No. 23-207

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,

Petitioners,

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.*

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

> CORY L. ANDREWS *Counsel of Record* JOHN M. MASSLON II WASHINGTON LEGAL FOUNDATION 2009 Massachusetts Ave., NW Washington, DC 20036 (202) 588-0302 Candrews@wlf.org

September 29, 2023

QUESTION PRESENTED

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES iv
INTEREST OF AMICUS CURIAE 1
STATEMENT1
SUMMARY OF ARGUMENT5
ARGUMENT7
I. THE DECISION BELOW CONTRAVENES THIS COURT'S PREEMPTION PRECEDENTS 7
II. THE NINTH CIRCUIT'S FLAWED TCA CON- STRUCTION FLOUTS THIS COURT'S SAV- ING-CLAUSE JURISPRUDENCE
III. This Is An Important Question That Merits Review
CONCLUSION17

iii

TABLE OF AUTHORITIES

Page(s)

CASES:

AT&T v. Cent. Off. Tel., Inc., 524 U.S. 214 (1998) 12, 13, 14
Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)
Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246 (2004)
<i>Epic Sys. v. Lewis</i> , 138 S. Ct. 1612 (2018)10, 11
Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000)
Home Depot USA, Inc. v. Jackson, 139 S. Ct. 1743, 1748 (2019)11
Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019)1
Morales v. Trans World Airlines, Inc., 504 U.S. 374 (1992)
Nat'l Meat Ass'n v. Harris, 565 U.S. 452 (2012) 4, 6, 8, 9
RadLAX Gateway Hotel v. Amalgamated Bank, 566 U.S. 639 (2012)
Russello v. United States, 464 U.S. 16, 23 (1983)11
<i>Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co.</i> , 204 U.S. 426 (1907)

TABLE OF AUTHORITIES (continued)

Page(s)

Viking River Cruises, Inc. v. Moriana,
142 S. Ct. 1906 (2022)1

STATUTES:

The Family Smoking Prevention and Tobacco
Control Act, Pub. L. No. 111-31, 123 Stat. 1776
(2009)
21 U.S.C. § 331(a)
§ 331(c)2
§ 387b(5)2
§ 387g2
§ 387g(a)2
§ 387g(a)(1)(A)
§ 387g(a)(3)(A) 2, 16
§ 387g(a)(3)(A) 2, 16
§ 387g(b)(2)
§ 387g(e)(1)
§ 387p(a)(1) 3, 11
§ 387p(a)(2)(A) 2, 10
§ 387p(a)(2)(B) 3, 4, 10, 11
§ 387 note12
The Communications Act of 1934

The Commu	nications Act of 1934		
47 U.S.C. §	§ 414	12,	13

OTHER AUTHORITIES:

J. Harvie Wilkinson III, Assessing the Administrative State, 32 J. L. & Pol. 239 (2017).....16

INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as an amicus in important preemption cases to help ensure that federal law operates uniformly and efficiently, as Congress intended. See, e.g., Viking River Cruises, Inc. v. Moriana, 142 S. Ct. 1906 (2022); Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).

Federal law expressly prohibits States and localities from banning the sale of a tobacco product for failing to meet state or local standards that differ from the federal standard. Yet the Ninth Circuit, adhering to deeply flawed circuit precedent, permitted the State of California to do just that. WLF fears that the Ninth Circuit's flawed preemption precedent, if allowed to stand, will severely undercut Congress's ability to maintain uniform, nationwide product standards in regulated industries.

STATEMENT

Tobacco is among the most federally regulated products in America. For decades Congress has closely controlled the interstate marketing and use of tobacco products—from eliminating smoking on public transportation and setting a minimum age for

^{*} No party's counsel authored any part of this brief. No one, other than WLF and its counsel, contributed money for preparing or submitting this brief. All parties received timely notice of WLF's intent to file this brief.

tobacco sales to banning tobacco-product ads on television and radio.

In 2009, Congress authorized the Food and Drug Administration to regulate tobacco products in the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA). Among other things, the TCA prohibits cigarette flavors other than tobacco and menthol, 21 U.S.C. § 387g(a)(1)(A); bans the sale of "adulterated" tobacco products that don't conform to this federal standard, *id.* §§ 331(a), (c), 387b(5); and authorizes the FDA exclusively to decide whether to extend the federal ban to other tobacco products or flavors, *id.* § 387g(a).

The TCA also authorizes the FDA to set uniform, nationwide standards for tobacco products. The FDA must weigh the relative health effects of tobacco products by setting "tobacco product standards," id. § 387g; considering the illicit market for tobacco products in adopting such standards, *id.* §§ 387g(b)(2), (e)(1); gathering and studying data to take further "action" on "menthol or any artificial or natural flavor," *id.* § 387g(a)(1)(A); and adopting other tobacco product standards if the agency determines, after weighing "the risks and benefits to the population as a whole," that a revised standard "is appropriate for public health." the protection of the id. § 387g(a)(3)(A), (B).

Most relevant here, the TCA clarifies the role that States and localities may play in regulating tobacco. *First*, the TCA preempts "any" state or local requirement that imposes additional or different "tobacco product standards." *Id.* § 387p(a)(2)(A). *Second*, "except" for state and local laws expressly preempted by the preemption clause (e.g., laws imposing different tobacco product standards from the federal standard), the TCA otherwise preserves the authority of States, localities, federal agencies, the Armed Forces, and Indian tribes to enact "more stringent" measures "relating to or prohibiting the sale * * * of tobacco products by individuals of any age." *Id.* § 387p(a)(1). Because it is subject to the preemption clause, the preservation clause does not preserve state and local regulation of tobacco flavors. *Third*, the TCA saves from preemption state and local requirements "relating to the sale" of tobacco products to "individuals of any age" or "relating to fire safety standards." *Id.* § 387p(a)(2)(B).

In 2020, California enacted SB793, which bans the sale of flavored tobacco products within California. See Cal. Health & Safety Code § 104559.5(b)(1) (providing that tobacco retailers "shall not sell * * * a flavored tobacco product" in the State). Petitioners tobacco manufacturers, distributors, and retailers collectively sued the California Attorney General and the San Diego County District Attorney, contending that the TCA preempts California's flavor ban because it imposes a tobacco product standard that is different from the federal standard.

Although preserving their argument for appeal, petitioners conceded in the district court that their express-preemption claim was foreclosed by *R.J.* Reynolds Tobacco Co. v. County of Los Angeles, in which a panel majority declared that the TCA's tobacco product standards govern only how a "product must be produced." 29 F.4th 542, 556 (9th Cir. 2022). According to that majority, because the County's flavor ban targeted sales rather than production, it

escaped the TCA's preemption clause. *Id.* Alternatively, the *Los Angeles* majority held that the TCA's saving clause saved the County's flavor ban from preemption. In the majority's view, the County's flavor ban was no more than a "requirement [] relating to the sale * * * of[] tobacco products [to] individuals of any age." *Id.* at 548 (quoting 21 U.S.C. § 387p(a)(2)(B)). The court saw no statutory significance in the TCA's distinction between requirements "relating to" sales in the saving clause and those "prohibiting" sales in the preservation clause.

Judge Nelson dissented from that decision. Relying on this Court's holdings in *National Meat Ass'n v. Harris*, 565 U.S. 452 (2012), and *Engine Manufacturers Ass'n v. South Coast Air Quality Management District*, 541 U.S. 246 (2004), he explained that States and localities cannot escape preemption "by disguising [their] regulation as a sales ban." *Los Angeles*, 29 F.4th at 563. Because the County's ban fell within the TCA's preemption clause and was neither preserved nor saved, he would have held that it was expressly preempted. *Id.* at 566–57.

Given Los Angeles's sweeping holding, the district court dismissed petitioners' preemption suit. Pet. App. 2a, 13a. Petitioners appealed. While seeking summary affirmance of the dismissal to facilitate this Court's review, petitioners preserved their express preemption claim. The Ninth Circuit summarily affirmed. Pet App. 1a.

SUMMARY OF ARGUMENT

When the FDA approves a prescription drug as safe and effective for its intended use, nobody asks the California State Legislature to check the science. Congress would never permit the California State Assembly to convene a meeting of its Committee on Health, watch tutorials on pharmacology and biochemistry, attempt its own clinical trials, second-guess the FDA's weighing of the drug's therapeutic costs and benefits, "improve" the drug with a redesign, and then enact a statewide ban on the sale of the FDA-approved design.

Just as it would not let local politicians tinker with the design of a federally approved prescription drug, Congress would not let them overhaul the product standards for one of the most highly regulated FDA-authorized products in America. Yet the Ninth Circuit decided that California could do just that. That decision was compelled by the circuit's prior holding in *Los Angeles*, which held that States and localities may evade TCA preemption simply by banning the sale of products that do not meet state and local standards. 29 F.4th at 556.

But if California and Los Angeles County may ban FDA-authorized tobacco products by imposing state and local standards that differ from the TCA's, then every State and locality can do the same. That would contravene Congress's plainly stated statutory language, which expressly prohibits States and localities from banning the sale of tobacco products that do not meet state or local standards. By blessing California's state-wide flavor ban, the Ninth Circuit once again discards Congress's statutory purpose and invites an avalanche of contradictory state and local standards.

No matter the Ninth Circuit's view, California cannot escape preemption simply by recasting its flavor ban as a regulation of tobacco sales rather than tobacco production. The Supremacy Clause does not turn on such word play. This Court has twice reversed the Ninth Circuit for interpreting an express preemption clause in a way that allows States and localities to defeat federal product standards with a sales ban. "[I]t 'would make no sense," this Court has explained, "to allow state regulations to escape preemption because they addressed the purchase, rather than manufacture, of a federally regulated product." Nat'l Meat, 565 U.S. at 464. Standards always target the product itself, so a regulation of tobacco standards is preempted no matter if it is aimed at "production" or "sales." Engine Mfrs, 541 U.S. at 254. This case is no different.

Nor may California rely on a sweeping construction of the TCA's saving clause to escape preemption. This Court has rejected—repeatedly—such expansive readings. Indeed, many federal laws contain a broad saving clause that protects state and local regulatory power or preserves state and local remedies. States and localities have often argued that a saving clause permits them to act in a way that undermines the very law containing the saving clause. And time and again, the Court has rejected those arguments and held that a saving clause is not some kind of statutory self-destruct mechanism. Because the Ninth Circuit's reading of the TCA's saving clause conflicts with this Court's consistent construction of federal saving clauses, the Court should intervene. In carefully crafted, plain language, Congress told California not to do this. California did it anyway, and the Ninth Circuit approved. Such willful subversion of the Supremacy Clause should not be allowed to stand.

ARGUMENT

I. THE DECISION BELOW CONTRAVENES THIS COURT'S PREEMPTION PRECEDENTS.

The TCA tasks the FDA with maintaining uniform tobacco product standards—including flavors in tobacco products—based on a careful weighing of varied factors, including public health. States and localities may not countermand that congressional regulatory scheme. Yet California's flavor ban elevates the State's tobacco flavor standard over the federal standard. The Supremacy Clause won't allow that.

According to the Ninth Circuit, however, because California's flavor ban does not dictate "how [a] product must be produced," it is not a tobacco product "standard" but merely a "sales" ban. *Los Angeles*, 29 F.4th at 556. Contrary to the Ninth Circuit's view, Congress's ability to safeguard the federal interests at stake in the TCA does not turn on such semantics. Put differently, a standard is a standard for preemption purposes no matter how it is enforced or described. California historically has been reluctant to learn this lesson.

This Court's holding in *Engine Manufacturers* proves the point. There, California prohibited anyone from purchasing or leasing vehicles that flunked California's stringent emissions requirements. 541 U.S. at 248. But the Clean Air Act forbade States from setting emissions standards different from the federal standards. *Id.* at 252. As it does here, California insisted that the challenged ban regulated only the "purchase" of vehicles, rather than their sale or manufacture. *Id.* at 248.

The Court roundly rejected that argument, which "confuses standards with the means of enforcing standards." Id. at 253. California could not, the Court explained, "engraft onto th[e] meaning of 'standard' a limiting component" by insisting that a "standard" means "only [a] production mandat[e] that require[s] manufacturers to ensure that the vehicles they produce have particular emissions characteristics." Id. Treating such restrictions "differently for preemption purposes would make no sense," the Court concluded, because a "manufacturer's right to sell federally approved vehicles is meaningless" without a "purchaser's right to buy them." Id. at 255. Simply put, "a standard is a standard even when not enforced through manufacturer-directed regulation." Id. at 254. So too here.

National Meat reaffirms this sensible view of federal preemption. There, a California law banned the sale of meat from non-ambulatory animals. 565 U.S. at 463–64. A trade group suing on behalf of meatpackers and processors argued that the Federal Meat Inspection Act (FMIA) preempted state "requirements * * * which are in addition to, or different than those made under [the FMIA]." *Id.* at 458. But because the FMIA preempted only production mandates, California argued that its state-wide sales ban escaped preemption. *Id.* at 463. This Court unanimously disagreed. Although the FMIA's preemption clause does "not usually foreclose state regulation of the commercial sales activities of slaughterhouses," California's sales ban was preempted. *Id.* "[I]t 'would make no sense,"" the Court explained, "to allow state regulations to escape preemption because they addressed the purchase, rather than manufacture, of a federally regulated product." *Id.* at 464. A contrary holding, the Court explained, would have allowed California to "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.* at 464. To allow States to circumvent federal law so easily "would make a mockery of the FMIA's preemption provision." *Id.*

As these cases confirm, federal preemption does not turn on categorical framing or clever phrasing. It makes no difference how a State or locality enforces its contrary product standard. Whether it compels manufacturers to comply or prohibits retailers from selling nonconforming goods, any state or local product standard that seeks to override the federal standard is preempted.

The Ninth Circuit's holding upends this commonsense view of federal preemption. And it does so by reading a preemption clause that preempts "any" requirement that differs from the federal standard as one preempting only requirements about "how [a tobacco] product must be produced." Pet. App. 25a. That reading not only defeats the TCA but also "make[s] a mockery" of federal preemption. Nat'l Meat, 565 U.S. at 464. This Court should grant review to vindicate Congress's vital federal interest in uniformity.

II. THE NINTH CIRCUIT'S FLAWED TCA CON-STRUCTION FLOUTS THIS COURT'S SAVING-CLAUSE JURISPRUDENCE.

Reasonably construed, the TCA does not preempt California's imposing age-based or firesafety regulations on tobacco products. But it prohibits California from defeating federal tobacco product standards under the guise of regulating "sales." The TCA's preemption and saving clauses are clear about that. Put differently, a state or local law may complement the TCA; it may never impede it. Holding otherwise, the panel majority in *Los Angeles* botched the TCA's statutory scheme by ignoring vital canons of statutory construction and this Court's saving-clause cases.

"[W]ith respect to a tobacco product," the TCA preempts "any requirement which is different from, or in addition to," federal tobacco product standards. 21 U.S.C. § 387p(a)(2)(A). The TCA's saving clause restores only a narrow sliver of what the preemption clause takes away. States and localities may enact "requirements relating to the sale" of tobacco products to "individuals of any age" or "relating to fire safety standards." *Id.* § 387p(a)(2)(B). The Ninth Circuit transformed this narrow sliver into a plank. In reading the TCA's saving clause expansively, the Ninth Circuit ignored two fundamental rules of statutory construction.

First, it failed to read the TCA's preemption, savings, and preservation clauses in context with the TCA itself. "A statute's meaning does not always turn solely on the broadest imaginable definition of its component words." *Epic Sys. v. Lewis*, 138 S. Ct. 1612, 1631 (2018). A court, after all, construes statutes, not isolated provisions "in a vacuum." *Home Depot USA*, *Inc. v. Jackson*, 139 S. Ct. 1743, 1748 (2019) (cleaned up). A court must always "read [a statute's] words in their context and with a view to their place in the overall statutory scheme." *Id*. Reading a clause out of context can wreak havoc on the operation of the rest of the statute. This case shows how.

Unlike the preservation clause, which preserves non-preempted requirements "relating to or prohibiting the sale" of tobacco products, 21 U.S.C. § 387p(a)(1), the TCA's saving clause says only that the preemption clause "does not apply to requirements relating to the sale" of tobacco products. Id. § 387p(a)(2)(B). Because "Congress acts intentionally" whenever it "includes particular language in one section of a statute but omits it in another section," Russello v. United States, 464 U.S. 16, 23 (1983), Congress's choice to omit the words "or prohibiting" from a nearly identical phrase in the saving clause must be given effect. Here that means giving effect to Congress's choice that States and localities cannot ban the sale of tobacco products based on their own unique product standards.

Second, the Ninth Circuit ignored "the commonplace of statutory construction that the specific governs the general." RadLAX Gateway Hotel v. Amalgamated Bank, 566 U.S. 639, 645 (2012). "The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission." Id. That is the situation here, where a broad reading of a saving clause goes against specific provisions ensuring that the FDA sets "national standards controlling the manufacture of tobacco products and the * * * ingredients used in such products." 21 U.S.C. § 387 note.

This Court has interpreted many saving clauses in other federal laws. Time and again, it has refused to allow a saving clause to upset Congress's carefully chosen regulatory scheme. Instead, it has always read the saving clause in a way that is incompatible with the Ninth Circuit's reading here.

1. Morales v. Trans World Airlines, Inc., 504 U.S. 374 (1992). The Airline Deregulation Act contains a saving clause held over from the Federal Aviation Act. Nothing in the FAA, the clause says, "shall in any way abridge or alter the remedies now existing at common law or by statute, but the provisions of this chapter are in addition to such remedies." *Id.* at 378.

The ADA bars the States from regulating airline prices, routes, or services. *Id.* at 378–79. The *Morales* plaintiffs argued that the FAA's saving clause saved that bar from preempting their state-law deceptive advertising claim. Rejecting this argument, *Morales* observes that "the specific governs the general." *Id.* at 385. Congress, *Morales* concludes, does not "undermine [a] carefully drawn statute through a general savings clause." *Id.* A saving clause cannot overcome a specific provision—such as the "prices, routes, or services" bar—that divides authority between state and federal governments.

2. AT&T v. Cent. Off. Tel., Inc., 524 U.S. 214 (1998). "Nothing in this [law]," the Communications Act of 1934 says, "shall in any way abridge or alter

the remedies now existing at common law or by statute." 47 U.S.C. § 414.

A set of rules in the Communications Act required AT&T to sell its services only at rates it filed with the government. A telephone-service broker brought state-law claims that, if successful, would have required AT&T to provide service at a rate lower than AT&T's filed rates. *Id.* at 222–23. *AT&T* holds that the federal rate-filing rules preempt the broker's state-law claims.

The Communications Act's general saving clause, the Court said, changes nothing: "The savings clause cannot in reason be construed as continuing in customers a common law right, the continued existence of which would be absolutely inconsistent with the provisions of the act." *Id.* at 227–28 (quoting *Tex.* & *Pac. Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907)). In other words, the Court explained, "the act cannot be held to destroy itself." *Id.* at 228.

3. Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000). The National Traffic and Motor Vehicle Safety Act contains a saving clause that says "compliance with' a federal safety standard 'does not exempt any person from any liability under common law." 529 U.S. at 868.

Sued for omitting airbags from the 1987 Honda Accord, Honda invoked a regulation under the Act that made airbags merely an optional safety feature. The plaintiff answered with the Act's saving clause. The Court rejected that argument. Geier reiterated that this Court "has repeatedly declined to give broad effect to savings clauses where doing so would upset the careful regulatory scheme established by federal law." *Id.* at 870. Put another way, a saving clause "does *not* bar the ordinary working" of "pre-emption principles." *Id.* at 869. And because the Act's regulation made airbags optional, the plaintiff's state-law claims, which could succeed only if federal law required airbags, were preempted—the saving clause notwithstanding. *Id.* at 874–86.

Here, if Congress had meant for the TCA to exempt from preemption *every* state and local ban on tobacco sales, it would have made no sense for Congress to single out "requirement[s] * * * relating to tobacco product standards" as a subcategory of nonpreempted requirements. Nor would the saving clause need to narrow "sales" with the qualifiers "individuals of any age" and "relating to fire safety standards."

While the Ninth Circuit relied on the TCA's saving clause to discard specific provisions of the TCA, *Morales*, *AT&T*, and *Geier* all use a specific statutory provision to limit the scope of a saving clause. The Ninth Circuit's reading thus conflicts with this Court's understanding, grounded in sound principles of statutory interpretation, that a federal saving clause is not an invitation for States and localities to undermine federal law. If that understanding is to continue to hold sway, the petition must be granted.

III. THIS IS AN IMPORTANT QUESTION THAT MER-ITS REVIEW.

This case matters. California's sales ban on all flavored tobacco products is not a subtle encroachment on federal power. Rather, it is an aggressive nullification of federal law. Left in place, the Ninth Circuit's holding would allow States and localities to evade other federal product standards by merely framing a contrary standard as a sales ban. It also threatens to lay waste to years of FDA work while exposing companies to liability for selling FDA-authorized products.

This is not wild speculation. As the petition highlights, hundreds of jurisdictions have enacted similar laws, spurring litigation (and separate opinions) in four courts of appeals. Pet. 33–34. There is thus no reason to await further percolation. The stakes are high. "The marketing of tobacco constitutes one of the greatest basic industries of the United States." 7 U.S.C. § 1311. California's ban shuts the door to one of the nation's largest markets for flavored tobacco.

National uniformity in tobacco product standards protects manufacturers and consumers alike. It allows for manufacturers to operate under one set of rules—federal rules—instead of dozens or even hundreds of sets of potentially conflicting rules. Without uniformity, manufacturers are forced to either comply with a thicket of conflicting, overlapping, and burdensome state and local standards or risk liability from state and local law enforcement and regulators. Regardless of the choice made, these increased risks raise the cost of doing business nationwide. All too often, those costs are ultimately passed on to consumers.

The Ninth Circuit's misreading of the TCA's preemption clause also invites second guessing of the FDA's studied conclusions on how best to balance the TCA's multifaceted policy objectives. The *Los Angeles* panel majority's holding, if allowed to stand, will prevent Congress from accomplishing those objectives by subjecting tobacco manufacturers to a jumble of disparate product standards, eradicating the federal uniformity that Congress decided is an essential element of federal tobacco regulation. California's flavor ban is thus a naked affront to federal law.

What's more, the FDA has expertise that California lacks. The FDA's work "requires deep knowledge of the human body and the biological effects of the substances we ingest." J. Harvie Wilkinson III, *Assessing the Administrative State*, 32 J.L. & Pol. 239, 246 (2017). And the TCA requires more still. Indeed, the current federal tobacco product standards reflect the FDA's studied determination, after weighing "the risks and benefits to the population as a whole," that a revised standard is not "appropriate for the protection of the public health." 21 U.S.C. §§ 387g(a)(3)(A), (B).

These complex issues are best handled by the FDA, with its teams of doctors, scientists, statisticians, and economists, and not by the California General Assembly or California voters, however wise and well-intentioned they may be. Even apart from the TCA's plainly written express preemption clause, this Court has repeatedly recognized that when an agency's regulatory judgment reflects a careful

balancing of competing considerations under a comprehensive federal scheme, any state or local law that could disrupt the balance struck by the agency is preempted. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349–51 (2001); *Geier*, 529 U.S. at 874–86. That is this case.

California is perfectly free to uphold state interests; it should continue its traditional role of regulating when, where, how, and to whom tobacco products are sold—including age-based and fire-safety regulations. But this Court must intervene and respond whenever any State or locality brazenly subverts federal law. This is just such a case.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

CORY L. ANDREWS *Counsel of Record* JOHN M. MASSLON II WASHINGTON LEGAL FOUNDATION 2009 Massachusetts Ave., NW Washington, DC 20036 (202) 588-0302 candrews@wlf.org

September 29, 2023