Case No. 25-8060

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROCKY PATEL PREMIUM CIGARS, INC., et al.,
Plaintiffs-Appellants,

v.

ROB BONTA,
in his official capacity as Attorney General of the State of California,
Defendant-Appellee.

On Appeal from the Denial of a Preliminary Injunction by the United States District Court for the Central District of California, D.C. No. 8:25-cv-02244-MRA-PD

CORRECTED BRIEF OF PUBLIC HEALTH, MEDICAL, AND COMMUNITY ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

BYRON RAPHAEL LLP
Jordan Raphael
811 Wilshire Blvd., 17th Floor, Los Angeles, California 90017
(213) 291-9800

Of counsel:
CAMPAIGN FOR TOBACCO-FREE KIDS
Dennis A. Henigan
Andrew R. Tardiff
1400 I Street, N.W., Suite 1200, Washington, D.C. 20005
(202) 481-9366

Attorneys for *Amici Curiae*

DISCLOSURE STATEMENT

Pursuant to Fed. R. App. 26.1(a), *amici curiae* are all non-profit public health, medical, or community organizations committed to reducing disease and mortality caused by tobacco products. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: March 3, 2026

/s/ Jordan Raphael
Jordan Raphael
Attorney for *Amici Curiae*

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With the consent of the parties, *amici curiae* public health, medical, and community organizations submit this brief urging the Court to uphold the District Court's order denying Plaintiffs-Appellants' motion for preliminary injunction.[1] Overturning that order on federal preemption grounds would greatly impede California's enforcement of its retail sales ban of flavored tobacco products and would stymie other state and local efforts to prevent the death and suffering caused by tobacco products.[2]

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are thirteen national and state medical, public health, and community organizations working on a daily basis to reduce tobacco-related disease and mortality: African American Tobacco Control Leadership Council; American Cancer Society Cancer Action Network; American Lung Association; Americans for Nonsmokers' Rights; Asian Pacific Partners for Empowerment, Advocacy, and Leadership (APPEAL); Breathe California of the Bay Area, Golden Gate, and

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[1] *Amici curiae* affirm that no party's counsel authored this brief in whole or in part, and that no party, party's counsel, or other person (other than *amici curiae*, their members, or their counsel) contributed money that was intended to fund preparing or submitting this brief. *See* Fed. R. App. R. 29(a)(4)(E).

[2] This *amicus* brief will address only the District Court's holding that Appellants are unlikely to succeed on their claim that California's Unflavored Tobacco List statute is expressly preempted by the federal Family Smoking Prevention and Tobacco Control Act (TCA). It will not address Appellants' First Amendment arguments.

Central Coast; California Academy of Family Physicians; Campaign for Tobacco-Free Kids; Kaiser Permanente; LGBT Cancer Network; Parents Against Vaping E-cigarettes (PAVe); Public Health Institute; and Truth Initiative. They include organizations with programs to assist individuals to quit the use of tobacco products, those representing physicians who counsel young patients and their families about the hazards of tobacco use, and parents struggling to free young people from nicotine addiction. They recognize that state and local governments play a crucial role in reducing the health harms caused by tobacco products, and advocate for strong state and local tobacco control policies. Accordingly, *amici* have strong interests in ensuring that state and local governments retain their expressly preserved authority to address the death and disease caused by tobacco products. Indeed, many of the *amici* have previously filed briefs in the Ninth Circuit and other courts in cases addressing claims of federal preemption of state and local tobacco control laws.[3]

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[3] These cases include: *23-24 94th Grocery Corp. v. New York City Board of Health*, 685 F.3d 174 (2d Cir. 2012); *National Association of Tobacco Outlets, Inc., v. City of Providence*, 731 F.3d 71 (1st Cir. 2013); *R.J. Reynolds Tobacco Co. v. Becerra*, Case No. 20-cv-1990 (S.D. Cal. 2020); *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022); *R.J. Reynolds Tobacco Co. v. County of San Diego*, 529 F. Supp. 3d 1147 (S.D. Cal. 2021); *Neighborhood Market Ass'n v. County of San Diego*, 529 F. Supp. 3d 1123 (S.D. Cal. 2021); *R.J. Reynolds v. Bonta*, No. 22-56052 (9th Cir. 2022); and *R.J. Reynolds Tobacco Company v. City of Edina*, 60 F.4th 1170 (8th Cir. 2023).

RELEVANT BACKGROUND

At the beginning of this century, the Supreme Court recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 161 (2000). Despite considerable progress reducing smoking prevalence over the past twenty-six years, tobacco use remains the leading cause of preventable death in the U.S., with smoking alone killing approximately 490,000 Americans each year[4] – more than alcohol, AIDS, car accidents, illegal drugs, murders and suicides combined.[5] Smoking is a primary driver of chronic disease, causing 30% of all cancer deaths,[6] at least 25% of deaths from cardiovascular disease, including heart attack and stroke,[7] and 80% of all

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[4] U.S. DEP'T OF HEALTH & HUM. SERVS., *Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the Surgeon General* (2024), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/tobacco-surgeon-general-reports/about/2024-end-tobacco-disparities.html.

[5] U.S. DEP'T OF HEALTH & HUM. SERVS., *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf .

[6] Farhad Islami *et al.*, *Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States, 2019, 74 CA Cancer J. Clin.* 405 (2024), https://doi.org/10.3322/caac.21858.

[7] CNTRS. FOR DISEASE CONTROL & PREVENTION, Health Effects of Cigarettes: Cardiovascular Disease, 2025, https://www.cdc.gov/tobacco/about/cigarettes-and-cardiovascular-disease.html (Sept. 17, 2024).

deaths from COPD.[8] Smoking also increases the risk of developing Type 2 Diabetes by 30-40%.[9] Critically, there is no safe tobacco product.[10] Use of any tobacco product contributes to health risks, including use of any cigar.[11]

Following extensive review of the available research on the roles of flavors in cigars, the U.S. Food and Drug Administration (FDA) concluded that "the addition of characterizing flavors to tobacco products, including cigars, increases product appeal and makes tobacco products easier to use, particularly among youth."[12] Cigar publications also recognize that "flavored cigars serve as a bridge

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[8] U.S. DEP'T OF HEALTH & HUM. SERVS., Let's Make the Next Generation Tobacco-Free: Your Guide to the 50th Anniversary Surgeon General's Report on Smoking and Health (2014) (citing U.S. Dep't of Health & Hum. Servs., The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General (2014)), https://www.hhs.gov/sites/default/files/consequences-smoking-consumer-guide.pdf.

[9] U.S. DEP'T OF HEALTH & HUM. SERVS., *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General* 544 (2014).

[10] CNTRS. FOR DISEASE CONTROL & PREVENTION, "Nicotine Pouches", Jan. 31, 2025, https://www.cdc.gov/tobacco/nicotine-pouches/index.html; *see also* CNTRS. FOR DISEASE CONTROL & PREVENTION, "Health Effects of Vaping", Jan. 31, 2025, https://www.cdc.gov/tobacco/e-cigarettes/health-effects.html.

[11] According to the United States Food and Drug Administration: "[A]ll cigars are harmful and potentially addictive..." Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,150 (Apr. 25, 2014).

[12] U.S. FOOD AND DRUG ADMIN., *Scientific Assessment of the Impact of Flavors in Cigar Products* 20 (Mar 2022), https://web.archive.org/web/20241223141121/https://www.fda.gov/media/157595/download.

to premium cigars for the uninitiated"—"an entryway into the world of cigar smoking."[13] Many cigars marketed as "premium" are "directly flavored with syrups, liquors and food products," including "vanilla, rum, honey and dozens of other flavors."[14]

Contrary to Appellants' assertion that youth usage of premium cigars is "non-existent," *see* Opening Br. 9, data demonstrate that "premium" cigars are not just appealing to youth but also are used by youth. A 1999 report by the HHS Office of Inspector General found that 20 teens out of 167 sampled reported spending more than $10 for a cigar, and one had spent $55 on a single cigar.[15] In addition, National Survey on Drug Use and Health data show that cigar smokers aged 12-17 named premium cigar brands as products they smoked in the previous 30 days.[16]

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[13] David Savona, "*Cigars of a Different Flavor*," Cigar Aficionado, Jul./Aug. 2005, https://www.cigaraficionado.com/article/cigars-of-a-different-flavor-8595.
[14] *Id.*
[15] U.S. DEP'T OF HEALTH & HUMAN SERVS., Office of Inspector Gen., Youth Use of Cigars: Patterns of Use and Perceptions of Risk, (Feb 1999), at 8, http://oig.hhs.gov/oei/reports/oei-06-98-00030.pdf.
[16] SAMHSA, *Analysis of 2012 National Survey on Drug Use and Health Data* (2012).

When youth use cigars and other tobacco products, it can lead to a lifelong addiction. Nearly 80 percent of adult smokers begin smoking by age 18.[17] And roughly one-third of all youth who become regular smokers before adulthood will eventually die from smoking.[18] Delaying the age when young people first experiment or begin using tobacco can reduce the risk that they transition to regular or daily tobacco use.[19] Therefore, policies to prevent youth from using tobacco products are critical.

Fortunately, states and localities have long had the authority to protect their residents, and particularly their youth, from tobacco-related death and disease. At the dawn of the last century, the Supreme Court held constitutional both a city's outright ban on the sale of cigarettes, *see Austin v. State of Tennessee*, 179 U.S. 343, 348–49 (1900) ("[W]e think it within the province of the legislature to say how far they may be sold, or to prohibit their sale entirely…"), and a city's ordinance requiring a license to sell them, *see Gundling v. City of Chicago*, 177

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[17] UNITED STATES DEP'T OF HEALTH & HUM. SERVS., Substance Abuse & Mental Health Servs. Admin., *National Survey on Drug Use and Health*, *2014* (2016), http://doi.org/10.3886/ICPSR36361.v1.

[18] CNTRS. FOR DISEASE CONTROL & PREVENTION, Incidence of Initiation of Cigarette Smoking—United States, 1965-1996, 47 Morbidity & Mortality Wkly. Rep. 837 (1998), http://www.cdc.gov/mmwr/preview/mmwrhtml/00055070.htm.

[19] *See, e.g.*, S.A., Khuder et al., "Age at Smoking Onset and its Effect on Smoking Cessation," 24 Addictive Behav. 673 (1999).; B. D'Avanzo et al., Age at Starting Smoking and Number of Cigarettes Smoked, 4 Annals Epidemiology 455 (1994).

U.S. 183 (1900). In 1932, the Supreme Court upheld a conviction under state law prohibiting advertising cigarettes on a billboard. *Packer Corp. v. State of Utah*, 285 U.S. 105, 108 (1932) ("It is not denied that the state may, under the police power, regulate the business of selling tobacco products … and the advertising connected therewith…" (citing cases)). These early Supreme Court decisions demonstrate the wisdom of Justice Brandeis' idea of state governments as "laborator[ies]," that, "if its citizens choose," may "try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 263, 387 (1932) (Brandeis, J., dissenting). In addressing the health harms of tobacco, California has exemplified this notion. In 1988, California voters approved Proposition 99, making California the first state in the nation to dedicate tobacco tax proceeds to tobacco use prevention and cessation.[20] A decade later, the state became the first in the nation to eliminate smoking in bars.[21]

In fact, as this Court is well aware, the history of tobacco product regulation in the United States is "almost exclusively" a story of states and local governments. *See R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, 29 F.4th

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[20] A Roeseler & D. Burns , The Quarter That Changed the World, 19 Tobacco Control i3 (Supp. 1 2010), https://tobaccocontrol.bmj.com/content/tobaccocontrol/19/Suppl_1/i3.full.pdf.

[21] A. Hyland et al., Smoke-Free Air Policies: Past, Present and Future, 21 Tobacco Control 154 (2012). https://tobaccocontrol.bmj.com/content/tobaccocontrol/21/2/154.full.pdf.

542, 548 (9th Cir. 2022). Indeed, their "longstanding role as the primary regulators of tobacco products" was born of necessity. *Cnty. of Los Angeles*, 29 F.4th at 549. Until Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009,[22] the FDA lacked any regulatory authority over tobacco products. *See Brown & Williamson*, 529 U.S. at 126.

When Congress took that step to create a larger role for the federal government in tobacco control, it was careful to preserve states' traditional regulatory authority through a "unique 'preservation sandwich.'" *Cnty. of Los Angeles*, 29 F.4th at 555. The top layer of that sandwich—the preservation clause—"broadly preserves state, local, and tribal power to enact *any* regulation concerning tobacco products that is 'in addition to or more stringent' than those promulgated by the TCA," including those "'relating to or prohibiting the sale … or use of tobacco products by individuals of any age.'" *Id.* at 550 (quoting 21 U.S.C. § 387p(a)(1) (emphasis original). The middle layer of that sandwich—the preemption clause—"overrides the preservation clause in the case of any conflict between the two provision's terms." *Cnty. of Los Angeles*, 29 F.4th at 551. That provision only applies, however, to "requirement[s] under the provisions of [the TCA] relating to tobacco product standards, premarket review, adulteration,

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[22] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387 *et seq*.).

misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A). The bottom layer of that sandwich—the savings clause—"excepts various broadly defined categories from preemption," specifically those "'relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.'" *Cnty of Los Angeles*, 29 F.4th at 551 (quoting 21 U.S.C. § 387p(a)(2)(B)). Read in its entirety, the text demonstrates that "Congress made an 'explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products.'" *Cnty of Los Angeles*, 29 F.4th at 551 (quoting *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013)).

This broadly preserved authority has allowed California to continue to lead in tobacco control, including through its localities—entities that have sometimes been referred to as "local laboratories."[23] In 2019, Los Angeles County enacted a ban on the sale of flavored tobacco products,[24] and in 2020, San Diego County did

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[23] *See generally* Katherine Florey & Andrew Doan, *A Successful Experiment: California's Local Laboratories of Regulatory Innovation*, 66 UCLA L. REV. DISCOURSE 80 (2018).

[24] Los Angeles County, Cal., Code § 11.35.070(E) (2019).

the same.[25] California voters ultimately recognized the success of these policy experiments. In 2022, they overwhelmingly approved Proposition 31, thereby upholding S.B. 793,[26] which prohibited the sale of flavored tobacco products statewide.[27] Each of these measures were challenged by industry as being preempted by the TCA. This Court rejected each of those challenges in turn.[28] With these laws allowed to operate, California experienced a significant decrease in sales of both e-cigarettes and cigarettes compared to control states without such laws.[29]

However, California observed that some tobacco product manufacturers

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[25] San Diego County, Cal., Code of Regulatory Ordinances, tit. 3, div. 2, ch. 8, § 32.883(a) (2020).

[26] 63.4% of California voters voted in favor. *See* California Secretary of State, General Election State Ballot Measures (Nov. 8, 2022), https://elections.cdn.sos.ca.gov/sov/2022-general/ssov/ballot-measures-summary.pdf.

[27] The statute provides that "a tobacco retailer, or any of the tobacco retailer's agents or employees, shall not sell, offer for sale, or possess with intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavored enhancer." Cal. Health & Safety Code § 104559.5(b)(1).

[28] *Cnty. of Los Angeles*, 29 F.4th 542 (9th Cir. 2022); *R. J. Reynolds Tobacco Co. v. Bonta*, No. 23-55349, 2023 WL 4546550 (9th Cir. June 28, 2023), *cert. denied*, 144 S. Ct. 551 (2024).

[29] Fatma Romeh M. Ali et al., *Changes in E-Cigarette And Cigarette Sales in California and Neighboring States Following a Law Prohibiting flavored Tobacco Product Sales*, 115 Am J. Public Health 1933, 2025, https://ajph.aphapublications.org/doi/epdf/10.2105/AJPH.2025.308182 ("Prohibiting flavored tobacco product sales in California was associated with a 36.98% reduction in total milligrams of e-cigarette nicotine sold and a 10.55% reduction in cigarette pack sales, compared with control states.").

were marketing their products as "'clear' or ambiguously branded with flavor concepts (i.e., 'Blue' instead of 'Blueberry') in order to avoid flavor bans."[30] In 2024, the California Legislature considered AB-3218, which would establish an Unflavored Tobacco List (UTL). The Legislature determined that a UTL would "make enforcement easier": a UTL would both be shorter than a banned products list and relatively static, and therefore "easier to maintain and use for both enforcement officers and retailers looking to comply with flavored tobacco restrictions."[31] That bill was signed into law the same year.

ARGUMENT

I. The TCA Does Not Expressly Preempt California's UTL Law

The District Court correctly held that Appellants are unlikely to succeed on their claim that California's UTL law is expressly preempted by the TCA. As described above, the TCA's preemption clause refers to state and local regulation in eight limited areas: "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk

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[30] Assembly Floor Analysis, (May 20, 2024), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202320240AB3218#; *see also see also* Ali, supra note 29 (finding that decreases in tobacco sales after the ban "were partially offset by increased sales of products marketed as nontobacco flavored that contain synthetic cooling agents or other additives that deliver multisensory flavor experiences").

[31] *Id*.

tobacco products." 21 U.S.C. § 387p(a)(2)(A). On appeal, Appellants argue only that the preemption clause's "premarket review" provision is implicated by California's UTL statute. *See* Opening Br. 28-34.[32] It is not. "Premarket review" is the FDA review of new tobacco products to determine if they meet the TCA's standard for introduction into interstate commerce. California's UTL, on the other hand, is a state process to inform whether a product is unflavored and therefore not subject to the preexisting (and clearly not preempted) ban on the retail sale of flavored tobacco products. But even if Appellants were correct and the UTL does constitute "premarket review," the UTL would still be permissible under the TCA's broad savings clause, which renders the preemption clause inapplicable to requirements "relating to the sale, distribution, possession, information reporting to the State, [and] exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age…" 21 U.S.C. § 387p(a)(2)(B).

As discussed more fully below, Appellants' argument is inconsistent with the TCA, as previously interpreted by this Court, which preserves the preexisting broad authority of states and localities to protect their citizens, and particularly

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[32] On appeal, Appellants also make no argument that the UTL statute is impliedly preempted by federal law. Arguments not raised in an opening brief are waived. *See Zango, Inc. v. Kaspersky Lab, Inc.,* 568 F.3d 1169, 1177 n.8 (9th Cir. 2009).

their young people, from the devastating health harms of tobacco products, including Appellants' cigars.

A. California's UTL Law Is Not "Premarket Review"

The TCA affords the phrase "premarket review" a clear meaning: It is the federal process that Congress set forth in § 910 of the Act (codified at 21 U.S.C. § 387j) by which the FDA authorizes new tobacco products for introduction into interstate commerce in the United States. *See id.* § 387j. As explained by FDA, the TCA provides for three "premarket review pathways": (1) submission of a premarket tobacco product application (PMTA) under TCA § 910(b); (2) submission of a substantial equivalence report under TCA § 905(j)(1)(A); and (3) submission of a request for exemption under TCA § 905(j)(3).[33]

The TCA explicitly uses the term "premarket review" three times. First, TCA § 910(a)(2) is captioned "[p]remarket review required" and establishes when a new tobacco product requires premarket review. *See* 21 U.S.C. § 387j(a)(2). Second, TCA § 902(6)(A) provides that a tobacco product "required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i)" is an "adulterated" product. 21 U.S.C.

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[33] *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300, 55,302-03 (Oct. 5, 2021).

§ 387b(6)(A).[34] Thus, two of the TCA's three uses of this term expressly involve TCA § 910(a). The third is when TCA § 916 expressly preempts "addition[al]" or "different" requirements relating to "premarket review." *Id.* § 387p(a)(2)(A).

All this makes the Court's task—determining the "single, best meaning" of the latter phrase—a relatively easy one. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). The "'normal rule of statutory construction'" is that "'identical words used in different parts of the same act are intended to have the same meaning.'" *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995) (quoting *Department of Revenue of Ore. v. ACF Industries, Inc.,* 510 U.S. 332, 342 (1994)).[35] Statutes "should not be read as a series of unrelated and isolated provisions." *Gustafson*, 513 U.S. at 570. Here, the tools of statutory construction point in one direction: that TCA § 916(a)(2)(A)'s use of the term "premarket review" refers to the FDA process explicitly called "premarket review" in §§ 910(a)(2) and 902(6)(A), a process that occurs before a product can legally be "introduced or delivered for introduction into interstate commerce." 21 U.S.C.

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[34] "Adulterated" tobacco products cannot be introduced into interstate commerce. 21 U.S.C. § 331(a).

[35] To the extent § 387j(a)(2)'s use of "premarket review" is discounted because it is a section heading, headings in their own right "supply cues" as to Congress's intent. *Yates v. United States*, 574 U.S. 528, 540 (2015); *see also Almendarez–Torres v. United States*, 523 U.S. 224, 234 (1998) ("[T]he title of a statute and the heading of a section are tools available for the resolution of a doubt about the meaning of a statute.") (internal quotation marks omitted).

§387j(c)(1)(A). This is consistent with what this Court has already held: that the "eight limited exceptions … each … relate most obviously to the production or marketing stages—and not the retail sale—of tobacco products." *Cnty. of Los Angeles,* 29 F.4th at 553-54.

This is also a sensible interpretation of congressional intent, as premarket review is a complex process involving both scientific and social considerations. The keystone of premarket review for new tobacco products requiring a PMTA is a determination of whether the proposed product is "appropriate for the protection of public health." 21 U.S.C. § 387j(c)(2)(A). In making its assessment, FDA must consider "the risks and benefits to the population as a whole," including the risk of attracting non-smokers to the proposed product. *Id.* § 387j(c)(4). For relatively new tobacco product categories, like e-cigarettes, "limited data may exist from scientific studies," requiring the agency to adjudicate applications with less than perfect evidence. *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 14 (D.C. Cir. 2022) (quoting FDA guidance). It is eminently reasonable for Congress to explicitly protect against state and local interference with this complex process.

Moreover, this reading does not leave the preemption clause a "dead letter," as Appellants argue. *See* Opening Br. 38. To the contrary, the District Court offered two examples of state laws that would presumably be preempted by this clause: (1) "a state law that purports to penalize manufacturers of tobacco products

for making misrepresentations to the FDA during the premarket review application process, akin to the law considered in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)," and (2) "a state law that redefines what constitutes a premium cigar and requires that it be subject to federal premarket review before it can be added to the UTL." ECF No. 33 at 11. Appellants dismiss this concern with confident assertions that "a State would and could never do something like that" and Congress "would not need the statute to invalidate that exercise." Opening Br. 43. But the absence of a reference to "premarket review" in an otherwise detailed preemption clause addressing the production of tobacco products prior to their introduction into commerce, would create confusion on its own.[36] Hence, the Court should "see this express exemption as Congress's way of making more obvious what would likely occur as a matter of judicial construction." *State of Ala. ex rel. Siegelman v. U.S. E.P.A.*, 911 F.2d 499, 505 n.12 (11th Cir. 1990).

The UTL, however, is not implicated by the clause because it is not an additional or different requirement relating to premarket review. California's UTL law does, of course, impose requirements on manufacturers to provide certain information to inform the Attorney General's determination of whether a finished

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[36] *See generally Arizona v. Tohono O'odham Nation*, 818 F.3d 549, 561 n.7 (9th Cir. 2016) (finding interpretive support in *expressio unius est exclusio alterius* ("the expression of one thing is the exclusion of the other")).

product is unflavored. But the UTL simply aids the state in *determining* which products are, as unflavored products, not subject to the preexisting ban on retail sale. *Flavored tobacco products were banned before the UTL*; the UTL is an information reporting law designed to enhance enforcement of the existing retail sales ban, which this Court already has held is not preempted by federal law. *R.J. Reynolds v. Bonta,* No. 23-55349, 2023 WL 4546550 (9th Cir. June 28, 2023).

Contrary to the Appellants' assertion, *see* Opening Br. 33-35, the UTL is also not converted into a regulation of the manufacturers' "production or marketing stages" merely because it is directed at manufacturers. *See Cnty. of Los Angeles,* 29 F.4th at 553-54. This is best illustrated by examining what the law does *not* do. The law does *not* govern what tobacco products can be manufactured in California (or elsewhere) or how they are manufactured. It does *not* govern how manufactured tobacco products can be labeled or marketed, even if it might be "an incentive or motivator." *R. J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1175 (8th Cir. 2023) (quoting *U.S. Smokeless Tobacco*, 708 F.3d at 435). And, in fact, provided the manufacturer completes the requisite paperwork, it does *not* change what tobacco products can be sold in California[37]; flavored tobacco

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[37] If a manufacturer fails to apply for inclusion on the UTL of a tobacco product, the product is "deemed a flavored tobacco product" subject to the state's retail sale ban. Cal. Health & Safety Code § 104559.1(g), § 104559.1(s)(3), and § 104559.5(b)(1) Additionally, if a manufacturer applies for a tobacco product's

products were already banned. At bottom, UTL inclusion or exclusion changes nothing about the "production or marketing stages" for tobacco products.

Moreover, there are good reasons for directing this regulation at manufacturers instead of retailers, the most apparent of which is efficiency. The California Department of Tax and Fee Administration reports over 23,000 licensed tobacco retailers in the state.[38] Requiring each retailer, for example, to apply for inclusion of unflavored products it wishes to sell could result in millions of duplicate applications.

Finally, Appellants suggest that somehow state laws that are innovative are thereby preempted by federal law, *see* Opening Br. 35-37, but cite nothing in the text of the TCA to support such a notion. Indeed, the breadth of state authority preserved by the TCA to encompass innovative state laws to prevent tobacco-related disease and death is an important public health benefit of the TCA.

For all these reasons, the UTL is not "premarket review" within the meaning of the TCA.

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inclusion and the Attorney General "reasonably determines" that the product has a characterizing flavor, he "shall decline to include [it] on the UTL." *Id.* § 104559.1(e).

[38] California Department of Tax and Fee Administration, California Cigarette & Tobacco Products Licensees, https://www.cdtfa.ca.gov/taxes-and-fees/cigarette-licensees.htm (last updated Feb. 2, 2026). There are also scores of licensed tobacco product distributors and wholesalers.

B. Even If the UTL Law Does Constitute "Premarket Review," the Law Would Still Be Permitted under the TCA's Savings Clause

Even if this Court were to find that the UTL constitutes "premarket review" within the meaning of TCA § 916(a)(2)(A), the UTL would still be permissible under the TCA's savings clause. The preemption of "premarket review" expressly "does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age." 21 U.S.C. § 387p(a)(2)(B). As this Court previously held, this provision "reinforces what [the TCA] first established in the preservation clause: that the regulation and prohibition of tobacco product sales falls squarely within the purview of states, localities, and tribal entities." *Cnty. of Los Angeles*, 29 F.4th at 555.

California's UTL would fall under several of these exceptions. Most clearly, the UTL "relate[s] to the sale" of tobacco products. If a product is of a category required to be on the UTL but is not, it is deemed "flavored," and its sale is prohibited in California.[39] It also relates to "information reporting to the State." It requires manufacturers to report flavor-related information to the state to ensure strong enforcement of the state's sales ban.[40]

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[39] Cal. Health & Safety Code §§ 104559.1(g), 104559.1(s)(3), and 104559.5(b)(1).
[40] Cal. Health & Safety Code § 104559.5(b).

Therefore, even if California's UTL statute were regarded as a form of "premarket review," it undeniably comes within the scope of the TCA's savings clause and is not preempted by federal law.

C. Appellants' Interpretation Would Result in an Absurd Reading of the Tobacco Control Act

As noted, the underlying California flavor ban applies to sales by a "tobacco retailer," *see* Cal. Health & Safety Code § 104559.5(b)(1), and this Court has already determined that this retail sales ban is not preempted by the TCA. *R. J. Reynolds v. Bonta*, No. 23-55349, 2023 WL 4546550 (9th Cir. June 28, 2023). Appellants are asking this Court to hold that a subsequent statute that allows the state to merely *clarify* what products are not subject to that ban *is* preempted. This would be an absurd reading of congressional intent and cannot be the "single, best meaning" of the statute. *Loper Bright*, 603 U.S. at 400. Quite simply, it would make no sense for Congress to have preserved the states' historically broad authority to prohibit the sale of certain tobacco products because of their harm to public health and, in the same statute, preclude states from determining which specific products are, and are not, subject to that prohibition in order to enhance its enforcement to ameliorate the harm to public health. This nonsensical reading of the TCA, clearly at odds with this Court previous holdings, should be rejected.

CONCLUSION

For these reasons, the Court should affirm the District Court's denial of a preliminary injunction.

Dated: March 3, 2026

Respectfully submitted,

/s/ *Jordan Raphael*
Jordan Raphael
BYRON RAPHAEL LLP
811 Wilshire Blvd., 17th Floor,
Los Angeles, California 90017
T: (213) 291-9800
E: jraphael@byronraphael.com

Of counsel:
Dennis A. Henigan
Andrew R. Tardiff
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street, N.W., Suite 1200
Washington, D.C. 20005
T: 202-304-9928
E: dhenigan@tobaccofreekids.org
E: atardiff@tobaccofreekids.org

Attorneys for *Amici Curiae*

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FOR THE NINTH CIRCUIT

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CERTIFICATE OF CONFERENCE

I hereby certify that, pursuant to Fed. R. App. P. 29(a)(2), on February 2nd, 2026, I contacted counsel for both Appellants and Appellee by electronic mail and phone seeking consent to file the subject Brief of Amici Curiae and that counsel for Appellants and Appellee provided their consent on February 20th, 2026, and February 2nd, 2026, respectively.

/s/ Jordan Raphael
Jordan Raphael
Attorney for *Amici Curiae*

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I hereby certify that on this 3rd day of March 2026, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Ninth Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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Jordan Raphael
Attorney for *Amici Curiae*