No. 22A____

IN THE

Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY; R.J. REYNOLDS VAPOR COMPANY; AMERICAN SNUFF COMPANY, LLC; SANTA FE NATURAL TOBACCO COMPANY, INC.; MODORAL BRANDS INC.; NEIGHBORHOOD MARKET ASSOCIATION, INC.; AND MORIJA, LLC DBA VAPIN' THE 619,

Applicants,

v.

ROBERT BONTA, 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,

Respondents.

To the Honorable Elena Kagan, Associate Justice of the Supreme Court of the United States and Circuit Justice for the Ninth Circuit

Application from The United States Court of Appeals for the Ninth Circuit (No. 22-56052)

EMERGENCY APPLICATION FOR WRIT OF INJUNCTION

NOEL J. FRANCISCO
Counsel of Record
CHRISTIAN G. VERGONIS
RYAN J. WATSON
ANDREW J. M. BENTZ
CHARLES E.T. ROBERTS
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
njfrancisco@jonesday.com

Counsel for Applicants

QUESTION PRESENTED

Twice in the last two decades, this Court has reversed the Ninth Circuit for allowing states to use sales bans to evade express federal preemption of state standards. In *Engine Manufacturers*, this Court rejected the Ninth Circuit's conclusion that California could escape preemption of state vehicle emissions "standards" by banning the purchase (but not the manufacture) of cars that did not meet state standards. *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 254 (2004). The Court held that "a standard is a standard even when not enforced through manufacturer-directed regulation." *Id.* And in *National Meat*, this Court rejected the Ninth Circuit's conclusion that California could avoid express preemption of state manufacturing standards by framing the state law as a sales ban. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 464 (2012). To hold otherwise "would make a mockery of the [Act's] preemption provision." *Id.* Nonetheless, in *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022) ("*Los Angeles County*"), the Ninth Circuit held that states can evade the federal Tobacco Control Act's express preemption of state product standards through a sales ban. As Judge Nelson explained in dissent in that case, the Ninth Circuit has repeated the same errors as it did in *Engine Manufacturers* and *National Meat* and "allow[ed] states … to defeat [the] entire purpose" of the Act's preemption provisions. *Id.* at 561 (Nelson, J. dissenting). *Los Angeles County* bound the Ninth Circuit in this case, which presents the same question:

Whether the Tobacco Control Act expressly preempts state and local laws that prohibit the sale of flavored tobacco products.

CORPORATE DISCLOSURE STATEMENT

Applicant R.J. Reynolds Tobacco Company is a direct, wholly owned subsidiary of R.J. Reynolds Tobacco Holdings, Inc.; R.J. Reynolds Tobacco Holdings, Inc. is a direct, wholly owned subsidiary of Reynolds American Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco, p.l.c., a publicly traded company.

Applicant R.J. Reynolds Vapor Company is a direct, wholly owned subsidiary of RAI Innovations Company; RAI Innovations Company is a direct, wholly owned subsidiary of Reynolds American, Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco, p.l.c., a publicly traded company.

Applicant American Snuff Company, LLC is a direct, wholly owned subsidiary of Conwood Holdings Inc.; Conwood Holdings Inc. is a wholly owned subsidiary of Reynolds American Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco, p.l.c., a publicly traded company.

Applicant Santa Fe Natural Tobacco Company, Inc. is a direct, wholly owned subsidiary of Reynolds American Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco, p.l.c., a publicly traded company.

Applicant Modoral Brands Inc. is a subsidiary of RAI Innovations Company; RAI Innovations Company is a subsidiary of Reynolds American Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco,

p.l.c., a publicly traded company.

Applicant Neighborhood Market Association, Inc. has no parent corporation and no publicly held corporation owning 10% or more of its stock exists.

Applicant Morija, LLC dba Vapin' the 619 has no parent corporation and no publicly held corporation owning 10% or more of its stock exists.

PARTIES TO THE PROCEEDING

Applicants, who were the Plaintiffs-Appellants in the Ninth Circuit, are R.J. Reynolds Tobacco Company, R.J. Reynolds Vapor Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., Modoral Brands Inc., Neighborhood Market Association, Inc., and Morija, LLC dba Vapin' the 619.

Respondents, who were the Defendants-Appellees in the Ninth Circuit, are Robert Bonta, 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.

RELATED PROCEEDINGS

R.J. Reynolds Tobacco Co., et al. v. Bonta, et al., No. 3:22-cv-01755, U.S. District Court for the Southern District of California. Order denying preliminary injunction and denying injunction pending appeal entered Nov. 15, 2022.

R.J. Reynolds Tobacco Co., et al. v. Bonta, et al., No. 22-56052, U.S. Court of the Appeals for the Ninth Circuit. Order denying injunction pending appeal entered Nov. 28, 2022.

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OTHER AUTHORITIES

To the Honorable Elena Kagan, Associate Justice of the United States Supreme Court and Circuit Justice for the Ninth Circuit:

Pursuant to Rule 22 of this Court and the All Writs Act, 28 U.S.C. § 1651(a), Applicants R.J. Reynolds Tobacco Company et al. respectfully seek an emergency injunction prohibiting enforcement of California Senate Bill 793 ("SB793") pending the appeal, and the filing and disposition of a petition for certiorari seeking review, of their federal-preemption challenge to SB793. That statute, which bans the retail sale of all "flavored tobacco products" in the State of California, is set to go into effect no later than December 21, 2022. Immediate action by this Court is therefore needed to avoid the irreparable harm that California's law will cause Applicants and numerous others. The Ninth Circuit denied Applicant's emergency motion for an injunction pending appeal on November 28, 2022.

This request arises from the Ninth Circuit's decision to effectively ignore the Tobacco Control Act's express-preemption provision and permit states to completely prohibit the sale of flavored tobacco products for failing to meet state "tobacco product standards." Absent immediate judicial intervention, Applicants will suffer irreparable harm because they will be unable to sell their products in one of the Nation's largest markets. For example, entities like R.J. Reynolds Tobacco Company will be unable to sell menthol cigarettes—which make up approximately one-third of the cigarette market—in California. Likewise, Modoral will be entirely shut out from California, and thus stands to lose millions of dollars a year, because it only produces flavored tobacco products. And many smaller entities, including family-owned retailers, will likely have to close shop entirely and lay off their employees. None of

this damage can be compensated, even if California's law is ultimately declared unconstitutional, given the State's sovereign immunity.

Applicants are also likely to obtain certiorari review in this Court and succeed on the merits of their express-preemption claim. As to the merits, the federal Tobacco Control Act ("TCA") preempts "*any*" state law (like SB793) that sets a tobacco product standard (such as a ban on flavors) that differs from federal standards, and the TCA does not save from preemption laws (like SB793) that categorically prohibit the sale of such products. 21 U.S.C. § 387p(a). The Ninth Circuit's contrary decision in *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022) ("*Los Angeles County*"), which controlled the outcome of this case below, is manifestly wrong and a petition for certiorari in that case is pending before this Court. *See* No. 22-338 (U.S.). As Judge Nelson's dissent explained in *Los Angeles County*, this Court has "twice reversed" the Ninth Circuit for committing the very same error as below, that is, allowing states to use sales bans to evade express federal preemption of state standards. 29 F.4th at 562 (Nelson, J., dissenting) (citing first *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246 (2004); and then *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012)).

Moreover, at least four Justices are likely to grant certiorari on this issue. The Ninth Circuit's interpretation of the TCA directly conflicts with numerous decisions from this Court (including *Engine Manufacturers* and *National Meat*). The Ninth Circuit's interpretation is also inconsistent with the reasoning of other circuits and implicates important issues. And this case presents an ideal vehicle.

Finally, the public interest and equities strongly favor an injunction. An injunction will merely preserve the status quo that has existed for decades in California, while preventing irreparable harm to Applicants and other adverse consequences, such as driving consumers to the illicit market for products that evade federal and state regulation altogether.

Alternatively, the Court should treat this application as a petition for a writ of certiorari before judgment, grant certiorari, and issue an injunction pending review.

OPINIONS BELOW

The Ninth Circuit's order is not reported, but is reproduced at App.1a. The district court's order is not reported, but is reproduced at App.2a–3a. The Ninth Circuit's prior binding opinion, *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, on which the orders below relied, is reported at 29 F.4th 542.

JURISDICTION

The district court denied Applicants' motion for a preliminary injunction and for an injunction pending appeal on November 15, 2022. App.2a–3a. Consistent with Rule 23.3, Applicants sought an injunction pending appeal from the Ninth Circuit. The Ninth Circuit denied the motion for an injunction pending appeal on November 28, 2022. App.1a. This Court has jurisdiction under 28 U.S.C. §§ 1254(1) & 1651, and it may grant the requested relief under 28 U.S.C. § 1651(a).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions (including 21 U.S.C. §§ 387g & 387p) are at App.46a–85a.

STATEMENT OF THE CASE

A. Legal Background.

Long before California considered prohibiting flavored tobacco products, Congress enacted a comprehensive regime distributing authority over tobacco product regulation between FDA and state and local governments. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA). Among other things, the Act amended the federal Food, Drug, and Cosmetic Act to grant FDA primary authority to regulate tobacco products. *See* 21 U.S.C. §§ 387–387s.

The TCA addresses flavors in tobacco products in a section entitled "Tobacco product standards." *Id.* § 387g. In that section, Congress created a "[t]obacco product standard[]" prohibiting characterizing flavors in cigarettes other than tobacco or menthol. *Id.* § 387g(a)(1)(A) (establishing this tobacco product standard); *id.* § 387g(a)(2) (calling it a "tobacco product standard[]"); *id.* § 387g(a)(3)(A) (same). Congress, moreover, enforced that standard through a sales ban, providing that any cigarettes containing impermissible characterizing flavors are "adulterated" and cannot be sold. *Id.* §§ 387b(5), 331(a), (c). Congress left it to FDA to decide, subject to various requirements, whether to extend that prohibition to other tobacco products or flavors. *E.g.*, *id.* § 387g(a).

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

The preservation clause generally preserves "the authority of" states, localities, the Armed Forces, federal agencies, and Indian tribes to promulgate measures that are "in addition to, or more stringent than, requirements" under the TCA, including "measure[s] *relating to or prohibiting the sale* … of tobacco products by individuals of any age." *Id.* § 387p(a)(1) (emphasis added). But while the preservation of those entities' authority is broad, when it comes to state and local governments, it has an express exception: If a state or local law falls within the TCA's preemption clause, that law is not protected by the preservation clause. *Id.* (stating that the preservation clause applies "[e]xcept as provided in [the preemption clause]").

The preemption clause then prohibits states and localities from "establish[ing] … *any requirement*" that "is different from, or in addition to," federal requirements "relating to *tobacco product standards*, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." *Id.* § 387p(a)(2)(A) (emphasis added). It thus preempts both requirements "relating to" *and* "prohibiting" tobacco product sales if they differ from federal tobacco product standards.

The savings clause then provides an exception to preemption. It saves state and local "requirements *relating to the sale* … of, tobacco products by individuals of any age." *Id.* § 387p(a)(2)(B) (emphasis added). But unlike the preservation clause, the savings clause does not reference—and so does not save—local power to enact "requirements … *prohibiting the sale*" of those products. *Compare id.* (savings clause), *with id.* § 387p(a)(1) (preservation clause).

B. California Bans the Sale of Flavored Tobacco Products.

There has been a surge in states and localities restricting, and sometimes completely banning, the sale of flavored tobacco products. *See Los Angeles County*, 29 F.4th at 551 (identifying more than 300 restrictions). The County of Los Angeles joined that trend in 2019. And the State of California followed the County's model in 2020. That year, the Governor of California signed SB793 into law, which provides that tobacco retailers "shall not sell … a flavored tobacco product" in the state. SB793, § 104559.5(b)(1). SB793 was set to go into effect on January 21, 2021, but a referendum challenging the law qualified to be on the ballot for the November 8, 2022 general election. *See* Cal. Sec'y of State, *Qualified Statewide Ballot Measures, November 8, 2022, Statewide Ballot Measures: Proposition 31*, https://tinyurl.com/y6cwbuyr (last visited Nov. 28, 2022). Accordingly, the referendum suspended operation of SB793 unless and until it was "approved by a majority of voters." *Wilde v. City of Dunsmuir*, 9 Cal. 5th 1105, 1111 (2020); *see* Cal. Const. art. IV, § 8(c)(2).[1]

On November 8, 2022, Californians went to the polls and approved SB793 by a margin of 63.5% to 36.5%. Cal. Sec'y of State, *State Ballot Measures – Statewide Results*, https://tinyurl.com/hhtmc43u (last visited Nov. 29, 2022). Absent judicial intervention, SB793 will go into effect by December 21, 2022. *See* Cal. Const. art. II, § 10(a); Cal. Elec. Code § 15501(b).

[1] Applicants filed suit immediately after SB793's enactment, but because the referendum qualified after that lawsuit was filed, the district court dismissed that suit without prejudice on ripeness grounds. *See R.J. Reynolds Tobacco Co. v. Becerra*, No. 20-CV-1990, 2021 WL 3472697, at *1 (S.D. Cal. Aug. 6, 2021).

SB793 makes it illegal to "sell, offer for sale, or possess with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer." SB793, § 104559.5(b)(1) (reproduced in full at App.82a–85a). A "[f]lavored tobacco product" includes "any tobacco product that contains a constituent that imparts a characterizing flavor." *Id.* § 104559.5(a)(4). A "[c]onstituent," in turn, is defined as "any ingredient, substance, chemical, or compound … *that is added by the manufacturer* … during the processing, *manufacture*, or packing of the tobacco product." *Id.* § 104559.5(a)(2) (emphasis added). And a "[t]obacco product" is "[a] product containing, made, or derived from tobacco or nicotine that is intended for human consumption," including "cigarettes," "chewing tobacco," "snuff," and electronic nicotine systems. Cal. Health & Safety Code § 104495(8)(A)(i)–(ii).

California thus bans retailers from selling "[f]lavored tobacco product[s]," including menthol cigarettes. In fact, SB793 bans products even if FDA has found them to be "appropriate for the protection of the public health,"[2] and even if FDA has authorized them to be marketed as presenting lower health risks than cigarettes.[3]

C. Procedural History.

Applicants R.J. Reynolds Tobacco Company, R.J. Reynolds Vapor Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., and

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[2] *E.g.*, FDA Decision Summary PM0000011 (Nov. 10, 2015) (authorizing a mint snus product), https://tinyurl.com/mw56k4ps.

[3] *E.g.*, FDA News Release, *FDA Grants First-Ever Modified Risk Orders to Eight Smokeless Tobacco Products* (Oct. 22, 2019)(authorizing marketing of flavored snus products as having "a lower risk [than cigarettes] of" certain diseases), https://tinyurl.com/y6ruvbdz.

Modoral Brands Inc. manufacture and distribute various tobacco products for sale in California, including menthol-flavored cigarettes. App.15a. Applicant Neighborhood Market Association, Inc. is a California-based non-profit trade association comprised of various tobacco retailers, wholesalers, and manufacturers, many of whom sell flavored tobacco products. *Id.* Applicant Morija, LLC, which does business as Vapin' the 619, is a San Diego-based tobacco retailer that exclusively sells electronic smoking devices and e-liquid tobacco products. *Id.* Because all are subject to California's ban, they collectively filed suit as soon as Californians approved SB793 in November 2022. App.5a. And they immediately sought a preliminary injunction and injunction pending appeal because the ban is set to go into effect no later than December 21, 2022. *Id.* Nevertheless, Plaintiffs recognized that their express-preemption claim, which served as the basis for the relief sought, was foreclosed in the district court (and the Ninth Circuit) by *Los Angeles County*, 29 F.4th 552. *Id.*

a. Like California's SB793, Los Angeles County's Ordinance banned the sale of flavored tobacco products. Relevant to this case, Reynolds and certain affiliates (collectively, "Reynolds") sued the County, arguing that the TCA preempted the Ordinance. As Reynolds argued, a ban on the sale of flavored tobacco products is a paradigmatic "tobacco product standard." And because the County's ban is broader than the federal one, it is "different from" and "in addition to" the federal standard under the TCA's preemption clause.

A divided panel of the Ninth Circuit upheld the Ordinance. *See Los Angeles County*, 29 F.4th 542. The majority concluded that "tobacco product standards" are

limited to regulations of how a "product must be produced"—a limitation found nowhere in the statutory text. *Id.* at 556. And because the Ordinance "merely" bans the *sale* of flavored tobacco products, the majority concluded that it is not a preempted tobacco product standard. *Id.* The court also reasoned that not limiting "tobacco product standards" to production regulations "would render much of the preceding preservation clause a nullity." *Id.* at 554.

The majority alternatively held that the TCA's savings clause saved the Ordinance. *Id.* at 558. "A ban on the sale of flavored tobacco products is, simply put, a requirement that tobacco retailers or licensees throughout the County not sell flavored tobacco products. It therefore fits within the savings clause as a 'requirement[] relating to the sale ... of[] tobacco products [to] individuals of any age.'" *Id.* (quoting 21 U.S.C. § 387p(a)(2)(B)). The majority refused to give effect to the statutory distinction between requirements "relating to … sales," on the one hand, and those "prohibiting sales," on the other. Instead, it held that the savings clause's reference to the former included the latter, notwithstanding the statute's clear distinction between the two.

Judge Nelson dissented. He explained that Los Angeles's ban falls within the preemption clause and is neither preserved nor saved. He began with this Court's decisions in *Engine Manufacturers*, 541 U.S. 246, and *National Meat*, 565 U.S. 452, which "[both] … reversed [the Ninth Circuit] for interpreting an express preemption clause to allow states and municipalities to defeat its entire purpose with a sales ban." *Los Angeles County*, 29 F.4th at 561 (Nelson, J., dissenting). Judge Nelson explained

that those cases establish that "states can't get around" preemption "by disguising [their] regulation as a sales ban." *Id.* at 563. Those cases thus require "hold[ing] that Los Angeles's ban is covered by the preemption clause." *Id.* Judge Nelson also noted that the majority's reasoning was inconsistent with the Second Circuit's reasoning in *U.S. Smokeless*, because that court "upheld a more limited regulation" and "was careful to avoid implying that a complete sales ban would be permissible." *Id.* at 564.

Judge Nelson further explained that the "preservation clause does not apply to the preemption clause at all" because it is qualified by the words "'[e]xcept as provided in' … the preemption clause." *Id.* Instead, the preservation clause clarifies that no other section of the Act has express preemptive effect and that federal agencies and Indian tribes are unaffected by the preemption clause. *Id.* at 565. Finally, Judge Nelson concluded that the savings clause does not save the County's ban because the clause saves only age-based requirements. *Id.* "Any other reading makes the clause '[to] individuals of any age' superfluous." *Id.*

The plaintiffs in *Los Angeles County* then filed a petition for writ of certiorari, which remains pending. *See* No. 22-338 (U.S. filed Oct. 7, 2022). This Court has since called for a response. *Id.* (Nov. 22, 2022).

b. Shortly after voters approved California's ban on the sale of flavored tobacco products, Applicants filed suit, arguing that SB793 is preempted. Applicants moved for a preliminary injunction and an injunction pending appeal, but conceded that the Ninth Circuit's opinion in *Los Angeles County* required denial of injunctive relief, while noting that they preserved their arguments for appeal. App.5a. The district

court denied Applicants' motion for preliminary injunction. App.2a–3a. The Ninth Circuit denied a motion for an injunction pending appeal. App.1a. To further facilitate this Court's review, Applicants have also filed a motion for summary affirmance in the Ninth Circuit. This emergency application follows.

REASONS FOR GRANTING THE APPLICATION

The All Writs Act, 28 U.S.C. § 1651(a), authorizes a Circuit Justice or the Court to issue an injunction pending appeal. In the context of constitutional claims, an injunction is appropriate when applicants face irreparable harm, when they are likely to obtain certiorari review and succeed on the merits of their claims, and when the public interest would not be harmed. *See Tandon v. Newsom*, 141 S. Ct. 1294, 1296–97 (2021) (per curiam) (citing *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 66 (2020)); *Lucas v. Townsend*, 486 U.S. 1301, 1305 (1988) (Kennedy, J., in chambers) (citing same factors and considering whether there is a likelihood of granting certiorari and "fair prospect" of reversal). The Court also has discretion to issue an injunction "based on all the circumstances of the case," without the injunction "be[ing] construed as an expression of the Court's views on the merits" of the case. *Little Sisters of the Poor Home for the Aged v. Sebelius*, 571 U.S. 1171 (2014).

Applying these factors, Applicants here are entitled to an injunction because they face imminent, irreparable harm; they are likely to obtain certiorari review and succeed on the merits; and an injunction will preserve the decades-old status quo, thereby allowing this Court time to decide the merits without letting loose the grave irreparable harm that California's law will inflict.

I. ABSENT AN IMMEDIATE INJUNCTION, APPLICANTS FACE IRREPARABLE HARM.

In no fewer than 22 days, Applicants will be shut out of one of the Nation's largest markets for flavored tobacco products. And absent immediate judicial intervention, they will suffer significant and irreparable financial and other harms.

Being forced to comply with a preempted law itself constitutes irreparable harm. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381–82 (1992). Moreover, the costs of complying with an unlawful statute constitute irreparable harm because sovereign immunity will prevent recovery of *any* money damages if and when the statute is set aside. *See, e.g.*, *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam) (irreparable harm where there was "no guarantee of eventual recovery" for financial harm); *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and concurring in the judgment) ("[C]omplying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs."). And unlawful government enforcement, too, can result in irreparable injury to a business's goodwill and reputation. *See, e.g.*, *Stuhlberg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001).

Applicants stand to suffer all three of these distinct forms of irreparable harm. *First*, being forced to comply with a law that violates the Supremacy Clause constitutes irreparable harm per se. *See Morales*, 504 U.S. at 381. As explained below, *infra* Part II, there is no doubt that California's law is unconstitutional.

Second, even beyond the constitutional violation, SB793 will cause Applicants substantial financial losses. For example, entities like R.J. Reynolds Tobacco Company will be unable to sell menthol cigarettes in one of the Nation's largest markets. And menthol cigarettes make up approximately one-third of the cigarette market. FTC, *Cigarette Report for 2019* (2021), https://tinyurl.com/5xx237xj. It is even worse for other Applicants. Modoral, which exclusively manufactures "flavored tobacco products," will be entirely cut off from one of the Nation's largest markets. App.38a (Canary-Garner Decl. ¶ 8). That will result in a loss of millions of dollars in gross revenue per year. *Id.* And family-owned retailer Vapin' the 619 will likely have to close up shop completely and lay off its employees. App.42a (Sylvester Decl. ¶¶ 7–8). Numerous other applicant-retailers face the same fate. App.45a (Mansour Decl. ¶ 7). And still other Applicants will have to spend tens of millions of dollars on marketing-related activities to compete within the State of California for former consumers of their flavored products who do not wish to stop using tobacco products. App.34a (Silva Decl. ¶ 7). These financial injuries are all irreparable given sovereign immunity. *See Ala. Ass'n of Realtors*, 141 S. Ct. at 2489.

Third, Applicants stand to lose customer goodwill and suffer reputational harm as a result of California's absolute ban of products they either manufacture or sell. Once Reynolds' flavored tobacco products are removed from store shelves, some customers will resort to using other, non-Reynolds tobacco products and may never pledge the same brand loyalty they once had to Reynolds' products, even if SB793 is ultimately invalidated. App.34a–35a (Silva Decl. ¶ 9); App.38a–39a (Canary-Garner

Decl. ¶ 9). Similarly, if SB793 is not preliminarily enjoined, retailers, such as Vapin' the 619, will likely have to close shop, losing customers whose patronage the retailers have worked hard to earn. App.42a (Sylvester Decl. ¶¶ 7–8); App.45a (Mansour Decl. ¶ 7).

For these reasons, Applicants face immediate irreparable harm absent action by this Court.

II. APPLICANTS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

Under the Tobacco Control Act, states and localities have broad authority to regulate the sale of tobacco products. They can raise the minimum purchase age, restrict sales to particular times and locations, and enforce licensing regimes. But one thing they cannot do is completely prohibit the sale of those products for failing to meet the state's or locality's preferred tobacco product standards. That is because the TCA's preemption clause specifically denies states and localities the power to enact "*any* requirement which is different from, or in addition to," federal "tobacco product standards." 21 U.S.C. § 387p(a)(2)(A) (emphasis added). Despite that clause, however, the Ninth Circuit has held that a state can evade preemption by simply framing its law as a ban on the sale of products that do not meet the state standard.

That precedent directly conflicts with this Court's precedents. Indeed, as Judge Nelson's dissent in *Los Angeles County* noted, "[i]n the last two decades, the Supreme Court has twice reversed [the Ninth Circuit] for failing"—based on the same rationale—"to find California regulations expressly preempted." 29 F.4th at 562 (Nelson, J., dissenting) (citing first *Engine Mfrs.*, 541 U.S. 246; and then *Nat'l Meat*,

565 U.S. 452). Thus, it is (at a minimum) likely that Applicants are correct on the merits of their express-preemption claim.

It is also likely that at least four Justices will vote to grant certiorari review. Not only does the Ninth Circuit's decision conflict with this Court's precedents (reason enough to grant certiorari), the Ninth Circuit's reasoning is also inconsistent with that of other circuits that have considered the TCA's preemption provisions. This case presents an exceptionally important question that has arisen in four circuits.[4] And it is an ideal vehicle to decide that question. For these reasons, Applicants are likely to obtain certiorari and succeed on the merits of their claim before this Court.

A. Applicants Are Likely Correct on the Merits of Their Claim.

Applicants are likely correct on the merits of their express-preemption claim. *See Tandon*, 141 S. Ct. at 1296–97 (citing *Roman Cath. Diocese of Brooklyn*, 141 S. Ct. at 66). That is because the TCA's preemption clause plainly preempts California's flavor ban, and the TCA's savings clause does not save it. *See Los Angeles County*, 29 F.4th at 562 (Nelson, J, dissenting).

1. The TCA's preemption clause preempts California's flavor ban.

a. The TCA's preemption clause preempts "*any*" state or local "requirement which is different from, or in addition to," federal "tobacco product standards." 21 U.S.C. § 387p(a)(2)(A) (emphasis added). Nonetheless, the Ninth Circuit's precedent holds that as long as a state or local law enforcing such a requirement is

[4] The same issue is currently pending before the Eighth Circuit in *City of Edina*, No. 20-2852 (8th Cir.), which was argued on May 12, 2021.

framed as a sales ban, the state or local law is not preempted. The court explained that Los Angeles's Ordinance was "merely banning the *sale* of a certain type of tobacco product, not dictating how that product must be *produced*." *Los Angeles County*, 29 F.4th at 556 (emphasis added). That, in the Ninth Circuit's view, was dispositive, because "tobacco product standards" do not include sales regulations or prohibitions. The same reasoning carries over to this case: Because California "merely" bans the sale of flavored tobacco products, it is not preempted.

The Ninth Circuit's precedent conflicts with this Court's repeated admonition that states and localities cannot evade preemption by simply enforcing their standards at the point of sale. In *Engine Manufacturers*, this Court rejected the Ninth Circuit's decision to impose such an atextual limitation on a preemption clause. There, California prohibited the purchase of cars that did not meet local emission standards. 541 U.S. at 248–49. The Clean Air Act, however, expressly preempted states from adopting "*standard[s]* relating to the control of emissions from new motor vehicles." 42 U.S.C. § 7543(a) (emphasis added).

As in *Los Angeles County*, California argued that a "standard" was only "a 'production mandate'" applicable to manufacturers; thus, the *purchase* requirement was not preempted. *Engine Mfrs.*, 541 U.S. at 254–55. But this Court specifically rejected that attempt to "engraft onto th[e] meaning of 'standard' a limiting component" found nowhere in the statutory text. *Id.* at 253. Instead, looking to the dictionary definition of "standard," the Court concluded that a "standard" applies to the final product, not simply how it is made. *Id.* Standards "target" the product itself,

which means preempted "standard-enforcement efforts … can be directed to manufacturers or purchasers." *Id.* In other words, "a standard is a standard even when not enforced through manufacturer-directed regulation." *Id.* at 254.

The same is true here. A tobacco product *standard* applies to the final product, not simply to how the product is made. *See* 21 U.S.C. § 387g(a)(4)(B)(i). A sales ban and a manufacturing ban are just different ways of enforcing a standard. In either case, what is being enforced is a *standard* (no characterizing flavors in tobacco products). Indeed, like California's law here, *federal* tobacco product standards are *also* enforced at the point of sale. *Id.* §§ 331(a), (c), 387b(5); *see also* 21 C.F.R. § 1162.1(b) (proposed 2022) (proposing, as part of a "[p]roduct [s]tandard for [m]enthol in [c]igarettes," to ban the sale of menthol cigarettes). Such enforcement mechanisms, however, do not change the fact that the sales prohibitions are enforcing product *standards*. The Ninth Circuit's conclusion that tobacco product standards in the TCA are limited to production regulations is thus irreconcilable with *Engine Manufacturers*.

It is also irreconcilable with the TCA's plain text. The TCA specifically says that tobacco product standards can govern a tobacco product's "properties," "constituents," and "additives." 21 U.S.C. § 387g(a)(4)(B)(i). Those words likewise refer to the final product—*not* merely the production of the product. In other words, a product standard governs *what* may be produced, not just *how* it may be produced.

Indeed, the TCA makes it patently clear that the type of law at issue here—a ban on flavored tobacco products—is a paradigmatic "tobacco product standard." The

section titled "Tobacco product standards" contains two tobacco product standards, the very first of which is a ban on characterizing flavors in cigarettes (other than tobacco and menthol). *Id.* § 387g. It bans cigarettes that "contain, as a constituent … or additive, an artificial or natural flavor (other than tobacco or menthol) … that is a *characterizing flavor* of the tobacco product or tobacco smoke." *Id.* § 387g(a)(1) (emphasis added). The next two provisions also call that prohibition a "tobacco product standard[]." *Id.* §§ 387g(a)(2), 387g(a)(3)(A).

The statute also expressly describes "tobacco product standard[s]" as encompassing "provisions respecting the construction, components, *ingredients, additives, constituents, … and properties* of the tobacco product," *id.* § 387g(a)(4)(B)(i) (emphasis added)—which plainly covers the regulation of flavors. *See, e.g.*, *R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 879 (D. Minn. 2020) ("*Edina*") ("[T]here can be no dispute that a provision respecting the flavor of a tobacco product is a provision respecting a 'propert[y]' of that product."), *appeal pending*, No. 20-2852 (8th Cir. argued May 12, 2021); 21 U.S.C. § 387(1) (defining "additive[s]" to include "substances intended for use as a flavoring"); *Webster's Third New Int'l Dictionary* 486 (1986) (defining "constituent" as "an essential part" of the product).

And lest there be any doubt, FDA too has repeatedly concluded that restrictions on flavors—including sales bans—are tobacco product standards. *See* 21 C.F.R. § 1162.1(b) (proposed 2022) (proposing, as part of a "[p]roduct [s]tandard for [m]enthol in [c]igarettes," to ban the sale of menthol cigarettes); FDA, *Illicit Trade*

in Tobacco Products after Implementation of an FDA Product Standard 4 (Mar. 15, 2018) (explaining FDA was "considering establishing a *product standard* prohibiting the manufacture, *sale, and distribution* of tobacco products with certain characterizing flavors" (emphasis added)).[5]

Thus, the Ninth Circuit's artificial limitation of "tobacco product standards" not only conflicts with *Engine Manufacturers* but also with the text of the TCA itself.

b. Even if tobacco product standards were somehow limited to production mandates (they are not), the Ninth Circuit's conclusion conflicts with *National Meat*, 565 U.S. 452. There, California banned slaughterhouses from selling meat from animals that could not walk. Manufacturers argued that the Federal Meat Inspection Act ("FMIA") preempted California's law. That Act prohibited states from adopting "[r]equirements … with respect to premises, facilities and operations of any establishment … which are in addition to, or different than those made under [the FMIA]." *Id.* at 458. Unlike here, this provision was textually limited to production mandates. And like Los Angeles County, California argued that its rule was not preempted because it regulated sales, not manufacturing. *Id.* at 463.

This Court, however, unanimously rejected the argument. "[I]f the sales ban were to avoid the FMIA's preemption clause, then any State could impose any

[5] Further examples abound. *See* FDA, *Menthol in Cigarettes, Tobacco Products; Request for Comments*, 78 Fed. Reg. 44,484, 44,485 (July 24, 2013); FDA, *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018); FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes* (Nov. 15, 2018), https://tinyurl.com/27z227hb.

regulation on slaughterhouses just by framing it as a ban on the sale of meat produced in whatever way the State disapproved. That would make a mockery of the FMIA's preemption provision." *Id.* at 464.

So too here. "[E]ven if it were necessary to show a direct ban on [production], [SB793] 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*, 482 F. Supp. 3d at 879 (citing *Nat'l Meat*, 565 U.S. 452). In that way, California's ban does regulate how tobacco products must be produced. *See id.*[6]

c. The Ninth Circuit's attempt to distinguish the TCA from the statutes in *Engine Manufacturers* and *National Meat* is unavailing. According to its reasoning, the TCA's "preservation clause" makes all the difference. *Los Angeles County*, 29 F.4th at 556. Because that clause preserves local authority to enact laws "relating to or prohibiting the sale" of tobacco products, 21 U.S.C. § 387p(a)(1), the court concluded that the preemption clause must be limited to regulations "dictating how th[e] product must be produced." *Los Angeles County*, 29 F.4th at 556. Otherwise, the preservation clause would be a "nullity." *Id.* at 554.

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[6] Indeed, even under the Ninth Circuit's reasoning, SB793 *is* directed "at the manufacturing stage." *Los Angeles County*, 29 F.4th at 555. SB793 bans the sale of "any tobacco product that *contains* a constituent that imparts a characterizing flavor." SB793, § 104559.5(a)(4) (emphasis added). And a "[c]onstituent," in turn, is defined as "any ingredient, substance, chemical, or compound … that is *added by the manufacturer … during* the processing, *manufacture*, or packing of the tobacco product." *Id.* § 104559.5(a)(2) (emphasis added).

That gets things exactly backwards. "By its terms, the preservation clause does not apply to the preemption clause at all." *Id.* at 564 (Nelson, J., dissenting). Rather, the preservation clause is explicitly subject to the preemption clause. It says: "[E]xcept as provided in [the preemption clause] …." "Thousands of statutory provisions use the phrase 'except as provided in …' followed by a cross-reference in order to indicate that one rule should prevail over another in any circumstance in which the two conflict." *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1070 (2018). That is precisely what Congress did here. And that dispenses with the Ninth Circuit's suggestion that "[i]t is unlikely that Congress would purport to preserve something for state and local authority, only to preempt it in the very next provision." *Los Angeles County*, 29 F.4th at 556. The preservation clause thus in no way distinguishes the TCA from the statutes in *Engine Manufacturers* or *National Meat*.

Nor does Applicants' interpretation nullify the preservation clause, contrary to the Ninth Circuit's suggestion. That clause serves other critical functions, which do not "affect the preemption clause." *Id.* at 564 (Nelson, J., dissenting).

First, the preservation clause also applies to federal agencies, the military, and Indian Tribes. Those entities are not subject to the preemption clause at all, 21 U.S.C. § 387p(a)(1); the preservation clause clarifies that they are free to set their own tobacco product standards. *See Los Angeles County*, 29 F.4th at 565 (Nelson, J., dissenting).

Second, the preservation clause clarifies "that other sections of the TCA do not have any preemptive effect." *Id.* at 564. The preservation clause says that only those categories listed in the preemption clause have express preemptive effect. The preservation clause also rebuts any suggestion that Congress through the TCA occupied the field of tobacco regulation. Thus, under the preservation clause, states and localities retain broad authority over how tobacco products are sold, so long as their laws do not amount to product standards (or other preempted categories of regulation). Laws raising the minimum purchase age, restricting sales to particular times and locations, and enforcing licensing regimes are all preserved.

* * *

In sum, the Ninth Circuit's precedent directly conflicts with *Engine Manufacturer*'s admonition that a "standard" applies to the final product and that states therefore cannot circumvent preemption by targeting sales. *See* 541 U.S. at 254. And it conflicts with *National Meat*'s reaffirmation that allowing states to avoid preemption simply by framing their product standards as a "ban on the sale" of nonconforming products would "make a mockery of the … preemption provision." *See* 565 U.S. at 464.

2. The TCA's savings clause does not save California's flavor ban.

In *Los Angeles County*, the Ninth Circuit alternatively held that the TCA's savings clause saves state and local sales prohibitions. But the savings clause saves "requirements relating to … sale[s]," not "requirements prohibiting sales." *See* 21 U.S.C. § 387p(a)(2)(A). The Ninth Circuit's interpretation of the savings clause

nullifies that distinction and, in so doing, renders the preemption clause a dead letter, once again contravening *Engine Manufacturers* and *National Meat*. And given Congress's careful distinction between requirements "relating to the sale" and requirements "prohibiting the sale"—language that this Court has said must be given effect—the Ninth Circuit's interpretation also conflicts with this Court's recent decision in *Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1938 (2022).

a. The Ninth Circuit held that even if a sales prohibition fell within the TCA's preemption clause, it would nonetheless be saved by the TCA's savings clause, which saves requirements "relating to the sale" of tobacco products. *Los Angeles County*, 29 F.4th at 552. That interpretation of the savings clause, however, "make[s] a mockery of the [TCA's] preemption provision" because there is nothing for the preemption clause to do. *See Nat'l Meat*, 565 U.S. at 464. Under the decision below, a locality is free to set its own tobacco product standard, as long as it frames its law as a ban on the *sale* of products that do not meet that standard. As this Court explained in *Engine Manufacturers*, "if 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 scheme." 541 U.S. at 255.

It gets worse. Throughout the TCA, Congress intended to preempt not just state tobacco product standards but also state requirements for labeling and good manufacturing standards (among others). 21 U.S.C. § 387p(a)(2)(A). Thus, the Ninth Circuit's opinion means that a state can easily circumvent the preemption clause and establish its own good manufacturing standards, such as a requirement that

manufacturers use certain equipment. Similarly, the decision means that a state can establish its own labeling standards, such as requiring cigars and e-cigarettes to carry the state's mandated warning label, even if FDA has mandated a different one.[7] All the state has to do is ban the *sale* of products that do not meet a state's good manufacturing or labeling requirements. The Ninth Circuit's interpretation of the savings clause thus conflicts with *Engine Manufacturers* and *National Meat*, both of which held that states cannot use sales bans to circumvent a preemption clause.

b. The Ninth Circuit's precedent also directly conflicts with this Court's recent decision in *Ysleta*, 142 S. Ct. 1938. As this Court has long and repeatedly instructed, statutory provisions must fit "into an harmonious whole." *E.g.*, *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 100 (2012); *Mkt. Co. v. Hoffman*, 101 U.S. (11 Otto) 112, 116 (1879) ("every part of a statute must be construed in connection with the whole, so as to make all the parts harmonize, if possible, and give meaning to each"). And one clause cannot be construed as being "inconsistent with the [other] provisions of the act." *AT&T Co. v. Cent. Off. Tel., Inc.*, 524 U.S. 214, 227–28 (1998).

In *Ysleta*, this Court specifically applied those interpretive rules to conclude that the words "regulation[s]" and "prohibition[s]" must be given independent meaning, especially when used in the same statute. 142 S. Ct. at 1938. *Ysleta* interpreted the Restoration Act's bar on Indian Tribes' offering "gaming activities which are prohibited by the laws of … Texas." *Id.* at 1935 (quoting Ysleta del Sur

[7] While other laws would preempt state labeling of cigarettes and smokeless tobacco, 15 U.S.C. §§ 1334 & 4406(b), only the TCA expressly preempts labeling of other tobacco products.

Pueblo and Alabama and Coushatta Indian Tribes of Texas Restoration Act, Pub. L. No. 100-89, § 107(a), 101 Stat. 666, 668 (1987)). Texas argued that this provision subjected Tribes to all Texas gaming *regulations* (not just to outright prohibitions). This Court rejected that reading, relying on a separate provision of the Act that said the Act was not a "grant of civil or criminal regulatory jurisdiction to … Texas." *Id.* at 1935–36 (quoting Pub. L. No. 100-89, § 107(b), 101 Stat. at 669).

"Perhaps the most striking feature about [the Act's] language," the Court reasoned, "is its dichotomy between prohibition and regulation." *Id.* at 1938. "[T]o prohibit something means to 'forbid,' 'prevent,' or 'effectively stop' it …." *Id.* (quoting *Webster's Third*, *supra*, at 1813). By contrast, "to regulate something is usually understood to mean to 'fix the time, amount, degree, or rate' of an activity 'according to rule[s].'" *Id.* (quoting *Webster's Third*, *supra*, at 1913). "Frequently, then, the two words are 'not synonymous.'" *Id.* (quoting *Black's Law Dictionary* 1212 (6th ed. 1990)). This Court further highlighted its "usual presumption that 'differences in language like this convey differences in meaning.'" *Id.* at 1939 (quoting *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1723 (2017)). And *Ysleta* emphasized that a construction that renders "regulations simultaneously both (permissible) prohibitions and (impermissible) regulations" had to be rejected. *Id.* Accordingly, laws that "merely regulate[]" gaming do not apply to the Tribe. *Id.* at 1937.

The Court also emphasized that if the words were not given different meanings, then the Restoration Act's provision stating that the act was not a "grant of civil or criminal regulatory jurisdiction" would "be left with no work to perform."

Id. at 1938–39. That result would defy "yet another of our longstanding canons of statutory construction—this one, the rule that we must normally seek to construe Congress's work 'so that effect is given to all provisions, so that no part will be inoperative or superfluous, void or insignificant.'" *Id.* at 1939.

Finally, the Court rejected a supposed line-drawing problem when it came to regulations and prohibitions. Texas argued that distinguishing between the two would be "unworkable." *Id.* at 1943. According to Texas, courts "might be called on to decide whether 'electronic bingo' qualifies as 'bingo' and thus a gaming activity merely regulated by Texas, or whether it constitutes an entirely different sort of gaming activity absolutely banned by Texas and thus forbidden as a matter of federal law." *Id.* That could lead to further litigation. The Court "appreciate[d] these concerns" but they did "not persuade." *Id.* "Most fundamentally, they are irrelevant. It is not our place to question whether Congress adopted the wisest or most workable policy, only to discern and apply the policy it did adopt. If Texas thinks good governance requires a different set of rules, its appeals are better directed to those who make the laws than those charged with following them." *Id.* at 1943–44.

The Ninth Circuit's interpretation of the TCA—that it saves sales prohibitions—conflicts with *Ysleta*. Foremost, the savings clause only saves "requirements relating to the sale" of tobacco products. 21 U.S.C. § 387p(a)(2)(B). Under *Ysleta*, that cannot include prohibitions, since the TCA's text explicitly distinguishes between requirements "relating to the sale" and requirements "prohibiting the sale."

The TCA's preservation clause provides, "Except as provided in [the preemption clause], nothing [in the TCA] shall be construed to limit the authority of" state and local governments, federal agencies, the military, and Indian tribes, "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* <u>*or*</u> *prohibiting* the sale, distribution, [or] possession" of "tobacco products by individuals of any age." *Id.* § 387p(a)(1) (emphasis added). It thus gives state and local governments, federal agencies, the military, and Indian tribes broad authority, including the authority to adopt requirements "relating to *or* prohibiting" the sale of tobacco products. But as its text also makes clear, it is subject to the exception set forth in the preemption clause.

The preemption clause, then, takes away from state and local governments (but not others) part of the broad power conferred by the preservation clause. Under the preemption clause, state and local governments cannot enact "*any requirement* which is different from, or in addition to," federal tobacco product standards. *Id.* § 387p(a)(2)(A) (emphasis added). The capacious phrase "any requirement" sweeps in both requirements "relating to" and "prohibiting" the sale of tobacco products—both are preempted if they are "different from, or in addition to," federal standards.

Finally, the savings clause restores only part of what the preemption clause takes away. It says the preemption clause "does not apply to requirements *relating to* the sale" of tobacco products. *Id.* § 387p(a)(2)(B) (emphasis added). But absent is any

reference to the power to impose requirements "*prohibiting* the sale" of tobacco products—meaning that state and local governments still lack that power.

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 savings clause, shows that Congress deliberately excluded sales prohibitions from the class of non-preempted laws in the savings clause. Congress generally "acts intentionally and purposely" when it "includes particular language in one section of a statute but omits it in another." *Collins v. Yellen*, 141 S. Ct. 1761, 1782 (2021). 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 only way to reconcile the TCA's preemption-related clauses is to recognize that while local governments have broad authority to regulate the sales process, one thing they may not do is absolutely prohibit the sale of products that fail to meet their preferred product standards. The Ninth Circuit's contrary reading renders the TCA "a jumble." *Ysleta*, 142 S. Ct. at 1939. And it leaves the preemption clause with "no work to perform, its terms dead letters all." *Id.*; *see also supra* Part I.A.1 (explaining that this interpretation also conflicts with *Engine Manufacturers* and *National Meat*).

The Ninth Circuit's contention that the distinction between regulation and prohibition would "create a hopelessly inadministrable standard," *Los Angeles County*, 29 F.4th at 559, also conflicts with *Ysleta*, which rejected that kind of "appeal to public policy." 142 S. Ct. at 1943–44. As Judge Nelson explained in dissent in *Los Angeles County*, "[t]hat the line might be hard to draw in some hypothetical future

case is no reason to throw the baby out with the bathwater. We must avoid reading statutes in absurd ways, … but no canon of statutory interpretation requires us to avoid any reading … under which one can craft an absurd argument." 29 F.4th at 566 (Nelson, J., dissenting). And in all events, *this* case presents no line-drawing issue at all, because SB793 *bans* the sale of flavored tobacco products. *See infra* Part IV.C.

c. Finally, as Judge Nelson concluded, the savings clause also does not apply for a second reason. "The savings clause only saves for states the authority to enact age requirements." *Los Angeles County*, 29 F.4th at 565 (Nelson, J., dissenting). This much is clear from the clause's limitation to "requirements relating to the sale … of[] tobacco products [to] *individuals of any age*." 21 U.S.C. § 387p(a)(2)(B) (emphasis added). "Any age" must mean "individuals of a particular age"; that is, only state requirements that are age-based are saved. The Ninth Circuit, however, interpreted "any age" to mean "all ages," thus rendering the phrase "by individuals of any age" wholly superfluous. *Los Angeles County*, 29 F.4th at 565 (Nelson, J., dissenting). That conflicts with numerous cases instructing that statutory provisions should not be rendered meaningless. *E.g.*, *Corley v. United States*, 556 U.S. 303, 314 (2009).

* * *

For all these reasons, Applicants are clearly correct on the merits. The Ninth's Circuit's approval of California's SB793 is contrary to this Court's decisions in *Engine Manufacturers*, *National Meat*, and *Ysleta*.

B. At Least Four Justices Are Likely To Grant Certiorari.

As noted above, the Ninth Circuit's interpretation of the TCA is in conflict with this Court's decisions and the TCA's text. *See supra* Part II.A. That alone would

warrant this Court's review. *See* S. Ct. R. 10(c). But there are still more reasons for review, making it even more likely that the Court will grant certiorari and reverse. *See Lucas*, 486 U.S. at 1305 (Kennedy, J., in chambers). The Ninth Circuit's decision conflicts with the reasoning of decisions from other courts of appeals. *See* S. Ct. R. 10(a). The issues are of imperative public importance. *See id.*; *infra* Part IV. And this case presents an ideal vehicle.

1. The Ninth Circuit's decision conflicts with the reasoning of decisions from other courts of appeals.

The Ninth Circuit's decision in *Los Angeles County* conflicts with the reasoning of decisions of the First and Second Circuits. *See U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013) ("*NATO*"); *see also Los Angeles County*, 29 F.4th at 564 (Nelson, J. dissenting) (noting that the decision below conflicts with the reasoning of *U.S. Smokeless*). In contrast to the Ninth Circuit, the First and Second Circuits upheld local restrictions on flavored tobacco products based on reasoning that would not permit a blanket prohibition.

In *U.S. Smokeless*, the Second Circuit considered a New York City ordinance that limited the sale of flavored tobacco products to tobacco bars. 708 F.3d at 431. Tobacco manufacturers sued the city, arguing that the TCA expressly preempted the ordinance. The Second Circuit, however, held that the TCA did not preempt the ordinance because it was "[a] local sales *regulation* that does not clearly infringe on the FDA's authority to determine what chemicals and processes may be used in making tobacco products." *Id.* at 434 (emphasis added). The court emphasized that

this was so because the ordinance still "allows [flavored tobacco products] to be sold within New York City, although to a limited extent." *Id.* at 436. By contrast, the court explained, "any purported sales ban that in fact 'functions as a command' to tobacco manufacturers 'to structure their operations' in accordance with locally prescribed standards would not escape preemption simply because the City 'fram[ed] it as a ban on the sale of [tobacco] produced in whatever way [it] disapproved.'" *Id.* at 434 (quoting *Nat'l Meat*, 565 U.S. at 972–73). In other words, as Judge Nelson opined, the Second Circuit "did adopt a version of the [Ninth Circuit's] sales vs. manufacturing distinction," but "it was careful to avoid implying that a complete sales ban would be permissible." *Los Angeles County*, 29 F.4th at 564 (Nelson, J., dissenting).

Likewise, the law at issue in the First Circuit *regulated* the sale of flavored tobacco products—it did not *prohibit* sales completely. *NATO*, 731 F.3d at 74. In that case, a local ordinance made it "unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer, except in a smoking bar." *Id.* The First Circuit held that the ordinance was not preempted for the same reason the Second Circuit upheld New York City's ordinance: it "is not a *blanket prohibition* because it allows the sale of flavored tobacco products in smoking bars. Rather, it is a regulation 'relating to' sales…." *Id.* at 82 (emphasis added). The First Circuit concluded that this "distinguishe[d]" Providence's law from the law at issue in *National Meat*. *Id.*

By contrast, the binding precedent below upholds even a blanket prohibition. Like Los Angeles County's Ordinance, SB793 is different in kind from those upheld in *U.S. Smokeless* and *NATO*. SB793 has no exceptions. Consumers cannot purchase

menthol cigarettes, menthol-flavored vapor products, or various other flavored tobacco products *anywhere* in California. There is no exception for tobacco bars (as in *U.S. Smokeless*), smoking bars (as in *NATO*), or any other location. Thus, the Ninth Circuit's decision upholding a blanket ban conflicts with the rationale of these First and Second Circuit decisions, under which such a prohibition would be preempted.

2. The case presents issues of imperative public importance.

a. The proper test for TCA preemption is critically important for achieving Congress's objectives.

The question presented is of imperative public importance because it has far-reaching consequences for a significant industry in the national economy. Indeed, Congress has said, "The sale … of tobacco products … ha[s] a substantial effect on the Nation's economy." TCA § 2(10), 123 Stat. at 1777, *codified at* 21 U.S.C. § 387 note; *see* 7 U.S.C. § 1311 ("The marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare."), *repealed by* Pub. L. No. 108-357 (Oct. 22, 2004).

In recognition of the tobacco industry's significant role in the national economy and in order to protect against nonuniform and confusing tobacco regulations, Congress enacted the TCA, which includes a comprehensive scheme to regulate tobacco products nationwide. *See* 21 U.S.C. § 387 note. In taking that comprehensive approach to tobacco regulation, Congress granted FDA broad authority to regulate tobacco products. *See id.* ("It is in the public interest for Congress to enact legislation that provides [FDA] with the authority to regulate tobacco products and the

advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.").

Of course, Congress also recognized that states and localities should continue to play a role in regulating some aspects of tobacco products. Thus, Congress guaranteed that states and localities could continue their traditional role of regulating how tobacco products are sold—for example, through restrictions on licensing, where and when products can be sold, and ages for purchase. And to protect the federal government's exclusive authority to regulate certain aspects of tobacco products, including standards that apply to those products, Congress denied states and localities the power to enforce their own standards through sales bans.

The Ninth Circuit's decision has upended that statutory scheme and imperils Congress's careful design. Under the Ninth Circuit's rule, every state and locality may enact its own ban on flavored tobacco products; all they have to do is ban their sale. *See Engine Mfrs.*, 541 U.S. at 255. That is not what Congress intended. And the regulatory chaos augured by the Ninth Circuit's rule threatens the stable conditions that are necessary for the tobacco industry. By blessing SB793, that rule threatens what Congress sought to protect. *See* 21 U.S.C. § 387 note. As *amici curiae* have explained in *Los Angeles County*, SB793's economic impact will be catastrophic to small retailers and will also harm manufacturers. *See, e.g.*, Brief for E-Cigarette Businesses and Trade Associations as *Amici Curiae* Supporting Petitioners, *R.J. Reynolds Tobacco Co. v. County of Los Angeles,* No. 22-338 (U.S. Nov. 14, 2022).

b. The case is important because hundreds of jurisdictions have enacted similar laws, resulting in cases in four courts of appeals.

The Ninth Circuit is not the first appeals court to decide this issue. The issue has reached four federal courts of appeals, *see City of Edina*, No. 20-2852 (8th Cir. argued May 12, 2021); *Los Angeles County*, 29 F.4th 542; *NATO*, 731 F.3d 71; *U.S. Smokeless*, 708 F.3d 428. And it is sure to continue, since, as the Ninth Circuit below recognizes, hundreds of jurisdictions have enacted varying restrictions on flavored tobacco products. *Los Angeles County*, 29 F.4th at 551. That not only shows that this issue continues to arise throughout the country, but also that regulatory chaos already exists in direct defiance of Congress's design.

c. The case is also important given the far-reaching implications of the decision below.

The issue presented also goes beyond whether states and localities can ban the sale of flavored tobacco products.

First, tobacco product standards are not limited to flavors but cover any "propert[y]" of a tobacco product. 21 U.S.C. § 387g(a)(4)(B)(i). That includes the amount of nicotine in tobacco products, the length of cigars, the properties of batteries in e-cigarettes, the types of filters in cigarettes, and countless other aspects of tobacco products. And under the Ninth Circuit's rule, states and localities can target all of those "properties." Again, all the state or locality has to do is ban the *sale* of products that do not conform to their preferred product standards.

These concerns are not just hypothetical. For example, Utah has banned the sale of e-cigarettes that contain more than a certain amount of nicotine. Utah Admin.

Code r. R384-415-5. California lawmakers, in a proposed law, sought to ban cigarettes with single-use filters. Assemb. B. 1690, 2021–2022 Reg. Sess. (Cal. 2022) (as introduced Jan. 24, 2022). New York legislators are considering a similar ban on single-use filters. S.B. 1278, 2021–2022 Reg. Sess. (N.Y. 2021) (as introduced Jan. 8, 2021). Illinois bans e-cigarettes that contain certain ingredients, such as polyethylene glycol and medium chain triglycerides. 410 Ill. Comp. Stat. 86/20. And numerous states regulate the type of packaging that manufacturers can use for their e-cigarettes. *E.g.*, 430 Ill. Comp. Stat. 40/10; N.Y. Gen. Bus. Law § 399-gg(1); Me. Stat. tit. 22, § 1560-B(2); Mass. Gen. Laws ch. 270, § 27(b); 940 Mass. Code Regs. 21.05; Mich. Comp. Laws § 722.642b(1).

Thus, not only are states and localities enacting a slew of inconsistent bans on flavored tobacco products, but they are also now moving even further, usurping the authority Congress vested in FDA to set and enforce other tobacco product standards.

Second, the problem is also not limited to tobacco products. Throughout the U.S. Code, Congress has reserved to the federal government the exclusive power to set uniform product standards for a variety of industries. For example, Congress passed the Poultry Products Inspection Act ("PPIA") to "assur[e] that poultry products ... are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 451. To that end, the PPIA includes an express-preemption clause, which provides that any "[m]arking, labeling, packaging, or ingredient requirements ... in addition to, or different than, those made under [the PPIA] may not be imposed by any State." *Id.* § 467e. That ensures that labeling is consistent

throughout the country. Numerous other industries also rely on uniform, national product standards. *E.g.*, *id.* § 678 (animal slaughters); *id.* § 379r (nonprescription drugs); *id.* § 360k (medical devices); 42 U.S.C. § 7543(a) (vehicle emissions); 46 U.S.C. § 4306 (recreational vessels); 49 U.S.C. § 30103(b)(1) (motor vehicles).

But under the Ninth Circuit's opinion, businesses can no longer rely on Congress's words. All a state or locality needs to do to circumvent these preemption clauses is to frame its law as a ban on the sale of products that do not conform to its preferred requirements. So a state could skirt the PPIA's express-preemption clause by simply banning the sale of poultry products that do not use its preferred packaging, negating the preemption clause altogether. And that reasoning will carry over to numerous other preemption clauses throughout the U.S. Code.

The question presented is thus important not only for one of the largest industries in the country, but for numerous other industries as well.

3. This Case Presents an Ideal Vehicle.

This is an ideal vehicle for numerous reasons. *First*, further percolation of the question presented is not necessary. There have been three published circuit court opinions (and a dissent) on the issue. Those decisions have aired the issues, and the disagreement over how to interpret the TCA's preemption clauses is entrenched. It is now time for this Court to take up the issue. And even if there were no disagreement among the circuits, this Court routinely grants review in splitless preemption cases given the "importance of the pre-emption issue." *Wyeth v. Levine*, 555 U.S. 555, 563

(2009) (noting that certiorari was granted despite no split); *see, e.g.*, *Merck Sharp & Dohme Corp v. Albrecht*, 138 S. Ct. 2705 (2018) (granting certiorari in same situation).

Second, this issue was squarely pressed and passed upon below. There are no extraneous issues to prevent the Court from resolving this case once and for all. This Court's resolution of how to interpret the TCA's three preemption-related provisions would dispose of this case one way or another.

Third, this case also cleanly presents the core legal question: whether the TCA preempts a total prohibition on the sale of flavored tobacco products. There are no line-drawing problems when it comes to whether SB793 is a "prohibition." Some state and local restrictions on flavored tobacco products might present difficult questions regarding whether they are requirements "relating to" the sale of tobacco products or "prohibiting" their sale. But SB793 does not: it is a blanket ban on the covered products—a paradigmatic prohibition. So the Ninth Circuit's supposed administrability problem is not presented here. *Los Angeles County*, 29 F.4th at 559; *see also Ysleta*, 142 S. Ct. at 1943–44 (rejecting administrability problems as a reason to adopt an atextual interpretation).

Fourth, while this case is in a preliminary posture, the preemption issue is purely legal and so there is no need to wait to address it. Moreover, this Court has a separate petition before it presenting the same legal issue in a final judgment. Therefore, the Court should, at a minimum, issue an injunction against SB793 and grant the petition for writ of certiorari in *Los Angeles County*, No. 22-338 (U.S.).

III. THE PUBLIC INTEREST AND EQUITIES FAVOR AN INJUNCTION.

Where, as here, "the Government is the opposing party," the last two factors "merge": the government's interest is the public interest. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Those merged factors support an injunction here.

The primary purpose of a preliminary injunction is to preserve the status quo. *See Ramos v. Wolf*, 975 F.3d 872, 887 (9th Cir. 2020); *see also San Diegans for Mt. Soledad Nat'l War Mem'l v. Paulson*, 548 U.S. 1301, 1303 (2006) (Kennedy, J., in chambers) (granting stay to preserve the "status quo"); *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties …."). Enjoining SB793 will preserve the status quo that has existed for decades. A small delay of a controversial and unconstitutional law will not cause the State any harm. The government "cannot suffer harm from an injunction that merely ends an unlawful practice." *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013); *cf. Abbott v. Perez*, 138 S. Ct. 2305, 2324 (2018) (enjoining a statute can "seriously and irreparably harm the State" "*[u]nless* that statute is unconstitutional" (emphasis added)). And since SB793 is constitutionally preempted, it should never go into effect. After all, "it 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); *see Nken*, 556 U.S. at 435.

Other public interest factors favor a stay, too. Abruptly banning flavored tobacco products from the market while a petition for certiorari regarding the dispositive legal question is pending would harm the hundreds of thousands of adult

tobacco users who use such products (which Congress and FDA have allowed to remain on the market) and the companies like Applicants who sell those products.

Moreover, as FDA has recognized, there is already a widespread illicit trade in tobacco products. *See* FDA, *Deeming Tobacco Products*, 81 Fed. Reg. 28,973, 29,007 (May 10, 2016). 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 that evade federal and state regulation altogether. That will in turn lead to an increase in associated crimes. Scientific studies and the experiences of other countries that have banned flavored tobacco products confirm as much. *See* RAI Services Company, *Comment from RAI Services Company* 83–101 (Aug. 3, 2022) (discussing the risks of an increased illicit trade based on FDA's proposed federal ban of menthol as a characterizing flavor in cigarettes), https://tinyurl.com/mrzkne43.[8]

SB793 also may cause consumers to engage in risky product tampering and self-mentholation, given the relative ease of converting regular cigarettes to mentholated cigarettes and the ready availability of products suitable for mentholating cigarettes. *See id.* at 118–20. Moreover, because SB793 will severely restrict the availability of menthol-flavored, cartridge-based electronic nicotine

[8] The ban could also cause significant negative consequences for communities of color, including African Americans. *See id.* at 102–18. Because African American smokers in particular disproportionately prefer menthol cigarettes, California's ban would disproportionately harm them, including by exposing them to negative encounters with law enforcement. *See id.* at 102–07; *see also id.* at 104 (citing Letter from ACLU, et al., to Congressman Frank Pallone (Feb. 27, 2020)) (ACLU and others noting "concern[s] that law enforcement's attempts to enforce a menthol and flavored tobacco ban will undoubtedly lead" to such negative encounters).

delivery system products, adults who use those products may turn to combustible cigarettes. *See id.* at 79–82. And the ban may cause consumer confusion regarding the risks of tobacco products, potentially leading to more use of non-flavored tobacco products because consumers will naturally interpret that action as implying that flavored products are especially risky (as compared with non-flavored products that remain on the market). *See id.* at 122–28. Add to that the broader economic costs—to tobacco growers, wholesalers, and those whom they employ, as well as to state and federal tax revenues—and it is clear that the public interest favors a stay.

IV. ALTERNATIVELY, THIS COURT SHOULD TREAT THIS APPLICATION AS A PETITION FOR WRIT OF CERTIORARI BEFORE JUDGMENT, GRANT CERTIORARI, AND ISSUE AN INJUNCTION PENDING REVIEW.

In the alternative, this Court should treat this application as a petition for writ of certiorari before judgment, grant certiorari, and issue an injunction pending review. *See* S. Ct. R. 11 (citing 28 U.S.C. § 2101(e)). All the ordinary factors favor certiorari review. The Ninth Circuit's decision conflicts with this Court's precedents, along with the interpretive reasoning of other courts of appeals. In addition, this case implicates issues of imperative public importance, and it is a clean vehicle. Immediate determination in this Court is needed because California's ban is set to take effect no later than December 21. Finally, there is no need to wait for judgment below, because the Ninth Circuit is bound to follow its precedent in *Los Angeles County*.

CONCLUSION

This Court should grant this application. Alternatively, the Court should grant certiorari and issue an injunction pending resolution of the merits.

November 29, 2022

Respectfully submitted,

NOEL J. FRANCISCO
Counsel of Record
CHRISTIAN G. VERGONIS
RYAN J. WATSON
ANDREW J. M. BENTZ
CHARLES E.T. ROBERTS
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
njfrancisco@jonesday.com

Counsel for Applicants