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27 UNITED STATES DISTRICT COURT  
28 SOUTHERN DISTRICT OF CALIFORNIA

19 R.J. REYNOLDS TOBACCO  
20 COMPANY *et al.*,

21 *Plaintiffs,*

22 v.

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

28 *Defendants.*

Case No. 3:20-cv-01990-LAB-RBB  
Hon. Larry Alan Burns

**MEMORANDUM OF POINTS  
AND AUTHORITIES IN  
SUPPORT OF PLAINTIFFS'  
MOTION FOR PRELIMINARY  
INJUNCTION**

Hearing Date: November 23, 2020  
Time: 11:30 a.m.  
Courtroom: 14A

Complaint Filed: October 9, 2020

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1 **INTRODUCTION**

2 More than a decade ago, Congress prescribed the respective roles that federal  
3 and state actors would play in regulating tobacco products by enacting the Family  
4 Smoking Prevention and Tobacco Control Act of 2009 (the “TCA”). That Act  
5 enshrined one mandatory tobacco product standard related to flavors—a ban on  
6 cigarettes containing any characterizing flavors besides menthol or tobacco. That Act  
7 also empowered FDA to enact additional requirements for flavored tobacco  
8 products—but only if FDA judges that, among other findings, the requirements  
9 would be appropriate for the protection of the public health. FDA has repeatedly  
10 declined to prohibit sales of menthol or tobacco-flavored products. The TCA also  
11 addresses the balance of federal and state authority in three interlocking provisions.  
12 Those provisions make clear that while states can enact their own sales requirements  
13 for tobacco products, states are forbidden from enacting tobacco product standards  
14 that prohibit entire categories of flavored tobacco products.

15 A few weeks ago, California upended Congress’s balance. Senate Bill 793  
16 created a “new crime”: tobacco retailers are forbidden from selling, offering for sale,  
17 or even possessing any “flavored tobacco product” with intent to sell it anywhere in  
18 California. That categorical ban sweeps broadly, criminalizing menthol cigarettes,  
19 menthol-flavored vapor products, flavored smokeless tobacco products, and many  
20 otherwise lawful products.

21 California has the laudable aim of reducing youth use of tobacco products—  
22 an aim that Plaintiffs share. But SB793’s blunderbuss approach, which unjustifiably  
23 forbids the sale of the products to adults, is manifestly unconstitutional. The TCA  
24 expressly preempts SB793. The TCA also impliedly preempts SB793, which would  
25 thwart the TCA’s objective of leaving flavor bans in FDA’s hands based on FDA’s  
26 expert judgments about the health benefits and risks of such bans.

27 This Court should grant preliminary injunctive relief to Plaintiffs R.J.  
28 Reynolds Tobacco Company, R.J. Reynolds Vapor Company, American Snuff



1 Company, LLC, and Santa Fe Natural Tobacco Company (collectively, “Reynolds”),  
2 Philip Morris USA Inc., John Middleton Co., U.S. Smokeless Tobacco Company  
3 LLC, and Helix Innovations LLC (collectively, “PM USA”), Neighborhood Market  
4 Association (“NMA”), and MORIJA, LLC dba Vapin’ the 619. Plaintiffs clearly  
5 raise serious questions as to whether California’s ban is preempted and hence  
6 unconstitutional—indeed, for the reasons explained below, they are likely to succeed  
7 on the merits. SB793 would also inflict obvious irreparable harms above and beyond  
8 the many constitutional injuries at stake. As of January 1, 2021, Plaintiffs would lose  
9 the ability to sell their products in one of the Nation’s largest states, and cannot obtain  
10 monetary damages from the state to remedy that harm. In fact, dozens of members of  
11 NMA, including Vapin’ the 619, will likely close shop and lay off their employees.

12 Meanwhile, enjoining Defendants from enforcing California’s ban on flavored  
13 tobacco products would maintain the status quo that has existed for decades, so an  
14 injunction will not prejudice California or the public interest. California has no  
15 legitimate interest in enforcing an unconstitutional law, and the public always has an  
16 interest in enforcing the Constitution. An injunction would also avoid public health  
17 risks: severely restricting the availability of menthol-flavored cartridge-based  
18 electronic nicotine delivery system (“ENDS”) products could drive adult users to  
19 riskier combustible cigarettes or worse, the black market.

## 20 **BACKGROUND**

21 **1.** Long before California considered prohibiting flavored tobacco products,  
22 Congress enacted a comprehensive regime distributing authority over all aspects of  
23 tobacco regulation between FDA and states. In 2009, Congress enacted the Family  
24 Smoking Prevention and Tobacco Control Act of 2009 (the “Tobacco Control Act”  
25 or “TCA”), Public Law 111-31, 123 Stat. 1776 (the relevant provisions are provided  
26 in the attached Addendum). The Act granted FDA primary authority to regulate  
27 tobacco products. That approach allows “[FDA] to set national standards controlling  
28 the manufacture of tobacco products and the ... amount of ingredients used in such

1 products.” TCA § 3(3), 123 Stat. 1782 (codified at 21 U.S.C. § 387 note).

2 The TCA addresses the regulation of flavors in tobacco products at length, in  
3 a section entitled “[t]obacco product standards.” *See* 21 U.S.C. § 387g. Congress  
4 prohibited cigarettes from containing characterizing flavors other than tobacco or  
5 menthol. *Id.* § 387g(a)(1)(A). Congress enforced that standard through a sales ban,  
6 by providing that any cigarettes containing impermissible characterizing flavors are  
7 “adulterated,” and cannot be sold. *Id.* §§ 387b(5), 331(a), (c).

8 The TCA’s prohibition on characterizing flavors other than menthol and  
9 tobacco in cigarettes is a floor, not a ceiling, for FDA. Congress expressly authorized  
10 FDA to take further “action ... applicable to menthol or any artificial or natural  
11 flavor.” *Id.* § 387g(a)(1)(A). FDA may take such action by adopting an additional  
12 “tobacco product standard” upon finding that the “standard is appropriate for the  
13 protection of the public health.” *Id.* § 387g(a)(3)(A). Such standards can include  
14 “provisions respecting the construction, components, ingredients, additives,  
15 constituents ... and properties of the tobacco product.” *Id.* § 387g(a)(4)(B)(i).

16 In plain English: Congress left it to FDA to decide whether to prohibit menthol  
17 (or any other characterizing flavor) in tobacco products. If FDA wants to enact such  
18 a “tobacco product standard” (in the parlance of the Act), FDA must determine,  
19 among other things, that it is appropriate for the public health.

20 Given the primary role Congress assigned to FDA, Congress also addressed  
21 the relationship between federal and state authority to regulate tobacco products.  
22 Congress did so in three interrelated provisions:

23 **The Preservation Clause** preserves “the authority of” states, federal agencies,  
24 Indian tribes, and the U.S. Military to promulgate laws that are “in addition to, or  
25 more stringent than,” federal “requirements,” including “measure[s] relating to or  
26 prohibiting the sale ... or use of tobacco products by individuals of any age.” 21  
27 U.S.C. § 387p(a)(1). While the preservation of those entities’ authority is broad,  
28 when it comes to states, the Preservation Clause includes an exception: If a state’s

1 law falls within the Tobacco Preemption Clause, that law is not protected by the  
2 Preservation Clause. *Id.*

3 **The Preemption Clause**, in turn, prohibits states and localities from  
4 “establish[ing] ... any requirement” that “is different from, or in addition to,” any  
5 federal requirements “relating to tobacco product standards, premarket review,  
6 adulteration, misbranding, labeling ... or modified risk tobacco products” and other  
7 types of requirements. *Id.* § 387p(a)(2)(A). The Preemption Clause makes it possible  
8 for tobacco-product manufacturers to comply with a single set of product  
9 specifications—rather than grapple with potentially hundreds of different  
10 requirements set by different states and localities. *See* TCA § 3(3), 123 Stat. at 1782  
11 (codified at 21 U.S.C. § 387 note).

12 **The Saving Clause** then provides an exception to the Preemption Clause. As  
13 relevant here, states’ “requirements relating to the sale, distribution, possession, ...  
14 the advertising and promotion of, or use of, tobacco products by individuals of any  
15 age” are not preempted. 21 U.S.C. § 387p(a)(2)(B).

16 **2.** Since the TCA’s enactment, FDA has enforced the TCA’s baseline “tobacco  
17 product standard” related to flavors, that is, the prohibition on cigarettes containing  
18 characterizing flavors other than menthol or tobacco. Menthol and tobacco cigarettes  
19 are thus the only flavors on the market in the United States. Pursuant to the TCA, the  
20 Tobacco Products Scientific Advisory Committee has also studied “the issue of the  
21 impact of the use of menthol in cigarettes on the public health.” *Id.* § 387g(e)(1).  
22 Twice, FDA has sought information about the effects of menthol cigarettes.<sup>1</sup> And on  
23 both occasions, FDA received comments demonstrating that there is no scientific or  
24 other justification for FDA to limit or ban menthol in cigarettes. Menthol cigarettes  
25 do not pose a different health risk from other types of cigarettes, and menthol

26 \_\_\_\_\_  
27 <sup>1</sup> *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed.  
28 Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*,  
83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018).

1 cigarettes do not adversely affect smoking initiation, dependence, or cessation.<sup>2</sup>

2 FDA has also deemed ENDS products—often called e-cigarettes—as “tobacco  
3 products” subject to regulation under the TCA.<sup>3</sup> In January 2020, FDA announced  
4 that it was effectively banning the sale of flavored, cartridge-based ENDS products,  
5 other than tobacco- or menthol-flavored products.<sup>4</sup> And on September 9, 2020, FDA  
6 effectively banned all ENDS products unless the product is the subject of a timely  
7 filed premarket tobacco product application and under FDA review. *Enforcement*  
8 *Priorities* 3. FDA also continues to issue warning letters to entities that market or sell  
9 “unauthorized flavored, cartridge-based ENDS products” and other ENDS products  
10 marketed in ways that appeal to youth.<sup>5</sup> At every turn, FDA explained these actions  
11 were calibrated public-health decisions aimed at reducing youth tobacco usage in  
12 particular. In FDA’s view, its current “approach”—effectively banning flavored  
13

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14 <sup>2</sup> *E.g.*, RAI Services Company, *Comment Letter on Advance Notice of*  
15 *Proposed Rulemaking Regarding Menthol in Cigarettes, Tobacco Products* (Nov. 22,  
16 2013); RAI Services Company, *Comment Letter on Advance Notice of Proposed*  
17 *Rulemaking Regarding Regulations of Flavors in Tobacco Products* (July 18, 2018);  
18 Altria Client Serv., *Comment Letter on Advance Notice of Proposed Rulemaking*  
19 *Regarding Menthol in Cigarettes, Tobacco Products* (Nov. 22, 2013); *Comment*  
20 *Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors*  
21 *in Tobacco Products* (July 19, 2018).

22 <sup>3</sup> *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and*  
23 *Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control*  
24 *Act: Final Rule*, 81 Fed. Reg. 28,973, 28,976 (May 10, 2016).

25 <sup>4</sup> FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems*  
26 *(ENDS) and other Deemed Products on the Market Without Premarket Authorization*  
27 19 (revised Apr. 2020) (“Enforcement Priorities”), at <https://tinyurl.com/u22rjty>.

28 <sup>5</sup> *See, e.g.*, FDA News Release, *FDA Warns Manufacturers and Retailers to*  
Remove Certain E-cigarette Products Targeted to Youth from the Market (Apr. 27,  
2020), at <https://tinyurl.com/ybg9yny3>; FDA News Release, *FDA Notifies*  
Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and  
Youth-Appealing E-Liquids from Market for Not Having Required Authorization  
(July 20, 2020), at <https://tinyurl.com/y4shrbuf>.

1 vapor products except for menthol and tobacco—“strikes an appropriate balance  
2 between restricting youth access to such products, while maintaining availability of  
3 potentially less harmful options for current and former adult smokers who have  
4 transitioned or wish to transition completely away from combusted [tobacco- and  
5 menthol-flavored] tobacco products.” *Enforcement Priorities* 20; *see also* 81 Fed.  
6 Reg. at 29,011 (similar).

7 FDA’s efforts dovetail with Plaintiffs’ longstanding efforts to keep tobacco  
8 products away from youth. Reynolds and PM USA have rigorous standards to ensure  
9 their marketing is accurate and responsibly directed to adult smokers over age  
10 twenty-one. They also have strict compliance policies for retailers who sell their  
11 products to prevent youth from purchasing their products and support programs that  
12 train retailers to comply with age restrictions.

13 FDA’s and Plaintiffs’ efforts have proven successful in reducing youth  
14 cigarette smoking, which “has steadily declined over the past 2 decades.”<sup>6</sup> Those  
15 efforts have also succeeded in decreasing the number of youth using ENDS products:  
16 FDA’s latest report finds that “1.8 million fewer U.S. youth are currently using e-  
17 cigarettes compared to 2019.”<sup>7</sup> As FDA recognizes, “[t]his is good news.” *Id.* And  
18 Congress recently raised the age to purchase tobacco products to twenty-one. 21  
19 U.S.C. § 387f(d)(5).

20 **3.** Nonetheless, on August 28, 2020, the Governor of California signed Senate  
21 Bill 793 into law. Thus, as of January 1, 2021, California will criminalize commerce  
22 in nearly all flavored tobacco products. *See* Cal. Const. art. IV, § 8(c) (effective date).  
23 SB793 states that tobacco retailers “shall not sell, offer for sale, or possess with the

24 \_\_\_\_\_  
25 <sup>6</sup> A. Gentzke, et al. *Vital Signs: Tobacco Product Use Among Middle and*  
26 *High School Students—United States, 2011–2018*, 68(6) *Morbidity and Mortality*  
*Weekly Report* 157 (Feb. 2019), at <https://tinyurl.com/y5sjsxox>.

27 <sup>7</sup> FDA Statement, *National Survey Shows Encouraging Decline in Overall*  
28 *Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products* (Sept. 9,  
2020), at <https://tinyurl.com/y3rpwfph>.

1 intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor  
 2 enhancer.” SB793 § 14559.5(b)(1). California defines a “[t]obacco product” as “[a]  
 3 product containing, made, or derived from tobacco or nicotine that is intended for  
 4 human consumption,” including “cigarettes,” “chewing tobacco,” “snuff,” and  
 5 ENDS products. Cal. Health & Safety Code §§ 104495(a)(8)(A)(i), (a)(8)(A)(ii).

6 SB793 defines “[f]lavored tobacco product” as “any tobacco product that  
 7 contains a constituent that imparts a characterizing flavor.” *Id.* § 104559.5(a)(4).  
 8 SB793 defines “[c]haracterizing flavor” as “a distinguishable taste or aroma, or both,  
 9 other than the taste or aroma of tobacco, imparted by a tobacco product or any  
 10 byproduct produced by the tobacco product,” including “menthol.” *Id.*  
 11 § 104559.5(a)(1). SB793 thus bans tobacco retailers in California from selling nearly  
 12 any type of flavored tobacco product, including menthol cigarettes or menthol ENDS  
 13 products, and subjects them to criminal penalties. SB793 would ban a flavored  
 14 product even if FDA has authorized it to be sold after considering whether it is  
 15 “appropriate for the protection of the public health.”<sup>8</sup> And SB793 would ban flavored  
 16 products even if FDA has authorized manufacturers to market them as presenting  
 17 lower health risks when compared to using combustible cigarettes.<sup>9</sup> Anyone who  
 18 violates the law “is guilty of an infraction” and faces a \$250 fine per violation. *Id.*  
 19 § 104559.5(f). The ban excludes a handful of products, like shisha tobacco products,  
 20 premium cigars, and loose leaf pipe tobacco. *Id.* §§ 104559.5(c), (d), (e).

21 That prohibition will ban Plaintiffs from selling and distributing many of their  
 22 products within California. Reynolds and PM USA manufacture numerous  
 23

24 <sup>8</sup> *E.g.*, FDA News Release, *FDA Permits Sale of IQOS Tobacco Heating*  
 25 *System through Premarket Tobacco Product Application Pathway*, at  
<https://tinyurl.com/y5d7qhp>.

26 <sup>9</sup> *E.g.*, FDA News Release, *FDA Grants First-Ever Modified Risk Orders to*  
 27 *Eight Smokeless Tobacco Products* (authorizing marketing of Swedish Match’s  
 28 flavored snus products as having “a lower risk [than cigarettes] of mouth cancer,  
 heart disease, lung cancer, stroke, emphysema, and chronic bronchitis”), at  
<https://tinyurl.com/y6ruvbdz>; *see also* FDA, *Modified Risk Orders* (July 2020), at  
<https://tinyurl.com/y2bvbxv>.

1 “[f]lavored tobacco product[s],” including menthol cigarettes, menthol-flavored  
 2 vapor products, various flavored smokeless tobacco products, and other flavored  
 3 tobacco products (such as pouches and lozenges with tobacco-derived nicotine), that  
 4 they distribute for resale to consumers within California. Huckabee Decl. ¶¶ 6–7  
 5 (filed concurrently); Canary-Garner Decl. ¶ 4 (same); Yager Decl. ¶ 7 (same); Winch  
 6 Decl. ¶ 7 (same). Retailer Vapin’ the 619 as well as members of the Neighborhood  
 7 Market Association sell “flavored tobacco product[s].” Sylvester Decl. ¶¶ 1-4  
 8 (same); Somo Decl. ¶ 5 (same). Plaintiffs would continue to sell and distribute these  
 9 products for resale in California but for SB 793.

### 10 ARGUMENT

11 This Court should preliminarily enjoin Defendants from implementing or  
 12 enforcing the state’s ban on flavored tobacco products. A plaintiff is entitled to a  
 13 preliminary injunction if (1) “he is likely to succeed on the merits,” (2) he “is likely  
 14 to suffer irreparable harm” absent preliminary relief, (3) “the balance of equities tips  
 15 in his favor,” and (4) an “injunction is in the public interest.” *Winter v. Natural Res.*  
 16 *Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Under the Ninth Circuit’s “sliding scale”  
 17 test, injunctive relief is also appropriate where the plaintiff raises “serious questions”  
 18 as to the merits and “the balance of hardships tips sharply in plaintiff’s favor.” *Puente*  
 19 *Arizona v. Arpaio*, 821 F.3d 1098, 1103 n.4 (9th Cir. 2016).

20 This is a quintessential case warranting injunctive relief. As discussed below,  
 21 it is clear that federal law preempts California’s ban, thus there is little doubt that  
 22 Plaintiffs will succeed on the merits. But, at a minimum, Plaintiffs’ claims raise  
 23 “serious questions” on the merits. Without an injunction, Plaintiffs and numerous  
 24 Californians will face serious, uncompensable injuries. For example, if SB793 goes  
 25 into effect, it will devastate many retailers. In fact, dozens of NMA’s members,  
 26 including Vapin’ the 619, will likely have to close shop completely and lay off their  
 27 employees. Somo Decl. ¶ 7. By contrast, the state will suffer little or no harm from a  
 28 preliminary injunction because it would merely maintain the status quo temporarily.

1 **I. PLAINTIFFS RAISE SERIOUS QUESTIONS—INDEED ARE**  
2 **LIKELY TO SUCCEED—ON THE MERITS.**

3 **A. The TCA Expressly Preempts California’s Ban.**

4 The TCA expressly preempts California’s ban on flavored tobacco products.  
5 That ban constitutes a “tobacco product standard” within the meaning of the TCA,  
6 because it prohibits tobacco products manufactured with flavors from being sold  
7 within the State. Under the TCA’s Preemption Clause, SB793 is preempted because  
8 it is “different from” or “in addition to” federal “requirement[s] ... relating to tobacco  
9 product standards.” 21 U.S.C. § 387p(a)(2)(A). California bans all “flavored tobacco  
10 product[s]”; federal law does not. And the Saving Clause does not save SB793,  
11 because California’s law is no mere “requirement[] relating to the sale” of “tobacco  
12 products by individuals of any age.” *Id.* § 387p(a)(2)(B). The Saving Clause must be  
13 read in harmony with the preemption clause. *Corley v. United States*, 556 U.S. 303,  
14 314 (2009). Thus, the Saving Clause must be limited to those laws that are actually  
15 sales requirements, not sales prohibitions. But far from merely regulating the time,  
16 place, or manner of tobacco product sales, SB793 would make it a crime to sell a  
17 staggering array of tobacco products to adult consumers, simply because  
18 manufacturers included menthol or other characterizing flavors in those products.  
19 That type of regulation does not qualify under the Saving Clause.

20 **1. California’s ban falls within the TCA’s Preemption Clause.**

21 As noted, the TCA’s Preemption Clause prohibits states from enacting “any  
22 requirement which is different from, or in addition to, any requirement under [the  
23 TCA] relating to tobacco product standards.” 21 U.S.C. § 387p(a)(2)(A). California’s  
24 ban on flavored tobacco products fits that description to a T, as the text of the TCA  
25 and FDA’s interpretations of the statutory language confirm.

26 **a.** Start with the TCA’s text. The section titled “tobacco product standards,”  
27 could not be clearer that prohibitions on flavors in tobacco products are “tobacco  
28 product standards.” *Id.* § 387g. The very first provision bans cigarettes that “contain,



1 as a *constituent* ... or *additive*, an artificial or natural flavor (other than tobacco or  
 2 menthol) or an herb or spice, ... that is a *characterizing flavor* of the tobacco product  
 3 or tobacco smoke.” *Id.* § 387g(a)(1) (emphasis added). The next provision then calls  
 4 that prohibition a “tobacco product standard[.]” *Id.* § 387g(a)(2).

5 Another subsection within “tobacco product standards” describes additional  
 6 “tobacco product standards” as standards that contain “provisions respecting the  
 7 construction, components, ingredients, additives, constituents, ... and properties of  
 8 the tobacco product.” *Id.* § 387g(a)(4)(B)(i). That provision unambiguously refers to  
 9 further restrictions or prohibitions on flavors in tobacco products. Making the point  
 10 yet clearer, the TCA defines “additives” to include “substances intended for use as a  
 11 flavoring.” *Id.* § 387(1). And a “constituent” ordinarily means “an essential part” of  
 12 the product. *Webster’s Third New International Dictionary* 486 (1981). So a  
 13 naturally-occurring flavor (such as the tobacco flavor of a cigarette) is a  
 14 “constituent,” while “additives” sweep in added enhancements.

15 Finally, “properties of the tobacco product” independently include flavors; a  
 16 product’s “property” ordinarily refers to an “attribute, characteristic, or quality” of  
 17 the product—like its flavor. *See Oxford English Dictionary*, “Property” (2020), at  
 18 <https://www.oed.com>.<sup>10</sup> In sum, as Judge Schiltz recently concluded, a state or local  
 19 law that bans flavors in tobacco products “fits comfortably within the description of  
 20 tobacco-product standards.” *R.J. Reynolds Tobacco Co. v. City of Edina*, 2020 WL  
 21 5106853, at \*3 (D. Minn. Aug. 31, 2020).

22 Unsurprisingly, FDA has repeatedly interpreted regulations of flavors in  
 23 tobacco products as “tobacco product standards.” FDA has issued advance notices of  
 24 proposed rulemaking contemplating the adoption of “tobacco product standard[s]”

25 \_\_\_\_\_  
 26 <sup>10</sup> *See also Webster’s Third* 1818 (defining “property” as “an effect that a  
 27 material object or substance has ... on one or more of the senses of an observer”); *JL*  
 28 *Bev. Co., LLC v. Beam, Inc.*, 318 F. Supp. 3d 1188, 1205 (D. Nev. 2018), *aff’d*, 2020  
 WL 2765083 (9th Cir. 2020) (listing “flavor” as a “characteristi[c] of the vodka”).

1 banning various flavored tobacco products, including menthol cigarettes and flavored  
 2 vapor products.<sup>11</sup> Indeed, in spring 2020, FDA described a proposed rule as “a  
 3 tobacco product standard that would ban characterizing flavors in all cigars,” FDA,  
 4 Unified Agenda, *Tobacco Product Standard for Characterizing Flavors in Cigars*  
 5 (Spring 2020), and explained that “restricting or eliminating the use of flavors in”  
 6 ENDS products would be a “tobacco product standard,” *Enforcement Priorities* 34.  
 7 These interpretations by FDA, the agency tasked with interpreting and implementing  
 8 the TCA, are, at a minimum, entitled to *Skidmore* deference. *Skidmore v. Swift & Co.*,  
 9 323 U.S. 134, 140 (1944).

10 California’s ban on flavored tobacco products thus manifestly qualifies as a  
 11 “requirement ... relating to tobacco product standards” within the meaning of the  
 12 Preemption Clause. 21 U.S.C. § 387p(a)(2)(A). And California’s product standard is  
 13 “different from,” and “in addition to,” the federal product standards, including the  
 14 tobacco product standard “respecting the ... additives”—*i.e.*, the “substances  
 15 intended for use as a flavoring”—and the “properties” of “tobacco product[s].” *See*  
 16 21 U.S.C. §§ 387(1), 387g(a)(4)(B)(i). California bans the sale of tobacco products  
 17 with characterizing flavors; federal law does not.

18 **b.** Notwithstanding the straightforward analysis above, some courts have  
 19 concluded that “a tobacco-product standard is a manufacturing regulation, and thus  
 20 that a sales regulation is not a tobacco-product standard unless it is a *de facto*  
 21 manufacturing regulation.” *Edina*, 2020 WL 5106853, at \*3 (emphasis omitted). But

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22  
 23 <sup>11</sup> *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed.  
 24 Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83  
 25 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018); *see also* FDA, Press Release (Nov. 15,  
 26 2018) (announcing intent to consider banning menthol cigarettes and flavored  
 27 cigars), at <https://tinyurl.com/y4kn533v>; *cf. Premarket Tobacco Product*  
 28 *Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566, 50,637  
 (proposed Sept. 25, 2019) (describing a tobacco product’s “characterizing flavor” as  
 a “product property”); *id.* at 50,637–42 (requiring “Characterizing flavor(s) (e.g.,  
 none, menthol)” to be listed as “Product properties”); *id.* at 50,570.

1 as Judge Schiltz explained, those courts “provided little in the way of justification—  
2 and, indeed, have sometimes provided little more than *ipse dixit*.” *Id.* As laid out  
3 above, such a “distinction is insupportable in light of the statutory text,” *id.*, and  
4 FDA’s actions under the Act. Indeed, the Tobacco Control Act makes clear that  
5 “tobacco product standards” cover more than just manufacturing: the Act explicitly  
6 lists “labeling” relating to “the proper use of the tobacco product” as an example. 21  
7 U.S.C. § 387g(a)(4)(C).

8 More fundamentally, the Supreme Court has explained in the preemption  
9 context that a *product* standard is distinct from—and broader than—a *manufacturing*  
10 standard. *See Engine Mfrs. Ass’n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246,  
11 255 (2004). In *Engine Manufacturers*, California had prohibited certain fleet  
12 operators from purchasing vehicles that did not comply with stringent state emissions  
13 standards. The Court held California’s law preempted by the Clean Air Act, which  
14 prohibited states from adopting their own emissions standards. *Id.* at 252. The Court  
15 specifically rejected California’s attempt to “engraft onto th[e] meaning of ‘standard’  
16 a limiting component,” namely that a “standard” meant “only a production mandate  
17 that requires manufacturers to ensure that the vehicles they produce have particular  
18 emissions characteristics.” *Id.* at 253 (emphasis omitted). California’s argument, the  
19 Court wrote, “confuses standards with the means of enforcing standards.” *Id.*  
20 Standards “target” the product itself, which means preempted “standard-enforcement  
21 efforts ... can be directed to manufacturers or purchasers.” *Id.* How a standard is  
22 enforced does not change the fact that there is a standard: “a standard is a standard  
23 even when not enforced through manufacturer-directed regulation.” *Id.* at 254;  
24 *compare Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Becerra*, 870 F.3d  
25 1140, 1148 (9th Cir. 2017) (no preemption of California law prohibiting sale of foie  
26 gras produced by force-feeding geese under Poultry Products Inspection Act, not  
27 because sales restrictions cannot be “ingredient requirements,” but because animal  
28

1 husbandry practices are not “ingredient requirements”).<sup>12</sup>

2 In fact, the Tobacco Control Act’s own product standard mirrors California’s  
3 language. The section entitled “Tobacco Product Standards” provides that a cigarette  
4 “shall not contain, as a constituent (including a smoke constituent) or additive, an  
5 artificial or natural flavor (other than tobacco or menthol) ... that is a characterizing  
6 flavor.” 21 U.S.C. § 387g(a)(1)(A). And that standard is enforced through a ban on  
7 the sale of offending products: a product that violates a tobacco product standard is  
8 considered “adulterated” and may not be sold. *Id.* § 331(a), (c); *id.* § 387b(5). In fact,  
9 most product standards operate by forbidding the sale of non-conforming products,  
10 not by prohibiting manufacturers from making the products. *See, e.g.*, 15 U.S.C.  
11 § 1192 (banning sale of fabrics failing to conform to flammability standards); *id.*  
12 § 1211 (banning sale of refrigerators failing to conform to safety standards); 21  
13 U.S.C. §§ 458(a)(2)-(4) (banning sale of adulterated poultry products); 42 U.S.C.  
14 § 7522(a) (banning sale of cars failing to conform to emissions standards).

15 In any event, even where (unlike here) a preemption clause is limited to state  
16 attempts to regulate manufacturing “operations,” the clause still applies where the  
17 state’s “sales ban ... functions as a command to [manufacturers] to structure their  
18 operations” in a particular way by imposing a “ban on the sale of [a product]  
19 produced in whatever way the State disapproved.” *Nat’l Meat Ass’n v. Harris*, 565  
20 U.S. 452, 464 (2012). Thus, “even if it were necessary to show a direct ban on  
21 ingredients (as opposed to flavors), [California’s law] is in effect such a ban. There  
22 is little difference between the government telling a manufacturer that it may not add  
23 an ingredient that imparts a flavor to a tobacco product and the government telling a  
24 manufacturer that it may not sell a tobacco product if it has added an ingredient that  
25 imparts a flavor.” *Edina*, 2020 WL 5106853, at \*4. In that way, California’s ban does

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26  
27 <sup>12</sup> In fact, the Tobacco Preemption Clause separately preempts state laws  
28 related to “good manufacturing standards” that are different from, or in addition to,  
federal standards. 21 U.S.C. § 387p(a)(2)(A). If tobacco product standards were  
limited to manufacturing standards, that would render product standards superfluous.

1 regulate manufacturing.

2 On this score, *National Meat*, 565 U.S. 452 (2012), controls. There the  
3 Supreme Court refused to allow California to use a sales ban as a workaround to an  
4 express preemption clause. That case addressed the scope of the preemption clause  
5 in the Federal Meat Inspection Act, which regulates slaughterhouses. *Id.* at 458. Like  
6 the TCA, the Meat Inspection Act’s preemption clause prohibits states from  
7 promulgating standards that are “in addition to, or different than those made under  
8 this [Act],” but allows states to “mak[e] requirement[s] or tak[e] other action,  
9 consistent with this [Act].” *Id.* at 458 & n.3 (quoting 21 U.S.C. § 678). Although the  
10 Act authorized slaughterhouses to receive and slaughter nonambulatory animals in  
11 certain circumstances, the California statute imposed a ban on buying or selling  
12 nonambulatory animals, effectively nullifying the federal law. The Court deemed  
13 California’s law preempted, explaining that “the sales ban ... functions as a command  
14 to slaughterhouses to structure their operations in the exact way” that California  
15 wanted. *Id.* at 464. The Court continued: “if the sales ban were to avoid [the Act’s]  
16 preemption clause, then any State could impose any regulation on slaughterhouses  
17 just by framing it as a ban on the sale of meat produced in whatever way the State  
18 disapproved.” *Id.* And “[t]hat would make a mockery of the FMIA’s preemption  
19 provision.” *Id.*; see also *Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013)  
20 (states cannot avoid preemption “by resorting to creative statutory interpretation or  
21 description at odds with the statute’s intended operation”).

22 The same is true here. If California could simply work around the preemption  
23 clause by framing its law a sales ban, the Preemption Clause would be rendered a  
24 nullity. Not only would that make a mockery of the Preemption Clause, it would also  
25 create perverse results. The TCA not only empowers FDA to ban additional flavors  
26 (like menthol) in tobacco products; FDA may also *compel* the inclusion of  
27 ingredients or features in tobacco products (for instance, if FDA determined that a  
28 particular substance or product design significantly reduced health risks). See 21

1 U.S.C. § 387g(a)(4)(B)(i). It would vitiate the TCA if states could end-run FDA’s  
2 prescribed tobacco product standard by banning *sales* of tobacco products containing  
3 the FDA-compelled ingredient or feature.

4 California’s law thus fits comfortably within the Preemption Clause. By  
5 regulating what may be in tobacco products that are sold within the state, California  
6 has created a tobacco product standard. And because that standard is in addition to  
7 and different from federal requirements, federal law preempts the state’s ban.

## 8 **2. The Saving Clause Does Not Apply.**

9 The TCA’s Saving Clause does not save SB793. “[O]nce the party challenging  
10 a regulation or ordinance establishes that it violates [a preemption clause], the burden  
11 is properly on the state ... to establish that [the Saving Clause] applies.” *Puerto Rico*  
12 *Tel. Co. v. Municipality of Guayanilla*, 450 F.3d 9, 21 (1st Cir. 2006); *see Carter v.*  
13 *Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1288 (C.D. Cal. 2008)  
14 (holding the same under the Food, Drug, and Cosmetic Act). California cannot meet  
15 its burden here. The Saving Clause allows states to enact requirements related to the  
16 sale of tobacco products. But the Savings Clause does not save *prohibitions* that use  
17 sales bans to enforce tobacco product standards. Reading the Saving Clause to give  
18 states free rein to enact any regulation of flavors in tobacco products—just by  
19 applying that regulation at the point of sale—would impermissibly nullify the  
20 Preemption Clause and upend the TCA’s division of federal and state powers.

21 **a.** It is a fundamental tenet of statutory interpretation that clauses must fit “into  
22 an harmonious whole,” *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 100 (2012),  
23 and that “effect is given to all its provisions.” *Corley*, 556 U.S. at 314. So the Saving  
24 Clause “cannot in reason be construed as” being “inconsistent with the [other]  
25 provisions of the act.” *Am. Tel. & Tel. Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214,  
26 228 (1998). Instead, the TCA’s Preservation, Preemption, and Saving Clauses must  
27 be read together. And the only way to make sense of those three clauses together is  
28 to conclude that the Saving Clause saves from preemption only laws that are actually

1 sales requirements, not sales prohibitions. Because SB793 is a categorical prohibition  
2 on sales of various tobacco products, the TCA forbids it.

3 Start with the Preservation Clause. As relevant here, that clause states: “*Except*  
4 *as provided in [the Preemption Clause], nothing [in the TCA] shall be construed to*  
5 *limit the authority of ... a State” and other entities “to enact ... any law ... with respect*  
6 *to tobacco products that is in addition to, or more stringent than, requirements*  
7 *established under [the TCA], including a law ... relating to or prohibiting the sale,*  
8 *distribution, [or] possession” of “tobacco products by individuals of any age.” 21*  
9 *U.S.C. § 387p(a)(1). The plain meaning of that provision is that the Preemption*  
10 *Clause includes exceptions to the rule preserving states’ authority to enact sales*  
11 *restrictions or prohibitions.*

12 The Preemption Clause then isolates particular types of requirements that  
13 would otherwise constitute permissible state laws under the Preservation Clause, but  
14 which the Preemption Clause expressly bars. Those preempted laws include “any  
15 requirement which is different from, or in addition to, any requirement under the  
16 [TCA] relating to tobacco product standards.” *Id.* § 387p(a)(2)(A).

17 Finally, the Saving Clause identifies exceptions to which the Preemption  
18 Clause “does not apply.” *Id.* § 387p(a)(2)(B). In other words, an exception to the  
19 exception. Those laws include “requirements relating to the sale, distribution, [or]  
20 possession” of “tobacco products by individuals of any age.” *Id.* Significantly, the  
21 Saving Clause does *not* include requirements “prohibiting the sale, distribution, [or]  
22 possession” of tobacco products, whereas the Preservation Clause mentions  
23 requirements “relating to *or prohibiting*” sale, distribution, or possession.

24 The only way to give meaning to all three provisions is to limit the Saving  
25 Clause to state laws that would otherwise fall within the Preemption Clause but  
26 involve sales requirements *relating to* sales, not sales *prohibitions*. Again, the  
27 Preservation Clause ordinarily respects state laws “relating to or prohibiting the sale,  
28

1 distribution, [or] possession” of “tobacco products.” So, under that clause, state laws  
2 relating to or prohibiting cigarette sales (for instance) are generally permissible.

3 The Preemption Clause then takes away states’ authority over laws that  
4 “relat[e] to tobacco product standards,” or other specified subjects of TCA  
5 requirements. So, under that clause, state laws restricting or prohibiting cigarette  
6 sales because (for instance) the cigarettes contain or fail to contain some required  
7 ingredient or product feature are preempted.

8 Finally, the Saving Clause restores states’ authority over otherwise-preempted  
9 laws “relating to the sale, distribution, [or] possession” of tobacco products. So,  
10 under that clause, states can *restrict* cigarette sales based on product ingredients or  
11 features—for instance, by restricting where retailers may sell flavored cigarettes or  
12 to whom they may sell. But the Saving Clause withholds from states the authority to  
13 enact requirements *prohibiting* the sale of products because they fail to meet the state-  
14 imposed product standard. Congress’s decision to use “relating to *or prohibiting*”  
15 sales in the Preservation Clause, but to omit “or prohibiting” from the nearly identical  
16 phrase in the Saving Clause, shows that Congress excluded sales prohibitions from  
17 the class of non-preempted laws in the Saving Clause. “[W]here Congress includes  
18 particular language in one section of a statute but omits it in another section of the  
19 same Act, it is generally presumed that Congress acts intentionally and purposely in  
20 the disparate inclusion or exclusion.” *Russello v. United States*, 464 U.S. 16, 23  
21 (1983). And “[c]ourts are required to give effect to Congress’ express inclusions and  
22 exclusions.” *Nat’l Ass’n of Mfrs. v. Dep’t of Def.*, 138 S. Ct. 617, 631 (2018).

23 The Saving Clause thus protects state laws regulating the time, place, and  
24 manner of tobacco product sales and distribution. But the Saving Clause does not  
25 apply here. SB793 falls under the Preemption Clause because its ban on flavored  
26 tobacco product sales is a “tobacco product standard.” And SB793 falls outside the  
27 Saving Clause, because the law entirely prohibits in-state flavored tobacco sales,  
28 rather than merely limiting avenues for sales of various flavored tobacco products.



1 Opinions from the First and Second Circuits further suggest that the Saving  
2 Clause does not save blanket bans on whole categories of flavored tobacco products.  
3 *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 435–36 (2d Cir.  
4 2013); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82  
5 (1st Cir. 2013) (*NATO*). Those courts held that New York and Providence ordinances  
6 restricting the sales of some flavored tobacco products fell within the Saving Clause  
7 because those ordinances were *not* blanket prohibitions. Neither applied to flavored  
8 cigarettes, and both laws allowed limited in-state, in-person sales of the flavored  
9 tobacco products subject to regulation. *See U.S. Smokeless*, 708 F.3d at 431, 435–36;  
10 *NATO*, 731 F.3d at 82. As the Second Circuit pointedly explained, the New York  
11 ordinance merely “regulates a niche product, not a broad category of products such  
12 as cigarettes or smokeless tobacco.” *U.S. Smokeless*, 708 F.3d at 436. Those laws  
13 starkly contrast with SB793’s total ban on whole categories of flavored tobacco  
14 product sales.

15 **b.** It would be unreasonable and untenable to interpret the Saving Clause as  
16 instead saving state laws that categorically ban tobacco products for failing to comply  
17 with the state’s tobacco product standards. That reading would override the textual  
18 relationship among the Preservation, Preemption, and Saving Clauses. If Congress  
19 meant for the TCA to categorically insulate all state prohibitions on tobacco sales  
20 from preemption, it would make no sense for Congress to have generally authorized  
21 “requirements relating to or prohibiting” sales in the Preservation Clause, and then  
22 identified “requirement[s] ... relating to tobacco product standards” as an *excepted*  
23 subcategory of preempted requirements.

24 Interpreting the Saving Clause to insulate all sales restrictions involving  
25 tobacco product standards from preemption would eviscerate the Preemption Clause.  
26 States could always avoid preemption by simply characterizing a tobacco product  
27 standard as a ban on the sale of tobacco products that failed to comply with the  
28 substance of that standard. *See Nat’l Meat*, 565 U.S. at 464. And “[t]hat would make

1 a mockery of the [TCA’s] preemption provision.” *Id.* For example, the Act authorizes  
 2 FDA to set standards governing the amount of nicotine contained in tobacco  
 3 products. 21 U.S.C. § 387g(a)(4)(A)(i). Those standards should preempt state and  
 4 local nicotine standards. *Id.* § 387p(a)(2)(A). Under a broad reading of the Saving  
 5 Clause, however, states and localities could establish more stringent nicotine  
 6 requirements by banning the sale of tobacco products that contain more nicotine than  
 7 the state would like.

8 Further, that interpretation of the Saving Clause would debilitate other key  
 9 aspects of the Preemption Clause, too. The Preemption Clause also covers  
 10 “premarket review, adulteration, misbranding, [and] labeling.” *Id.* Consider labeling.  
 11 If the Saving Clause saves prohibitions, a state could easily set its own labeling  
 12 “requirements” (such as requiring the state’s preferred warning about the risks of  
 13 tobacco products), by framing the requirement as a prohibition on the sale of tobacco  
 14 products that do not have the state’s preferred label.<sup>13</sup>

15 c. Finally, the Saving Clause contains a qualifier that independently means that  
 16 California’s ban is not saved. The phrase “by individuals of any age” limits the scope  
 17 of the Saving Clause to age-based requirements. That phrase expressly narrows the  
 18 category of permissible state requirements to those that turn on the age of the  
 19 individuals buying or using the regulated tobacco products, such as a requirement  
 20 that purchasers or users of tobacco products be above a minimum age. Because  
 21

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22 <sup>13</sup> To be sure, the one court to address the interrelationship between the  
 23 Preemption and Saving Clauses—the district court in *Edina*—held that the Saving  
 24 Clause covers both “requirements” and “prohibitions” because the Preemption and  
 25 Saving Clauses both refer to “requirements” but do not expressly refer to  
 26 prohibitions. 2020 WL 5106853, at \*5–6. That misreads the Act. The Preservation  
 27 Clause refers to “requirements,” explicitly including both measures “relating to”  
 28 sales and “prohibitions” on sales. The Preemption Clause then refers to  
 “requirements” writ large, such as those related to “tobacco product standards.” But  
 the Saving Clause then refers to only one type of “requirements”: requirements  
 “relating to” sales, not requirements that are “prohibitions.”

1 California has banned the sale of flavored tobacco products to all individuals, the  
2 Saving Clause does not apply.

3 \* \* \*

4 In sum, SB793 is a tobacco product standard because it bans the sale of all  
5 flavored tobacco products, including menthol. That standard is “different from” and  
6 “in addition to” federal product standards, which expressly allow the sale of menthol  
7 cigarettes and menthol-flavored ENDS products. California cannot circumvent that  
8 preemption by labelling SB793 a “sales” requirement.

9 **B. SB793 Is Also Preempted Because It Thwarts the TCA’s Objectives.**

10 SB793 also “actually conflicts with federal law,” and is preempted because it  
11 “stands as an obstacle to the accomplishment and execution of the full purposes and  
12 objectives of Congress.” *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)  
13 (quotations omitted). Specifically, California’s ban on flavored tobacco products  
14 would prevent FDA from executing its statutorily prescribed functions and upend the  
15 TCA’s carefully calibrated regulatory scheme. SB793 is preempted on this additional  
16 basis. *See Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000). That  
17 the Tobacco Control Act contains an express-preemption clause and a saving clause  
18 does not affect implied pre-emption principles. *See Geier v. Am. Honda Motor Co.*,  
19 529 U.S. 861, 872 (2000); *Hillman v. Maretta*, 569 U.S. 483, 498 (2013); *Edina*,  
20 2020 WL 5106853, at \*6.

21 **1.** SB793’s interference with the TCA’s statutory scheme is the type of conflict  
22 that federal law preempts regardless of whether the statutory scheme includes an  
23 express preemption clause or saving clause, as the TCA does. The Supreme Court  
24 has “decline[d] to give broad effect to saving clauses where doing so would upset the  
25 careful regulatory scheme established by federal law.” *United States v. Locke*, 529  
26 U.S. 89, 106 (2000); *see, e.g., Texas & Pacific Ry. Co. v. Abilene Cotton Oil Co.*, 204  
27 U.S. 426, 446 (1907) (broad savings clause did not save common-law rights “the  
28 continued existence of which would be absolutely inconsistent with the provisions of

1 the act”); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384-85 (1992) (same  
2 for broadly worded saving clause in Federal Aviation Act). If a saving clause “reads  
3 into a particular federal law toleration of a conflict that [conflict-preemption]  
4 principles would otherwise forbid, it permits that law to defeat its own objectives.”  
5 *Geier*, 529 U.S. at 872.

6 Thus, in *Geier*, the Supreme Court found a state law preempted,  
7 notwithstanding a broadly worded saving clause, where the relevant federal law was  
8 a federal safety standard providing for a gradual phase-in of airbags in cars. *Id.* at  
9 874–75, 879. The Court refused to recognize a state tort-law duty to equip cars with  
10 airbags immediately, reasoning that allowing states to impose such a duty would have  
11 “stood as an obstacle to the gradual passive restraint phase-in that the federal  
12 regulation deliberately imposed.” *Id.* at 881.

13 2. Here, SB793 impermissibly interferes with the TCA’s regulatory scheme.  
14 *First*, Congress charged FDA with promulgating tobacco product standards—  
15 including prohibitions on any characterizing flavors in tobacco products—pursuant  
16 to a thorough, health-centric process. FDA to date has repeatedly decided *not* to  
17 prohibit menthol in cigarettes, and has recently prohibited most flavored, cartridge-  
18 based ENDS products—except menthol or tobacco-flavored products. *Supra* p. 5.

19 FDA’s judgments necessarily reflect careful consideration of statutory factors.  
20 To promulgate a flavor ban, FDA would have to justify that ban as “appropriate for  
21 the protection of public health,” based on considering the “scientific evidence”  
22 underpinning three primary statutory factors: (i) “the risks and benefits” the proposed  
23 standard poses “to the population as a whole”; (ii) “the increased or decreased  
24 likelihood that existing users” would cease use, and (iii) “the increased or decreased  
25 likelihood” that the standard would prompt nonusers to start using tobacco products.  
26 21 U.S.C. § 387g(a)(3)(A)-(B)(i). And, importantly, FDA must consider whether the  
27 standard would create a “significant demand for contraband.” *Id.* § 387g(b)(2).  
28 FDA’s refusal to go so far—despite years of study, *supra* p. 4—suggests that the

1 scientific evidence needed for FDA to justify such a ban is lacking. FDA’s decisions  
2 not to propose menthol product standards for cigarettes reflect FDA’s judgment that,  
3 for now, menthol cigarettes should remain on the market.

4 The same is true with respect to FDA’s judgments regarding prohibitions on  
5 all flavored ENDS products except menthol- or tobacco-flavored products. FDA has  
6 specifically addressed the rise in youth vaping by announcing that FDA “intends to  
7 prioritize enforcement for lack of marketing authorization against any flavored,  
8 cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS  
9 product) that is offered for sale in the United States.” FDA, *Enforcement Priorities*  
10 2. In that vein, FDA has elected for now to effectively ban flavored, cartridge-based  
11 ENDS products—unless those products are tobacco- or menthol-flavored. *Id.* FDA  
12 has expressly kept certain menthol-flavored ENDS products on the market, partly to  
13 allow menthol cigarette smokers to transition to other “potentially less harmful”  
14 menthol-flavored products and because “[d]ata shows that . . . menthol-flavored  
15 ENDS products are not as appealing to minors as other flavored ENDS products.” *Id.*  
16 at 23–24, 39. In FDA’s view, “[t]his approach strikes an appropriate balance between  
17 restricting youth access to such products, while maintaining availability of potentially  
18 less harmful options for current and former adult smokers who have transitioned ...  
19 away from combusted tobacco products.” *Id.* at 20.

20 California’s ban on those very products and others permitted by FDA would  
21 thwart FDA’s public-health determinations regarding whether to prohibit flavored  
22 tobacco products. Unlike FDA, state laws could prohibit all flavored tobacco  
23 products no matter how compelling the scientific evidence that such bans could  
24 backfire and undermine health aims. The whole reason Congress entrusted FDA with  
25 making judgments about flavor-related product restrictions was because FDA is an  
26 expert agency better positioned to evaluate the scientific evidence and hew to  
27 Congress’s prescribed criteria. Allowing states to make decisions based on other  
28 criteria would thus undermine FDA’s ability to make decisions that promote public

1 health. FDA’s Director of the Center for Tobacco Products has warned that  
 2 “[d]ramatically and precipitously reducing availability of [ENDS] could present a  
 3 serious risk that adults, especially former smokers, who currently use ENDS products  
 4 and are addicted to nicotine would migrate to combustible tobacco products.”<sup>14</sup>

5 *Second*, California’s ban interferes with “the method chosen by Congress to  
 6 effectuate [its] objective.” *McDaniel v. Wells Fargo Invs., LLC*, 717 F.3d 668, 674  
 7 (9th Cir. 2013). “Conflict in technique can be fully as disruptive to the system  
 8 Congress erected as conflict in overt policy.” *Arizona v. United States*, 567 U.S. 387,  
 9 406 (2012). Here, the TCA created a detailed regulatory process as the sole method  
 10 for evaluating the design and sale of new tobacco products, such as ENDS. *See* 21  
 11 U.S.C. § 387j. To date, FDA has grounded its review of those products on the premise  
 12 that nicotine “is delivered through products that represent a continuum of risk and is  
 13 most harmful when delivered through smoke particles in combustible cigarettes.”<sup>15</sup>  
 14 Given that “continuum of risk,” FDA “strike[s] a balance between regulation and  
 15 encouraging development of innovative tobacco products that may be less harmful  
 16 than cigarettes.”<sup>16</sup>

17 Congress thus intended to subject each new tobacco product to *one* regulatory  
 18 assessment conducted by FDA, not multiple rounds of assessments by states. But if  
 19 SB793 stands, every state (and locality) could create its own standards and review  
 20 processes, upending the pathway Congress designated for evaluating new tobacco  
 21 products. “[I]f one State or political subdivision may enact such rules, then so may  
 22 any other; and the end result would undo Congress’s carefully calibrated regulatory

23  
 24 <sup>14</sup> *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883, Dkt. 120-1, at ¶ 15 (D.  
 Md. filed June 12, 2019) (Decl. of M. Zeller, Dir. of FDA Ctr. for Tobacco Prods.).

25 <sup>15</sup> FDA, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory*  
 26 *of Tobacco-Related Disease, Death* (July 2017), at <https://tinyurl.com/y8mgu3wh>.

27 <sup>16</sup> N. Sharpless, Acting Commissioner of FDA, *Testimony on FDA Regulation*  
 28 *of Electronic Nicotine Delivery Systems and Investigation of Vaping Illnesses before*  
*Committee on Energy and Commerce* (Sept. 25, 2019).

1 scheme.” *Engine Mfrs.*, 541 U.S. at 255.

2 **II. THE BAN WILL IRREPARABLY HARM PLAINTIFFS.**

3 Plaintiffs are very likely to succeed on the merits, and at a minimum have  
4 raised “serious questions” going to the merits. *Puente Arizona*, 821 F.3d at 1103 n.4.  
5 Because “the balance of hardships tips sharply in [plaintiff’s] favor,” an injunction is  
6 warranted. *Id.* Absent an injunction, SB793 will inflict “ongoing, worsening injuries”  
7 on Plaintiffs. *See Cuvillo v. City of Vallejo*, 944 F.3d 816, 833 (9th Cir. 2019).

8 To start, Plaintiffs will suffer harm because the state’s ban on flavored tobacco  
9 products is unconstitutional. Reynolds and PM USA desire to manufacture flavored  
10 tobacco products for resale in California—but California has made it illegal for  
11 retailers to sell those products. *See Huckabee Decl.* ¶¶ 6–7; *Canary-Garner Decl.*  
12 ¶¶ 3–4; *Yager Decl.* ¶ 7; *Winch Decl.* ¶ 7. Retailer Vapin’ the 619, as well as  
13 members of the Neighborhood Market Association, also desire to sell flavored  
14 tobacco products, but the state has made it illegal to do so. *Sylvester Decl.* ¶ 4; *Somo*  
15 *Decl.* ¶ 6. Being forced to comply with an unconstitutional law is by definition  
16 irreparable harm. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381  
17 (1992) (irreparable harm when government enforces a preempted law); *Am. Trucking*  
18 *Ass’ns v. City of Los Angeles*, 559 F.3d 1046, 1058 (9th Cir. 2009) (similar).

19 In addition, California’s law will cause Plaintiffs substantial financial losses.  
20 *Huckabee Decl.* ¶ 9; *Canary-Garner Decl.* ¶ 6; *Yager Decl.* ¶ 8; *Winch Decl.* ¶ 8;  
21 *Sylvester Decl.* ¶¶ 7-8; *Somo Decl.* ¶ 7. Indeed, dozens of NMA’s members,  
22 including Vapin’ the 619, will likely have to close shop completely and lay off their  
23 employees if California’s ban goes into effect. *Somo Decl.* ¶ 7; *Sylvester Decl.* ¶¶ 7-  
24 8. These financial injuries are irreparable because money damages are unavailable  
25 for preemption-based claims under § 1983 and the TCA, so Plaintiffs would not be  
26 able to obtain compensation for their significant, ongoing losses if this Court  
27 invalidates California’s unconstitutional law. *See, e.g., Zirkle Fruit Co. v. U.S. Dep’t*  
28 *of Labor*, 2019 WL 7819802, at \*9 (E.D. Wash. Sep. 11, 2019) (citing *Col. River*

1 *Indian Tribes v. Town of Parker*, 776 F.2d 846, 850–51 (9th Cir. 1995)); *see also*  
2 *Kentucky v. U.S. ex rel. Hagel*, 759 F.3d 588, 600 (6th Cir. 2014) (“a loss for which  
3 there is no remedy” because of sovereign immunity is “an irreparable harm”); *Texas*  
4 *v. EPA*, 829 F.3d 405, 433–34 (5th Cir. 2016); *Thunder Basin Coal Co. v. Reich*, 510  
5 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment) (same).

### 6 **III. THE EQUITIES AND PUBLIC INTEREST FAVOR PLAINTIFFS.**

7 To prevent enormous irreparable harm to Plaintiffs and countless others, all  
8 that Plaintiffs ask is that this Court preserve the status quo that has existed in  
9 California for decades. Doing so would not inflict any real harm on the state or the  
10 public interest. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (noting that those  
11 factors “merge when the Government is the opposing party”). California will not  
12 suffer any harm because the government does not have “an interest in the  
13 enforcement of an unconstitutional law.” *ACLU v. Ashcroft*, 322 F.3d 240, 247 (3d  
14 Cir. 2003), *aff’d*, 542 U.S. 656 (2004). “[I]t is always in the public interest to prevent  
15 the violation of a party’s constitutional rights.” *Melendres v. Arpaio*, 695 F.3d 990,  
16 1002 (9th Cir. 2012). It is also in the public interest to prevent the state from violating  
17 federal law. *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013).

18 An injunction will serve the public interest in other ways. Absent an injunction,  
19 the state’s ban will severely limit choices of adult consumers—choices that Congress  
20 and FDA have allowed adults to maintain. The ban could also drive consumers to the  
21 black market. As FDA has recognized, there is already a widespread black market in  
22 tobacco products. 81 Fed. Reg. at 29,007. If consumers cannot obtain flavored  
23 tobacco products from reputable establishments because of California’s ban, they  
24 may well try to obtain them from illicit sources. Not only could an increased black  
25 market present potential risks to consumers, but it would almost certainly lead to an  
26 increase in associated crimes. An injunction would thus serve the public interest.

### 27 **CONCLUSION**

28 The Court should grant the motion for a preliminary injunction.



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Respectfully submitted,

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