (2004), for the broad proposition that “a standard is a standard even  
23 when not enforced through manufacturer-directed regulation,” Pls.’ Mot. Prelim.  
24 Inj. 12 (quoting *Engine Mfrs. Ass’n*, 541 U.S. at 254). But the Clean Air Act  
25 preemption clause at issue bears no resemblance to the TCA’s, and the Court’s  
26 analysis flowed directly from the statutory text of the Clean Air Act, not the TCA.  
27 *See Engine Mfrs.*, 541 U.S. at 252 (“Statutory construction must begin with the  
28 language employed by Congress . . .”). That clause provided:

1 No State or any political subdivision thereof shall adopt or attempt to  
2 enforce any standard relating to the control of emissions from new motor  
3 vehicles or new motor vehicle engines subject to this part. No State shall  
4 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.

5 42 U.S.C. § 7543(a). Congress did not separate out product standards and sales  
6 restrictions for different preemptive treatment in the Clean Air Act as it did in the  
7 TCA. Instead, it broadened the preemption of measures relating to standards to  
8 sweep up not only standards themselves, but also any “attempt to enforce”  
9 standards that differ from the federal ones. The statute’s text made clear that  
10 “Congress contemplated the enforcement of emission standards through purchase  
11 requirements,” and the defendant implemented a purchase requirement related to  
12 emissions standards. *Engine Mfrs. Ass’n*, 541 U.S. at 254. These purchase  
13 restrictions were thus preempted as an “attempt to enforce” an emission standard.  
14 *See id.* This is not the approach Congress took regarding the TCA. Instead, it  
15 limited preemption specifically to “establish[ing] or continu[ing] in effect” only  
16 “requirement[s] . . . relating to tobacco product standards.” 21 U.S.C.  
17 § 387p(a)(2)(A). S.B. 793 does not establish—or continue in effect—any tobacco  
18 product standard.

19 *National Meat Association v. Harris*, 565 U.S. 452 (2012), similarly addressed  
20 a preemption clause bearing little resemblance to the statute at issue here.  
21 Regardless, Plaintiffs cite it for the broad proposition that sales restrictions are  
22 preempted because a “sales . . . ban functions as a command to [manufacturers] to  
23 structure their operations’ in a particular way by imposing a ‘ban on the sale of [a  
24 product] produced in whatever way the State disapproved.’ Pls.’ Mot. Prelim. Inj.  
25 13 (quoting *Nat’l Meat*, 565 U.S. at 464 (alterations in original)). First, the  
26 preemption clause of the Federal Meat Inspection Act (“FMIA”), 21 U.S.C.  
27 §§ 601–695, at issue did not set out different treatment for sales restrictions, *see id.*  
28 § 678, as does the TCA. *See Nat’l Ass’n of Tobacco Outlets*, 731 F.3d at 82 (finding

1 *National Meat* “easily distinguishe[d]” from the TCA because the FMIA “did not  
2 contain a savings clause that expressly exempted regulations ‘relating to the sale’ of  
3 the product from preemption”).

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

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

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

4  
5 **4. S.B. 793 Escapes Preemption Even Under a Broad Reading**  
6 **of “Relating to Tobacco Product Standards”**

7 As noted above, every court to address bans on the sale of flavored tobacco  
8 products have found them to be within the states’ authority under the TCA.  
9 Moreover, all but one has found that such bans are not “relating to tobacco product  
10 standards” at all and thus not subject to the Preemption Clause. *See City of Edina*,  
11 2020 WL 5106853, at \*3 (applying the Preemption Clause despite “[o]ther  
12 courts . . . holding . . . that a *sales* regulation is not a tobacco-product standard  
13 unless it is a de facto manufacturing regulation”). And even that court agreed that  
14 flavored tobacco sales bans are not preempted. Accordingly, under either analysis,  
15 S.B. 793 is not preempted.

16 In one respect, the Minnesota District Court departed from other courts,  
17 concluding that a retail sales ban on flavored tobacco products is “a provision  
18 respecting a ‘propert[y]’” of tobacco products, and thus “relating to tobacco product  
19 standards.” *Id.* at \*4 (quoting 21 U.S.C. § 387g(a)(4)) (alteration in original). It also  
20 concluded that “[t]here is little difference between the government telling a  
21 manufacturer that it may not add an ingredient that imparts a flavor to a tobacco  
22 product and the government telling a manufacturer that it may not sell a tobacco  
23 product if it has added an ingredient that imparts a flavor.” *Id.* (citing *Nat’l Meat*,  
24 565 U.S. at 464). As explained above, that analysis is incorrect. *See supra*,  
25 subsection I.A.3.a, at pp. 9–12 (explaining statutory distinction between sales  
26 restrictions and manufacturing restrictions); *supra*, subsection I.A.3.b, at pp. 12–15  
27 (explaining distinction between sales restrictions that act as manufacturing  
28 restrictions and those that do not).

///

1 But even under its analysis, the Minnesota District Court maintained section  
2 916’s distinction between tobacco manufacture and sales: “On its face, the  
3 Ordinance falls within the scope of the saving clause, as it is a ‘requirement[ ]  
4 relating to the sale . . . of . . . tobacco products by individuals of any age.’” *Id.* at \*4  
5 (quoting 21 U.S.C. § 387p(a)(2)(B)) (alterations in original). That is, the difference  
6 between *City of Edina*’s analysis and that of other courts’ that have addressed  
7 flavored tobacco sales bans, is superficial and all of them reach the same  
8 conclusion. Sales bans are expressly not preempted because of the TCA’s different  
9 treatment of measures “relating to sales,” which requires a different result for  
10 measures aimed at the manufacture of tobacco products and those aimed at the sales  
11 of tobacco products. Whether construed as outside the scope of the Preemption  
12 Clause or saved by the Savings Clause, S.B. 793 is not preempted. Congress  
13 expressly preserved the authority of states to enact sales restrictions, and S.B. 793 is  
14 exactly that.

15  
16 **5. S.B. 793 Escapes Preemption Whether or Not It Is Properly  
Construed as a Prohibition**

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

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

28 ///

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

19           Without support, Plaintiffs claim that the Preemption Clause refers to  
20 “‘requirements’ writ large” and therefore includes prohibitions. Pls.’ Mot. Prelim.  
21 Inj. 19 n.13. But Plaintiffs give no reason for their conclusion that “requirements”  
22 in the Savings Clause do not also include “‘requirements’ writ large” and thus  
23 prohibitions. The argument contradicts itself. Even accepting the premises that S.B.  
24 793 is a “prohibition” and that it is “relating to tobacco product standards,”  
25 Plaintiffs give no reason why such a prohibition is not also “relating to the sale” of  
26 tobacco products. Nor could they. *See Animal Legal Def. Fund v. U.S. Dep’t of*  
27 *Agric.*, 933 F.3d 1088, 1095 (9th Cir. 2019) (“[I]t is a well-established principle of  
28 statutory construction that the same words or phrases are presumed to have the

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

6 Finally, as explained above, if a prohibition of the sale of tobacco products  
7 establishes a preempted tobacco product standard, then the preservation of state  
8 authority to establish such prohibitions would be a nullity. *See U.S. Smokeless*,  
9 708 F.3d at 434; *supra* subsection I.A.2, p. 6.

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

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

#### 19 **B. S.B. 793 Is Not Impliedly Preempted**

20 Plaintiffs’ arguments that S.B. 793 is impliedly preempted start from a faulty  
21 premise. Implied preemption occurs only when it is “the clear and manifest purpose  
22 of Congress.” *Altria Grp.*, 555 U.S. at 77 (quoting *Santa Fe Elevator Corp.*,  
23 331 U.S. at 230). Moreover, the presumption against preemption “applies with  
24 particular force when Congress has legislated in a field traditionally occupied by  
25 the States,” *id.*, such as tobacco sales. That presumption also applies with particular  
26 force when Congress specifically legislated to maintain state authority as it did with  
27 the TCA. *See Cipollone*, 505 U.S. at 517 (“Congress’ enactment of a provision  
28 defining the pre-emptive reach of a statute implies that matters beyond that reach



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

3  
4 **1. That the FDA Need Follow a Specified Process to Ban**  
5 **Certain Products Nationally Does Not Usurp the States’**  
6 **Power to Ban Sales of Certain Products Within Their**  
7 **Borders**

8 Plaintiffs argue that if the FDA chooses not to take action against a particular  
9 product, it affirmatively intends for that product to remain on the market. Indeed,  
10 Plaintiffs make this argument twice: once as to menthol cigarettes, *see* Pls.’ Mot.  
11 Prelim. Inj. 21–22, and once as to flavored electronic nicotine delivery systems  
12 (“ENDS”), *see id.* at 22. But failure to take active steps to prohibit a product is not  
13 equivalent to an affirmative decision that the product should remain on the national  
14 market. *Cf. Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015)  
15 (rejecting as “prov[ing] too much” the defendant’s argument that “the FDA’s  
16 failure to issue specific regulations on [use of the word ‘natural’] is tantamount to a  
17 conscious decision by the agency to permit any use of this term a manufacturer sees  
18 fit”). That the FDA may not yet have gathered sufficient evidence to meet the strict  
19 standard Congress set for the FDA to ban menthol cigarettes, *see* Pls.’ Mot. Prelim.  
20 Inj. 21–22 (quoting 21 U.S.C. § 387g(a)(3), (b)(2)), does not mean that it has  
21 exercised its scientific expertise to determine that keeping menthol cigarettes in the  
22 U.S. market benefits the public health.

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

///

1 Like all tobacco products, ENDS are subject to the TCA’s premarket  
2 authorization provisions. *See* Deeming Tobacco Products to be Subject to the  
3 Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,102 (May 3, 2016)  
4 (expanding the TCA’s regulatory scheme to cover ENDS, among other products).  
5 As of the date of this filing, no ENDS product has received premarket  
6 authorization. *See* FDA, *Premarket Tobacco Product Authorization Orders* (Jan.  
7 21, 2020), [https://www.fda.gov/tobacco-products/premarket-tobacco-product-](https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders)  
8 [applications/premarket-tobacco-product-marketing-orders](https://www.fda.gov/tobacco-products/premarket-tobacco-product-marketing-orders). Accordingly, no ENDS  
9 product can lawfully be sold in the United States. *See* Guidance, *supra*, at 3 (“This  
10 guidance does not in any way alter the fact that it is illegal to market any new  
11 tobacco product without premarket authorization.”).

12 The FDA’s limited enforcement resources, however, have resulted in a policy  
13 of non-enforcement toward certain ENDS despite their unlawful status under the  
14 TCA and the notice-and-comment-promulgated Deeming Rule. But this  
15 discretionary allocation of enforcement priorities, even if read as a decision made  
16 “expressly [to keep] certain menthol-flavored ENDS products on the market,” Pls.’  
17 Mot. Prelim. Inj. 22, can hardly be read as expanding the preemptive scope of the  
18 TCA, especially in the face of the broad Preservation and Savings Clauses. The  
19 FDA’s enforcement priorities are no substitute for Congress’s express intent. *See*  
20 *Cipollone*, 505 U.S. at 516 (“[T]he purpose of Congress is the ultimate touchstone.”  
21 (quoting *White Motor Corp.*, 435 U.S. at 504)). Indeed, FDA non-enforcement  
22 policies of the kind Plaintiffs rely on have been found contrary to the TCA itself.  
23 *See Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 494 (D.  
24 Md. 2019) (“[T]he decision here, not to enforce the premarket review requirements  
25 against any manufacturers, . . . is inconsistent with the Tobacco Control Act and in  
26 excess of [the FDA’s] statutory authority, and it cannot stand.”). Moreover, given  
27 that no ENDS product has lawful status, California’s decision to prohibit a subset of  
28 ///

1 those products can hardly be said to “actually conflict[] with federal law.” Pls.’  
 2 Mot. Prelim. Inj. 20 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).<sup>5</sup>

3 **2. Congress Specifically Retained States’ Authority to Ban**  
 4 **Tobacco Products and Such Bans Are Not Impliedly**  
 5 **Preempted**

6 Plaintiffs also argue that S.B. 793 amounts to a “regulatory assessment” of  
 7 new tobacco products, and thus conflicts with the premarket authorization process  
 8 of the TCA. Pls.’ Mot. Prelim. Inj. 23. That process requires tobacco products “not  
 9 commercially marketed in the United States as of February 15, 2007,” receive  
 10 premarket authorization from the FDA prior to being marketed in the United States.  
 11 21 U.S.C. § 387j(a). Applicants must provide detailed information to the FDA,  
 12 including “full reports of all information . . . concerning investigations which have  
 13 been made to show the health risks of [the] tobacco product,” 21 U.S.C.  
 14 § 387j(b)(1)(A), “a full statement of the components, ingredients, additives, and  
 15 properties . . . of [the] tobacco product,” *id.* § 387j(b)(1)(B), and exemplars of both  
 16 the product and its labeling, *id.* § 387j(b)(1)(E)–(F). The FDA must then conduct a  
 17 particularized inquiry into the tobacco product in question and determine whether  
 18 its introduction “would be appropriate for the protection of the public health.” *Id.*  
 19 § 387j(c)(2)(A). S.B. 793 requires no such assessment, creates no new “review  
 20 processes,” Pls.’ Mot. Prelim. Inj. 23, and is instead fully consonant with the TCA.

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

25 <sup>5</sup> Ultimately, Plaintiffs resort to a policy argument, contending that unless  
 26 Senate Bill 793 is preempted, “state laws could prohibit all flavored tobacco  
 27 products no matter how compelling the scientific evidence that such bans could  
 28 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.

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

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

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

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

3 But even balancing the equities, Plaintiffs’ motion should be denied. In  
4 arguing they will suffer irreparable harm, Plaintiffs rely primarily on their claim  
5 that S.B. 793 is unconstitutional. *See* Pls.’ Mot. Prelim. Inj. 24 (“Being forced to  
6 comply with an unconstitutional law is by definition irreparable harm.”). But as  
7 demonstrated above, S.B. 793 is not unconstitutional. *See Ass’n des Éleveurs de*  
8 *Canards et d’Oies du Québec v. Harris*, 2:12-cv-05735-SVW-RZ, 2012 WL  
9 12842942, at \*11 (C.D. Cal. Sept. 28, 2012) (“[G]iven that Plaintiffs are unlikely to  
10 succeed on the merits, Plaintiffs’ argument that it is “in the public interest to  
11 terminate the unconstitutional application” of a statute’ is inapplicable.”).

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

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

1 sufficient to file suit until after the bans already went into effect. *See R.J. Reynolds*  
2 *v. County of Los Angeles*, 2020 WL 4390375, at \*1 (R.J. Reynold Tobacco Co.;  
3 American Snuff Co., LLC; and Santa Fe Natural Tobacco Co.); *U.S. Smokeless*,  
4 703 F. Supp. 2d at 332 (U.S. Smokeless Manufacturing Co.); *Neighborhood Market*  
5 *Ass’n v. County of San Diego*, Case No. 3:20-cv-01124-JLS-WVG (S.D. Cal. filed  
6 June 19, 2020) (Neighborhood Market Ass’n and Vapin’ the 619)

7 On the other side of the scale rests the state’s interest in the public health, *see*  
8 *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (“When the  
9 government is a party, [the balance of the equities and the public interest] factors  
10 merge.”), an undoubtedly compelling interest, *see Jacobson v. Massachusetts*,  
11 197 U.S. 11, 38 (1905) (“The safety and the health of the people . . . are, in the first  
12 instance, for th[e states] to guard and protect.”). Plaintiffs argue that “the state will  
13 suffer little or no harm from a preliminary injunction because it would merely  
14 maintain the status quo temporarily.” Pls.’ Mot. Prelim. Inj. 8. Plaintiffs do not,  
15 however, describe the status quo. Currently, smoking is “responsible for more than  
16 480,000 deaths per year in the United States” constituting “about one in five deaths  
17 annually.” Ctrs. for Disease Control, Smoking & Tobacco Use: Fast Facts, [https://](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm)  
18 [www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm) (last updated  
19 May 21, 2020). Moreover, the total economic cost in the United States is “more  
20 than \$300 billion a year.” *Id.* And “[e]ach day, about 2000 people younger than 18  
21 years smoke their first cigarette.” *Id.* Thousands more try other tobacco products  
22 like ENDS for the first time, placing them on the path to addiction.

23 Many of those underage users’ first tobacco product is a flavored one. The  
24 vast majority of youth who begin smoking start with a flavored product, including  
25 81.0% of ENDS users and 50.1% of cigarette users. Bridget K. Ambrose et al.,  
26 *Flavored Tobacco Product Use Among US Youth Aged 12–17 Years, 2013–2014*,  
27 314 J. Am. Med. Ass’n 1871, 1872 (2015). Indeed, in 2019, 86.4% of California  
28 high school students who used tobacco reported that they used a flavored product.

1 Cal. Dep't of Pub. Health, California Tobacco Facts and Figures 2019, at 12 (May  
2 2019), [https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH  
3 %20Document%20Library/ResearchandEvaluation/FactsandFigures/CATobacco  
4 FactsandFigures2019.pdf](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  
5 additional Californians, especially younger Californians, contracting a life-long  
6 addiction to nicotine.

7 **CONCLUSION**

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

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1 Dated: November 12, 2020

Respectfully Submitted,

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