No. 20-55930

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

R.J. REYNOLDS TOBACCO COMPANY; AMERICAN SNUFF COMPANY; AND SANTA FE NATURAL TOBACCO COMPANY,
Plaintiffs–Appellants,

V.

COUNTY OF LOS ANGELES; COUNTY OF LOS ANGELES BOARD OF SUPERVISORS; AND HILDA L. SOLIS, MARK RIDLEY-THOMAS, SHEILA KUEHL, JANICE HAHN, AND KATHRYN BARGER, EACH IN HIS OR HER OFFICIAL CAPACITY AS MEMBER OF THE BOARD OF SUPERVISORS,
Defendants–Appellees.

On Appeal from the United States District Court
for the Central District of California
No. 2:20-cv-4880
The Honorable Dale S. Fischer, District Judge

AMICUS BRIEF OF THE STATE OF CALIFORNIA IN SUPPORT OF APPELLEES

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INTEREST OF AMICUS CURIAE

"Courts and commentators frequently have recognized that the 50 states serve as laboratories for the development of new social, economic, and political ideas." *Fed. Energy Regulatory Comm'n v. Mississippi*, 456 U.S. 742, 788 (1982) (O'Connor, J., concurring in part). In particular, states and their localities have served as laboratories for the development of new tobacco policy for over three decades, with many of their innovations eventually becoming federal policy in the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 21 U.S.C. §§ 387–387u and amending scattered sections of 15 U.S.C. and 21 U.S.C.). For example, the Tobacco Control Act increased tobacco excise taxes for the purpose of reducing consumption, removed tobacco products from vending machines, and prohibited free samples of tobacco products, all of which were implemented in California and other states before its passage. To preserve the states' and their localities' role as architects of new tobacco policy, Congress included in the TCA a broad preservation clause that expressly disclaims federal preemption of almost all state and local authority over tobacco products. *See id.* § 916(a), 21 U.S.C. § 387p(a).

Recognizing that flavored tobacco products drive tobacco use initiation—especially among youth—states and localities around the country have

implemented retail sales prohibitions on flavored tobacco products. In California alone, at least 71 localities have prohibited the sale of all flavored tobacco products to consumers. *See* AM. NONSMOKERS' RIGHTS FOUND., MUNICIPALITIES PROHIBITING THE SALE OF FLAVORED TOBACCO PRODUCTS (2021).[1] The California Legislature similarly passed, and the Governor signed, a prohibition against retail sales of flavored tobacco products in 2020. *See* Act of Aug. 28, 2020 ("S.B. 793"), ch. 34, 2020 Cal. Stat. 1743 (to be codified at Cal. Health & Safety Code § 104559.5). That law is currently subject to a referendum, and will be put to the voters in California's November 2022 election. *See* Press Release, Cal. Sec'y of State, New Referendum Qualified for California's November 2022 Ballot (Jan. 22, 2021).[2]

This appeal implicates all of these public health measures, as well as the congressionally preserved role of states and localities as tobacco policy innovators. California has a clear interest in ensuring that it and its political subdivisions, its elected lawmakers and voters, can exercise their rightful authority to continue to regulate tobacco within California's borders. The State of California, by and

[1] Available at https://no-smoke.org/wp-content/uploads/pdf/flavored-tobacco-product-sales.pdf.

[2] Available at https://www.sos.ca.gov/administration/news-releases-and-advisories/2021-news-releases-and-advisories/js21002.

through California Attorney General Rob Bonta, therefore submits this brief in support of Appellees.

INTRODUCTION

Appellants' challenge to the Los Angeles County Ordinance is not unique. Across the country, plaintiffs—including several of the appellants and attorneys in this suit—have challenged these state and local "flavor bans," claiming them to be preempted by the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 21 U.S.C. §§ 387–387u and amending scattered sections of 15 U.S.C. and 21 U.S.C.). Unable to convince local and state lawmakers that their flavored tobacco products should remain stocked on local shelves, *see, e.g.*, Appellants' Br. 11–12 (citing tobacco industry position papers, including Appellants' own), Appellants have turned to the courts. But in every instance, courts have upheld restrictions on the sale of flavored tobacco products, finding them constitutional and consonant with the TCA. *See U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82–83 (1st Cir. 2013); *Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015); *R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 886 (D. Minn. 2020), *appeal docketed*, No. 20-2852 (8th Cir. Sept. 4, 2020); *R.J. Reynolds Tobacco Co.*

v. County of San Diego, Case No.: 20-CV-1290 JLS (WVG), 2021 WL 1174787, at *11 (S.D. Cal. Mar. 29, 2021), *appeal docketed*, No. 21-55348 (9th Cir. Apr. 13, 2021); *Neighborhood Market Ass'n v. County of San Diego*, Case No.: 20-CV-1124 JLS (WVG), 2021 WL 1174784, at *11 (S.D. Cal. Mar. 29, 2021).

As these courts have recognized, the TCA expressly preserves state and local authority to implement flavored product sales restrictions like the one challenged here. Instead of implementing a federal tobacco regime that "cleared the field" of state and local regulation, Congress installed the U.S. Food and Drug Administration ("FDA") as an additional regulator alongside state, local, and tribal entities already active in the tobacco regulatory space. Under the TCA, the FDA acts as the initial gatekeeper, determining which manufactured tobacco products may enter the United States in the first instance, while leaving downstream regulation—including the authority to tax or prohibit such tobacco products altogether—to the states and their localities. This accords with the historical background upon which Congress enacted the TCA, where states and localities took a lead role in tobacco regulation while the federal government confined its efforts almost exclusively to labeling and advertising restrictions. Congress retained federal control over labeling and advertising, introduced national regulation of manufacturing, and otherwise expressly preserved the broad, existing state and local authority over tobacco products.

The district court below correctly read the TCA as preserving that authority and preempting only measures that would necessarily interfere with the FDA's new gatekeeping authority and the federal government's already-established authority over labeling and advertising. This Court should affirm the district court's judgment and uphold Congress's express preservation of state and local authority to determine which tobacco products may be sold to consumers within their jurisdictions.

ARGUMENT

Congress did not enact the Tobacco Control Act in a vacuum. Instead, it is part of a decades-long evolution of tobacco regulation, responding to new revelations about the public health harms of tobacco products and new industry efforts to mitigate the impact of those revelations on its bottom line. Appellants argue that the TCA did not build upon existing state tobacco regulatory foundations, it displaced them. But the precisely worded delineation between state and federal authority over tobacco products in section 916 of the TCA belies that argument. And apart from the plain text of the statute, the historical context in which the TCA was enacted confirms section 916's preservation of virtually all state and local authority to regulate tobacco products—including authority to tax or prohibit the retail sales of entire categories of tobacco products like flavored tobacco products.

I. HISTORY OF TOBACCO REGULATION IN THE UNITED STATES

A. The Beginning of Contemporary Tobacco Regulation

Contemporary tobacco regulation in the United States began in 1964, when the Surgeon General issued a much-publicized report that demonstrated a causal link between cigarette use and the incidence of various diseases such as lung cancer and cardiovascular disease.[3] *See* PUB. HEALTH SERV., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 30 (1964) ("The array of information . . . clearly establishes an association between cigarette smoking and substantially higher death rates."). In response, Congress considered a number of legislative proposals to mitigate tobacco's public health harms, including placing tobacco under the jurisdiction of the FDA. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147–48 (2000) (describing the introduction of four bills between 1963 and 1965 that would have placed tobacco under FDA authority). Ultimately,

[3] Earlier tobacco regulation included some states banning sales of cigarettes entirely. *See, e.g.*, *Austin v. Tennessee*, 179 U.S. 343, 348–49 (1900) ("[W]e think it within the province of the legislature to say how far [cigarettes] may be sold, or to prohibit their sale entirely . . . ."). Such laws were repealed as cigarette use became the predominant form of tobacco use following World War I. *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 32 (2000) (tracking the history of state cigarette bans).

Congress decided to take a consumer education approach, requiring health warnings on cigarette packages and advertising with the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331–1340). In doing so, Congress cleared the field of state regulation "relating to smoking and health" of cigarette labeling or advertising, 15 U.S.C. § 1334(a)–(b) (1970), in order to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health," *id.* § 1331(2)(B).

In the following decades, Congress passed laws that strengthened and expanded the FCLAA's provisions, cementing the federal government's consumer education approach to tobacco control.[4] These laws adjusted the FCLAA's required warnings and expanded Congress's consumer education efforts. But none deviated from that consumer education approach. Congress prohibited cigarette advertising on any mode of transmission regulated by the Federal Communications Commission, Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222,

[4] *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (amending 15 U.S.C. §§ 1331–1339); Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175 (codified as amended in scattered sections of 12 U.S.C. and 42 U.S.C.); Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (amending 15 U.S.C. §§ 1331–1341); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (codified as amended at 15 U.S.C. §§ 4401–4408).

sec. 2, § 6, 84 Stat. 87, 89 (codified as amended at 15 U.S.C. § 1335); directed the U.S. Department of Health and Human Services ("HHS") to submit tobacco research reports to Congress, Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, sec. 2, § 505(b)(2), 61 Stat. 175, 178 (codified at 42 U.S.C. § 290aa-4(b)(2) (1988)); codified the Federal Trade Commission's 1972 expansion of health warnings to advertising, Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, sec. 4, § 4, 98 Stat. 2200, 2201–03 (amending at 15 U.S.C. § 1333); created an interagency committee within HHS to coordinate federal and private efforts to inform the public of the health risks of smoking, *id.* § 3(b), 98 Stat. at 2201 (codified as amended at 15 U.S.C. § 1341(b)); and placed smokeless tobacco under an education-based regulatory regime that mirrored the one covering cigarettes, *see* Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (codified as amended at 15 U.S.C. §§ 4401–4408).

B. A Shift Toward Youth Prevention

Congress's focus on consumer education proved inadequate for two main reasons. First, researchers developed a greater understanding of nicotine's addictive properties. Reviewing scientific literature concerning nicotine, the Surgeon General released a new report on tobacco in 1988 that concluded the "pharmacologic and behavioral processes that determine tobacco addiction are

similar to those that determine addiction to drugs such as heroin and cocaine." U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, A REPORT OF THE SURGEON GENERAL 15 (1988). Second, it became apparent that tobacco companies were purposefully and specifically marketing cigarettes to youth. For example, Appellant R.J. Reynolds introduced Joe Camel in 1988, which—"consistent with tobacco industry documents that indicate that a major function of tobacco advertising is to promote and maintain tobacco addiction among children"—was "far more successful at marketing Camel cigarettes to children than to adults." Joseph R. DiFranza et al., *RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children*, 266 JAMA 3149, 3149 (1991).

These two revelations made it clear that consumers were often becoming addicted to cigarettes before they were able to appreciate the risks of smoking and make an informed choice. In response, tobacco control efforts at all levels of government pivoted toward youth prevention. *See* INST. OF MED., NAT'L ACADS. OF SCI., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 118 (Richard J. Bonnie et al. eds., 2007) ("In the early 1990s, . . . national experts on tobacco use had begun to highlight the importance of smoking among youth. Studies showed that nearly 90 percent of adult smokers began smoking by the time they were 18 years old . . . .").

During this phase of tobacco regulation, the states and their localities led the way. This "burst of state action began in 1988, when the people of California passed Proposition 99," which "increased the excise tax on tobacco from 10 to 35 cents per pack and earmarked 20 percent of the new revenues for a statewide antismoking campaign." *Id.* at 119; *see also* Tobacco Tax and Health Protection Act of 1988, Proposition 99, 1988 Cal. Stat. A-269 (codified at Cal. Rev. & Tax. Code §§ 30121–30130). Unlike past tobacco taxes that were designed to generate revenue, Proposition 99 "was explicitly billed as a tobacco control measure." Robert L. Rabin, *Tobacco Control Strategies: Past Efficacy and Future Promise*, 41 LOY. L.A. L. REV. 1721, 1729 (2008); *see also* INST. OF MED., *supra*, at 120 ("[T]he general rule is that a 10 percent increase in the real price reduces . . . the rate of smoking among youth by 7 percent."). The measure also earmarked the revenue it raised for tobacco control, including research and community outreach. *See* Cal. Rev. & Tax. Code § 30122. Continuing the "burst of state action," and in light of the measure's success in reducing smoking rates, Massachusetts and Arizona enacted similar measures in 1992 and 1994, respectively. *See* Paul A. Lebel, *"Of Deaths Put on by Cunning and Forced Cause": Reality Bites the Tobacco Industry*, 38 WM. & MARY L. REV. 605, 636–37 (1997) (book review).

States and localities became laboratories for devising new and effective youth prevention efforts. For example, by 1994 "at least 30 cities in Minnesota, New

York, California, Maryland, New Jersey, and Louisiana ha[d] outlawed the use of cigarette vending machines." PETER D. JACOBSON & JEFFREY WASSERMAN, TOBACCO CONTROL LAWS: IMPLEMENTATION AND ENFORCEMENT 15 (1997). When public health research showed such laws to be effective in reducing youth access to cigarettes, *see id.*, other jurisdictions adopted them. Similarly, jurisdictions adopted prohibitions on free samples of the tobacco industry's addictive products. *See, e.g.*, Act of Aug. 11, 1995, ch. 415, § 6, 1995 Cal. Stat. 2395, 2991–92 (codified as amended at Cal. Health & Safety Code § 118950). These and other once-local policy innovations can now be found in federal regulations promulgated under the TCA. *See* 21 C.F.R. § 1140.14(a)(3) (vending machines); *id.* § 1140.16(d) (free samples).

Congress, too, turned to youth prevention. But its legislative action during this period deferred to the states for implementation. For example, in 1992, as part of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, 106 Stat. 323 (1992), Congress passed what has become known as the Synar Amendment, *id.* sec. 201, § 1926, 106 Stat. at 394–95 (codified as amended at 42 U.S.C. § 300x-26). This provision provides the states with grant money in exchange for passing a minimum age law and submitting reports demonstrating a certain level of enforcement and effectiveness. *See* 42 U.S.C. § 300x-26; *N.H. Motor Transp. Ass'n v. Rowe*, 448 F.3d 66, 78 n.12 (1st

Cir. 2006) ("The Synar Amendment indicates Congress'[s] intent that the states take the lead in addressing the underage smoking problem.").

C. 1994 Congressional Hearings and the State and Federal Responses

Thirty years after the 1964 Surgeon General Report, another seminal event in tobacco control occurred when Congress called the heads of the major tobacco companies to testify about the dangers posed by their products. At a congressional hearing in April 1994, each denied under oath the addictiveness of nicotine. *See Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health & the Env't*, 103d Cong. 628 (1994). A month after the April hearings, Mississippi filed the first state lawsuit against these tobacco companies, alleging conspiracy to conceal the health harms of cigarettes and other tobacco products from the consuming public. *See* Michael Janofsky, *Mississippi Seeks Damages from Tobacco Companies*, N.Y. TIMES, May 24, 1994, at A12. Other state lawsuits followed. Mississippi and three other early-filing states resolved their disputes through settlement. In 1998, the remaining 46 states and five territories joined together to secure the tobacco Master Settlement Agreement ("MSA") with the major manufacturers. Barry Meier, *Remaining States Approve the Pact on Tobacco Suits*, N.Y. TIMES, Nov. 21, 1998, at A1. This "landmark agreement," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 533 (2001), placed extensive restrictions on

the manufacturers' sales and marketing practices, and provided for annual payments to the states in perpetuity.[5]

A Congressional response to those hearings, however, did not materialize. Competing legislation was introduced into Congress to give the FDA explicit statutory authority to regulate tobacco, but none was enacted.[6] Instead, the FDA promulgated regulations in 1996 to assert jurisdiction over tobacco in the absence of Congressional action. *See Brown & Williamson*, 529 U.S. at 125. An industry challenge to those regulations ultimately reached the Supreme Court where, given the numerous failed attempts to statutorily grant the FDA jurisdiction over tobacco and the limited tobacco statutes Congress passed instead, the Court held "that Congress ha[d] clearly precluded the FDA from asserting jurisdiction to regulate tobacco products," and struck down the FDA regulations. *Id.* at 126.

States and localities, however, remained active. States enacted a host of new laws regulating the sale and use of cigarettes and tobacco products, including by placing restrictions on non-face-to-face tobacco sales, *see, e.g.*, Stop Tobacco

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[5] The text of the MSA can be found at http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf.

[6] *See, e.g.*, S. 527, 105th Cong. (1997); S. 1414, 105th Cong. (1997); S. 1415, 105th Cong. (1997); S. 1492, 105th Cong. (1997); H.R. 762, 105th Cong. (1997); H.R. 1244, 105th Cong. (1997); H.R. 3028, 105th Cong. (1997); S. 1530, 105th Cong. (1998); S. 1638, 105th Cong. (1998); S. 1648, 105th Cong. (1998); S. 1889, 105th Cong. (1998); H.R. 3474, 105th Cong. (1998); H.R. 3738, 105th Cong. (1998); H.R. 3868, 105th Cong. (1998); H.R. 3889, 105th Cong. (1998).

Access to Kids Enforcement ("STAKE") Act, ch. 685, 2002 Cal. Stat. 4129 (codified at Cal. Bus. & Prof. Code § 22963); requiring licensing up and down the distribution chain from manufacturer to retailer, *see, e.g.*, Cigarette and Tobacco Products Licensing Act of 2003, ch. 890, 2003 Cal. Stat. 6496 (codified at Cal. Bus. & Prof. Code §§ 22970–22995); and using cigarette and other tobacco taxes as a public health tool, *see, e.g.*, California Children and Families First Act of 1998, Proposition 10, 1998 Cal. Stat. A-287 (codified at Cal. Const. Art. XIII A, § 7; Cal. Const. Art. XIII B, § 13; Cal. Health & Safety Code §§ 130100–130155; Cal. Rev. & Tax. Code §§ 30131–30131.6) (nearly tripling the state's cigarette and tobacco taxes to fund anti-youth smoking and pre-K programs); *see also* 54 ORZECHOWSKI & WALKER, THE TAX BURDEN ON TOBACCO: HISTORICAL COMPILATION 2019, at 10–11 tbl. 6 (2019) (tracking dozens of state-level cigarette excise tax increases in the period 1998–2009). During this period, states even set manufacturing product standards through the use of uniform laws. *See, e.g.*, Act of Aug. 16, 2000, ch. 284, 2000 N.Y. Laws 2928 (codified at N.Y. Exec. Law § 156-c); California Cigarette Fire Safety and Firefighter Protection Act of 2005, ch. 633, 2005 Cal. Stat. 4830 (codified as amended at Cal. Health & Safety Code §§ 14950–14960) (adopting the New York ignition standard). And reflecting state authority to exclude certain tobacco products from their borders, states prohibited the distribution or sale of cigarette brands whose manufacturers failed to make

sufficient assurances of compliance with state law. *See, e.g.*, Cal. Rev. & Tax. Code § 30165.1(b).

D. The Family Smoking Prevention and Tobacco Control Act of 2009

In 2009, against the accumulated backdrop of state and local regulation, Congress passed and the President signed the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 21 U.S.C. §§ 387–387u and amending scattered sections of 15 U.S.C. and 21 U.S.C.), granting the FDA the jurisdiction over tobacco products the Supreme Court had found it previously lacked. Congress made clear that its goal was not to displace the decades of work done at the state and local levels, but to bolster and complement their work. Thus, cognizant of the extensive state regulation of tobacco products enacted before and since the FDA's initial foray into tobacco regulation in 1996, Congress included a broad Preservation Clause, TCA § 916(a)(1), 21 U.S.C. § 387p(a)(1), reserving to the FDA only those novel regulations introduced by the TCA—product standards, premarket review, adulteration, misbranding, registration, good manufacturing practices, and modified risk tobacco products—or previously already reserved to

the federal government—labeling and advertising, *see id.* § 916(a)(2), 21 U.S.C. § 387p(a)(2)(A).[7]

The TCA also modified the advertising and labeling regime put in place by the FCLAA and Federal Trade Commission. The TCA authorized the FDA to regulate both tobacco labeling, *see, e.g.*, *id.* § 202 (amending 15 U.S.C. § 1334), and health claims in tobacco advertising, *see id.* § 911, 21 U.S.C. § 387k. The law provides that manufacturers can apply to have a product be recognized as a "modified risk tobacco product," which, once accepted as such by the FDA, can be advertised "to reduce harm of the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 911(b)(1), 21 U.S.C. § 387k(b)(1). Finally, the TCA partially rolled back the FCLAA's preemption of cigarette labeling and advertising regulations, removing preemption as to measures addressing "the time, place, and manner . . . of the advertising or promotion of any cigarettes." *Id.* § 203 (amending 15 U.S.C. § 1334); *see also generally Lorillard Tobacco*, 533 U.S. at 551 (abrogated in part by TCA § 203) (holding that the

[7] Even then, the TCA enabled the states to enact and enforce certain requirements related to those manufacturing regulations. *See id.* § 916(a)(2)(B), 21 U.S.C. § 387p(a)(2)(B). For example, the TCA expressly preserved the existing state regulation of fire-safe cigarette product standards, despite placing the general regulation of tobacco product manufacturing under FDA authority. *See id.* (saving from preemption all measures "relating to fire safety standards for tobacco products").

original preemption language of the FCLAA made no "distinction between state regulation of the location as opposed to the content of cigarette advertising").

II. THE CONTEXT OF TOBACCO REGULATION MAKES CLEAR THAT FLAVOR BANS FIT SQUARELY WITHIN THE STATES' AUTHORITY

Section 916 of the TCA, 21 U.S.C. § 387p, sets out the relationship between state and federal authority over tobacco products, preserving broad state and local authority that includes the authority to prohibit retail sales of a class of tobacco products such as flavored tobacco products. Read in the historical context set out above in which the states and their localities have taken a primary role in regulating tobacco, the text of section 916 becomes even clearer.

Section 916 starts with the Preservation Clause, which sweeps broadly and preserves for the states and their localities virtually all regulatory authority over tobacco products except to set tobacco regulations less stringent than those imposed by the TCA. It includes the ability "to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under" the TCA. *Id.* § 916(a)(1), 21 U.S.C. § 387p(a)(1). It goes on to provide examples of state authority. State authority includes, but is not limited to, "law[s], rule[s], regulation[s], or other measure[s] relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age." *Id.*

The Preemption Clause follows, providing eight limited exceptions to the Preservation Clause. All of those exceptions address specific elements of the TCA that are of uniquely federal concern because they address the manufacture, labeling, or advertisement of tobacco products: "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, [and] modified risk tobacco products." *Id.* § 916(a)(2)(A), 21 U.S.C. § 387p(a)(2)(A) (preempting "any requirement which is different from, or in addition to, any requirement under [the TCA] relating to" those eight topics).

Finally, the Savings Clause returns some authority relating to these eight categories to the states. That is, states and localities may implement restrictions "relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products," under certain circumstances. Relevant here, they can do so when the restriction is "relating to the sale . . . of[] tobacco products." *Id.* § 916(a)(2)(B), 21 U.S.C. § 387p(a)(2)(B).

This three-part structure makes clear that the TCA preempts only state and local measures that (1) necessarily interfere with the new FDA-administered market gatekeeping functions established by the TCA; or (2) address advertising

and product labeling, which have been the province of the federal government for the better part of a century. *See id.* § 916(a)(2), 21 U.S.C. § 387p(a)(2)(A).

Apart from this limited express preemption, Congress acknowledged and preserved for states and localities the regulatory authority they had long exercised. Thus, for example, despite implementing national manufacturing standards, the TCA specifically carved out the uniform manufacturing standards that the states had already implemented regarding cigarette fire safety. *Id.* § 916(a)(2)(B), 21 U.S.C. § 387p(a)(2)(B) (exempting from preemption any requirement "relating to fire safety standards for tobacco products"). And the TCA signals its intent to let states and localities continue to push their regulations farther, preserving in section 916 state and local promulgation of measures "in addition to, or more stringent than, requirements" set out in the Act and declining to limit those jurisdictions' taxing authority, *id.* § 916(a)(1), 21 U.S.C. § 387p(a)(1), while elsewhere allowing state and local restrictions on cigarette advertising for the first time since 1965, *see id.* § 203 (amending 15 U.S.C. § 1334).

Appellants would have this Court believe that FDA is empowered to determine national tobacco policies comprehensively and now has the "primary role" in tobacco regulation. Appellants' Br. 9. Appellants thus claim that "Congress entrusted FDA to decide which flavored products *should* be available to adult consumers." *Id.* at 5 (emphasis added). But appellants are wrong; Congress

empowered the FDA to decide which tobacco products *could* be available to adult consumers in the United States by limiting the FDA's role to establishing only "national standards controlling the *manufacture* of tobacco products," TCA § 3(3), 21 U.S.C. § 387 note (emphasis added), and to continuing the federal program of "ensur[ing] that consumers are better informed," *id.* § 3(6), 21 U.S.C. § 387 note. States and localities then, from the pool of tobacco products that have met the regulatory requirements erected by the FDA, may impose their own, additional restrictions that direct whether those goods can be stocked by local retailers or at what price they may be sold. By express congressional design, primary authority over local tobacco policy was to remain in the hands of the states and localities.

1. Appellants misconstrue the import of the FDA establishing that marketing of a tobacco product is "appropriate for the protection of the public health," TCA § 910(c)(2)(A), 21 U.S.C. § 387j(c)(2)(A), implying that such determination reflects an affirmative federal judgment that the new product must be made available to all consumers, *see* Appellants' Br. 15–16, 24, 51–52, 56. But as explained above, the only new national standards Congress set out to set implement are those relating to "the *manufacture* of tobacco products and the identity, public disclosure, and amount of ingredients used in such products." TCA § 3(3), 21 U.S.C. § 387 note (emphasis added). Congress indicated no intent to set a national market or to ensure that the same products are available for retail sale

throughout the United States. Indeed, the congressional record makes clear that the "appropriate for the protection of the public health" standard was implemented because the "safe" or "safe and effective" standards used by FDA for foods, drugs, and medical devices would be inappropriate for tobacco products, since they are "inherently dangerous." H.R. Rep. No. 111-58, pt. 1, at 3 (2009), *as reprinted in* 2009 U.S.C.C.A.N. 468, 470. FDA approval of new tobacco products is thus part of its new gatekeeping role, requiring preapproval to prevent past tobacco industry practice of "design[ing] new products or modify[ing] existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease." *Id.* at 4, *as reprinted in* 2009 U.S.C.C.A.N. at 470. Premarket approval is a prophylactic measure, not an affirmative statement that introduction of a new product will increase public health.

The same is true of modified risk tobacco products. Authorization "to market [a tobacco product] as presenting lower health risks," Appellants' Br. 16, is not an affirmative determination that the product should be made available to all adult consumers. FDA approval instead advances the traditional consumer education goals of federal tobacco regulation, to prevent tobacco products from being "sold or distributed as modified risk products that do not in fact reduce risk or that increase risk." TCA § 2(37), 21 U.S.C. § 387 note.

2. The TCA explicitly preserves state and local authority to tax tobacco—"No provision of this chapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products," TCA § 916(a)(1), 21 U.S.C. § 387p(a)(1)—confirming that states and localities retain primary authority over local tobacco policy. As explained above, taxation is one of the most effective policy levers to impact consumption. *Supra*, p. 10. And in light of states' varying approaches to tobacco regulation, states have taken varying approaches to differential taxation of tobacco products. Kentucky, for example, in "recogni[tion] that increasing taxes on tobacco products should reduce consumption," implemented "relative taxes on tobacco products" reflecting Kentucky's understanding of those products "relative risk." Ky. Rev. Stat. Ann. § 138.140(6) (West). California, in contrast, taxes all tobacco products at the same rate, affecting their consumption rates equally. *See* Cal. Rev. & Tax. Code § 30123(b). When the TCA was passed, state jurisdictions varied as to whether some categories of cigarettes and tobacco products bore taxes at all. *See* 54 ORZECHOWSKI & WALKER, *supra*, at 47–109 tbl. 12 (2019) (listing variations in other tobacco products taxed by year). The TCA does not preempt these local policy choices; it expressly preserves them.

Moreover, "a power to tax is a power to exclude." *Smith v. Turner*, 48 U.S. (7 Ho.) 283, 461 (1849) (opinion of Grier, J.). Retention of state and local taxing authority bolsters the conclusion (above and beyond the express language of the

TCA's Preservation Clause) that the states and their localities must also retain the authority to prohibit retail sales of entire categories of tobacco products. In light of Congress's express words on taxation, reading the TCA as preempting state authority to prohibit retail sales bans as Appellants argue, *see* Appellants' Br. 41–42, would make avoiding federal preemption into a mere drafting exercise, *cf. id.* at 45–46 (arguing against the preemption analysis turning on the way a legislature characterizes the challenged legislation).

Retention of State and local taxing authority and broad savings of their ability to impose requirements on sale and distribution also undercuts Appellants' analysis of the FDA's statutorily mandated consideration of illicit trade in promulgating tobacco product standards. *See* Appellants' Br. 51–52. Pointing to that statutory mandate, Appellants insist that Los Angeles County's retail sales ban of menthol cigarettes cannot stand because it might increase illicit cigarette sales and "could cause severe adverse effects on the public." *Id.* at 53. But a primary driver of illicit tobacco sales is tax disparity between jurisdictions. *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-313, ILLICIT TOBACCO: VARIOUS SCHEMES ARE USED TO EVADE TAXES AND FEES (2011) (cataloguing schemes to divert low-tax cigarettes to high-tax states). And, ultimately, *any* local variation in product mix or price invites arbitrage. Even as Appellants read the statute, states and localities retain authority to create variations in local markets. Given the TCA's preservation

of such state and local authority, it cannot be that if the FDA makes a determination with reference to its impact on illicit tobacco sales,[8] states and localities are prohibited from enacting measures that might increase the risk of illicit sales.[9] To so hold would nullify the TCA's preservation of local and state authority to implement tobacco taxes and regulations.

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[8] The FDA has not even made the determinations that Appellant claims it has. Learning from local sales bans of menthol-flavored cigarettes, the FDA has since confirmed that it intends to promulgate a tobacco product standard "to prohibit menthol in cigarettes." *See* Press Release, FDA, FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers. Even at the time of Appellants' briefing, the FDA confirmed that inaction does not constitute an affirmative decision not to remove any particular product from the market. *See* Order 9, *African Am. Tobacco Control Leadership Council v. U.S. Dep't Health & Human Servs.*, Case No. 20-cv-04012-KAW (N.D. Cal. Nov. 12, 2020), ECF No. 34 ("FDA has not decided not to ban menthol."). Regarding ENDS, the FDA has similarly not made an affirmative determination that flavored products should remain on the market. The document Appellant relies on merely sets out the FDA's allocation of its enforcement priorities and resources. *See* FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) 2–3 (2020), https://www.fda.gov/media/133880/download ("This guidance document describes how we intend to prioritize our enforcement resources . . . [and] does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." (footnotes omitted)).

[9] Additionally, with respect to illicit tobacco sales, Congress has consistently backed state and local enforcement efforts instead of displacing them. For example, in 2006, Congress provided authority to state attorneys general and the chief law enforcement officers of localities to enforce the Contraband Cigarette Trafficking Act. *See* USA PATRIOT Improvement and Reauthorization Act of 2005, Pub. L. No. 109-177, § 121(f), 120 Stat. 192, 223–24 (amending 18 U.S.C.

3. The retention of state authority over fire safety standards, *see supra* p. 19, also demonstrates that preservation of state authority to enact and enforce "requirements relating to" particular areas include the authority to enact and enforce requirements that prohibit particular products. The TCA preserved state fire-safety standards in force at the time of the TCA's passage, which included prohibitions on their sale. *See, e.g.*, Cal. Health & Safety Code § 14955(a)–(b) (2007) (subjecting any manufacturer, distributor, wholesaler, or retailer that "knowingly sells or offers to sell cigarettes in violation of" California's fire-safe standards to civil penalties). Indeed, a fire-safety standard that is unaccompanied by a prohibition of non-conforming products would be meaningless. In preserving this authority to prohibit non-conforming products, Congress uses the same "relating to" language in section 916 that it does to preserve "requirements relating to the sale . . . of[] tobacco products." TCA § 916(a)(2)(B), 21 U.S.C. § 387p(a)(2)(B) (saving from preemption state and local "requirements . . . relating

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§ 2346). Similarly, in 2009—the same year it passed the TCA—Congress passed the Prevent All Cigarette Trafficking Act of 2009 ("PACT Act"), Pub. L. No. 111-154, 124 Stat. 1087 (amending 15 U.S.C. §§ 375–378; 18 U.S.C. § 2343(b), and codified at 18 U.S.C. § 1716E). The PACT Act federalized state tobacco tax and other laws, *see* 15 U.S.C. § 376a(a)(3)–(4), (d), and granted the states authority to enforce its provisions, *see id.* § 378(c)(1)(A). The current Congress also amended the PACT Act to now cover not only cigarettes and smokeless tobacco, but also ENDS, beginning in March 2021. *See* Preventing Online Sales of E-Cigarettes to Children Act, Pub. L. No. 116-260, div. FF, tit. VI, § 602, 134 Stat. 3136, 3136 (2021) (amending 15 U.S.C. § 375).

to fire safety standards for tobacco products"). Accordingly, Appellants' cribbed grammatical argument that the state requirements preserved in the Savings Clause excludes prohibitions, *see* Appellants' Br. 44–45 & n.18, fails in the face of the regulatory context of the TCA's passage.

4. Product standards are aimed at implementing the FDA's new role as gatekeeper of the U.S. tobacco market, setting standards for which products can be manufactured in the United States, or manufactured abroad and imported into the United States. *See* TCA § 902(5), 21 U.S.C. § 387b(5) (rendering tobacco products out of conformance with tobacco product standards "adulterated"); 21 U.S.C. § 331(a), (g) (prohibiting adulterated tobacco products from being "manufacture[d]" or "introduce[ed] or deliver[ed] for introduction into interstate commerce"). Appellants attempt to expand tobacco product standards beyond regulation of tobacco product manufacture to sweep up Los Angeles County's challenged sales ordinance as preempted, *see* Appellants' Br. 3, but those attempts, too, cannot be squared with the historical context of the TCA's enactment.

Appellants claim that tobacco product standards are not manufacturing regulations because such standards can impose labeling requirements and "a product's website can amount to labeling." *Id.* at 31. But Appellants ignore the FDA's own definition of labeling as part of tobacco product manufacturing. *See* 21 C.F.R. § 1140.3 (defining "manufacturer" as including one who "labels a

finished tobacco product"); *id.* § 1143.3(a)(1) ("For . . . tobacco products other than cigars, it is unlawful for any person to *manufacture* . . . such product unless the tobacco product package bears the . . . required warning statement on the package label . . . ." (emphasis added)). And they rely upon a case that does not address the TCA, but instead addresses the drug provisions of the Federal Food, Drug, and Cosmetics Act. *See* Appellants' Br. 31 (citing *United States v. Innovative Biodefense, Inc.*, Case No. SA CV 18-0996-DOC (JDEx), 2019 WL 2428670, at *4 (C.D. Cal. Feb. 22, 2019)). Even accepting Appellants' faulty premise, the inclusion of labeling as a potential provision in a tobacco product standard is simply a continuation of the comprehensive labeling regulation the federal government has implemented since 1965. Thus, that tobacco product standards can include labeling requirements cannot indicate any federal encroachment on state and local authority to determine which types of tobacco products can be sold at retail within their jurisdictions.

For the same reason, Appellants' resorting to the preemption of state and local measures relating to "modified risk tobacco products" and "premarket review" is unpersuasive. *See id.* The FDA's ability to determine whether certain health claims can be made—modified risk tobacco products—or whether a product can be marketed—premarket review—is again a continuation of already held federal authority over labeling and advertising, and not a new restriction on state and local

authority to determine which tobacco products may be sold at retail within their borders.

* * *

In sum, not only does the text of section 916 make clear that states and localities have authority under the TCA to prohibit classes of tobacco products from their jurisdictions, but so does the historical and regulatory background upon which the TCA was passed. Congress intended to preserve broad state and local authority, including the authority of Los Angeles County to prohibit retail sales of flavored tobacco products.

CONCLUSION

This Court should preserve Congress's intent to maintain the broad authority of states and their localities' over tobacco policy, as reflected in both the text of the TCA and the wider context of tobacco regulation throughout the United States. The judgment of the district court should be affirmed.

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9th Cir. Case Number(s) 20-55930

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