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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

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

Plaintiffs,

v.

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

Defendants.

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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INTRODUCTION

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

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

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

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

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

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

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

[1] *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018).

cigarettes do not adversely affect smoking initiation, dependence, or cessation.[2]

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

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[2] *E.g.*, RAI Services Company, *Comment Letter on Advance Notice of Proposed Rulemaking Regarding Menthol in Cigarettes, Tobacco Products* (Nov. 22, 2013); RAI Services Company, *Comment Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors in Tobacco Products* (July 18, 2018); Altria Client Serv., *Comment Letter on Advance Notice of Proposed Rulemaking Regarding Menthol in Cigarettes, Tobacco Products* (Nov. 22, 2013); *Comment Letter on Advance Notice of Proposed Rulemaking Regarding Regulations of Flavors in Tobacco Products* (July 19, 2018).

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

[4] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and other Deemed Products on the Market Without Premarket Authorization* 19 (revised Apr. 2020) ("Enforcement Priorities"), *at* https://tinyurl.com/u22rjty.

[5] *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/y4shrbuj.

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

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

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

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

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

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

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

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

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

[8] *E.g.*, FDA News Release, *FDA Permits Sale of IQOS Tobacco Heating System through Premarket Tobacco Product Application Pathway*, *at* https://tinyurl.com/y5d7qhpb.

[9] *E.g.*, FDA News Release, *FDA Grants First-Ever Modified Risk Orders to Eight Smokeless Tobacco Products* (authorizing marketing of Swedish Match's 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/y2bvbzxv.

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

ARGUMENT

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

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

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

A. The TCA Expressly Preempts California's Ban.

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

1. California's ban falls within the TCA's Preemption Clause.

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

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

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

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

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

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

[10] *See also Webster's Third* 1818 (defining "property" as "an effect that a material object or substance has … on one or more of the senses of an observer"); *JL 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").

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

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

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

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[11] *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018); *see also* FDA, Press Release (Nov. 15, 2018) (announcing intent to consider banning menthol cigarettes and flavored cigars), *at* https://tinyurl.com/y4kn533v; *cf. Premarket Tobacco Product 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.

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

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

husbandry practices are not "ingredient requirements").[12]

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

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

[12] In fact, the Tobacco Preemption Clause separately preempts state laws 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.

regulate manufacturing.

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

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

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

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

2. The Saving Clause Does Not Apply.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[13] To be sure, the one court to address the interrelationship between the Preemption and Saving Clauses—the district court in *Edina*—held that the Saving Clause covers both "requirements" and "prohibitions" because the Preemption and Saving Clauses both refer to "requirements" but do not expressly refer to prohibitions. 2020 WL 5106853, at *5–6. That misreads the Act. The Preservation Clause refers to "requirements," explicitly including both measures "relating to" 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."

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

* * *

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

B. SB793 Is Also Preempted Because It Thwarts the TCA's Objectives.

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

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

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

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

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

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

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

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

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

health. FDA's Director of the Center for Tobacco Products has warned that "[d]ramatically and precipitously reducing availability of [ENDS] could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products."[14]

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

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

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[14] *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.).

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

[16] N. Sharpless, Acting Commissioner of FDA, *Testimony on FDA Regulation of Electronic Nicotine Delivery Systems and Investigation of Vaping Illnesses before Committee on Energy and Commerce* (Sept. 25, 2019).

scheme." *Engine Mfrs.*, 541 U.S. at 255.

II. THE BAN WILL IRREPARABLY HARM PLAINTIFFS.

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

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

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

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

III. THE EQUITIES AND PUBLIC INTEREST FAVOR PLAINTIFFS.

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

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

CONCLUSION

The Court should grant the motion for a preliminary injunction.

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Respectfully submitted,

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