In the Supreme Court of the United States

R.J. REYNOLDS TOBACCO CO., ET AL.,

Applicants,

 \mathbf{v} .

ROB BONTA, ATTORNEY GENERAL OF CALIFORNIA, ET AL.,

Respondents.

OPPOSITION TO EMERGENCY APPLICATION FOR WRIT OF INJUNCTION

ROB BONTA
Attorney General of California
MICHAEL J. MONGAN
Solicitor General
RENU R. GEORGE
Special Assistant Attorney General
HELEN H. HONG*
Deputy Solicitor General
JAMES V. HART
Supervising Deputy Attorney General
PETER F. NASCENZI
TAYLOR ANN WHITTEMORE
Deputy Attorneys General

California Department of Justice 600 West Broadway, Suite 1800 San Diego, CA 92101 (619) 738-9693 Helen.Hong@doj.ca.gov *Counsel of Record

(Additional counsel listed on signature page)

TABLE OF CONTENTS

			Page
Intro	duction	n	1
State	ement .		3
	A.	Historical and legal background	3
		1. Tradition of state tobacco regulation	3
		2. The Tobacco Control Act	5
		3. State and local response to flavored tobacco products	8
		4. California's S.B. 793 and Proposition 31	11
	В.	Proceedings below	13
Argu	ment		16
I.		Reynolds' merits arguments cannot establish a clear right ief	17
	A.	Text, structure, and history establish that the TCA does not preempt S.B. 793	18
		1. Preemption clause	19
		2. Savings clause	25
	В.	The court of appeals' decision is consistent with this Court's precedents	32
	C.	The circuit conflict alleged by R.J. Reynolds is illusory	36
II.		equitable considerations do not support R.J. Reynolds' est for extraordinary injunctive relief	37
Conc	lusion.		42

TABLE OF AUTHORITIES

Page

CASES Ali v. Fed. Bureau of Prisons Altria Grp., Inc. v. Good Austin v. Tennessee Bates v. Dow Agrosciences LLC Brown v. Gilmore California v. Cabazon Band of Mission Indians Engine Manufacturers Ass'n v. South Coast Air Quality Management District FDA v. Brown & Williamson Tobacco Corp. Geier v. Am. Honda Motor Co. 529 U.S. 861 (2000)......24 Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago Lamps Plus, Inc. v. Varela Lorillard Tobacco Co. v. Reilly 533 U.S. 525 (2001)......4 Lux v. Rodrigues

Page
Morales v. Trans World Airlines, Inc. 504 U.S. 374 (1992)
National Ass'n of Tobacco Outlets, Inc. v. City of Providence 731 F.3d 71 (1st Cir. 2013)25, 34, 36, 37
National Meat Ass'n v. Harris 565 U.S. 452 (2012)
Puerto Rico v. Franklin Cal. Tax-Free Trust 579 U.S. 115 (2016)
R.J. Reynolds Tobacco Co. v. City of Edina 482 F. Supp. 3d 875 (D. Minn. 2020)25, 28, 30-32, 37
R.J. Reynolds Tobacco Co. v. County of Los Angeles 29 F.4th 542 (9th Cir. 2022)3, 5, 6, 8, 10, 14, 15, 20-26, 28-34, 36, 37
Respect Maine PAC v. McKee 562 U.S. 996 (2010)
Roman Catholic Diocese of Brooklyn v. Cuomo 141 S. Ct. 63 (2020)17
Sprietsma v. Mercury Marine 537 U.S. 51 (2002)
U.S. Smokeless Tobacco Mfg. Co. v. City of New York 708 F.3d 428 (2d Cir. 2013)
Wilde v. City of Dunsmuir 9 Cal. 5th 1105 (2020)
Winter v. Nat. Res. Def. Council, Inc. 555 U.S. 7 (2008)
Ysleta Del Sur Pueblo v. Texas 142 S. Ct. 1929 (2022)26, 27, 31, 35

	Page
STATUTES	
21 U.S.C.	
§ 387	
§ 387a	5
•	21
	21
ů ě	23
	22
	23
	28 21
• , ,	2, 5, 6, 8, 17, 19, 20, 22, 28, 30, 33, 34
2 2 7 7 7	
	2, 7, 8, 15, 18, 19, 21, 24-28
42 U.S.C.	
	34
• ` '	34
	33, 34
Cal. Bus. & Prof. Code	
§ 22963	5
§§ 22970-22995	5
Cal. Elec. Code § 15501(b)	13
Cal. Gov't Code § 9600(a)	11
Cal Haalth & Cafety Cada	
Cal. Health & Safety Code	11, 12. 24
3 10 10 00 10 (0) (1)	
Family Smoking Prevention and Toba	
	3 (2009)5
9 , ,	6
9 , ,	
	6, 39
9 , ,	
Y U(U)	

	Page
Ill. Comp. Stat. 685/4	5
Mass. Gen. Laws ch. 270, § 28 (2019)	10
Me. Rev. Stat. § 1560-D (2007)	10
N.D. Cent. Code § 12.1-31-10 (2003)	5
N.J. Stat. Ann. § 2A:170-51.6 (2008)	5, 10
N.J. Stat. Ann. § 2A:170-51.12 (2020)	10
N.M. Stat. § 57-2-14 (2000)	5
N.Y. Pub. Health Law § 1399-mm-1 (2020)	10
R.I. Admin. Code 50-15-6.10 (2020)	10
S.B. 793, Act of Aug. 28, 2020, Chapter 34, 2020 Cal. Stat. 1743 (codified at Cal. Health & Safety Code § 104559.5)	11
Utah Code Ann. § 76-10-105.3 (2003)	5
Vt. Stat. Ann. Title 7, § 1003(d) (2000)	5
W. Va. Code § 16-9A-9 (2001)	5
CONSTITUTIONAL PROVISIONS	
Cal. Const. Article II, § 9(a)	12
Cal. Const. Article II, § 10(a)	13
OTHER AUTHORITIES	
Ambrose, Flavored Tobacco Product Use Among US Youth Aged 12-17 years, 2013-2014, 314 J. Am. Med. Ass'n 1871 (2015)	9
Bonander, 24 Injury Prevention 193 (2018), https://tinyurl.com/3vyxxx95	5
Cal. Assembly Health Comm., Standing Comm. Health, S.B. 793 (Aug. 4, 2020), https://tinyurl.com/36md5w4f	11

Pa	ge
Cal. Official Voter Information Guide, Gen. Elec. Nov. 8, 2022, Proposition 31, Arguments and Rebuttals, https://tinyurl.com/3ry55wja	13
Cal. Sec'y of State, Unofficial Election Results, Proposition 31 (Dec. 2, 2022), https://tinyurl.com/tm2p8ve8	13
Cal. Senate Comm. on Health, Report on Flavored Tobacco Products (May 11, 2020), https://tinyurl.com/bmu8e8858, 9, 11, 38-	40
Campaign for Tobacco-Free Kids, States and Localities That Have Restricted the Sale of Flavored Tobacco Products (Oct. 18, 2022), https://tinyurl.com/my9uupux	10
CDC, Health Effects of Cigarette Smoking (Oct. 29, 2021), https://tinyurl.com/3zbj4kwe10,	39
CDC, Office on Smoking and Health, Summary of Scientific Evidence: Flavored Tobacco Products, Including Menthol (Feb. 2021), https://tinyurl.com/zysfta3p	40
CDC, Tobacco Use by Youth is Rising (Feb. 21, 2019), https://tinyurl.com/4ak9ezzt	9
CDC, Youth and Tobacco Use (Nov. 10, 2022), https://tinyurl.com/mr3rnxey	39
Comment, Docket No. FDA-2021-N-1349, Tobacco Product Standard for Menthol in Cigarettes (Aug. 2, 2022), https://tinyurl.com/37tv2hbv	41
Cornelius, Tobacco Product Use Among Adults-United States 2020, 71 Morb. Mortal. Wkly. Rep. 397 (2022), https://tinyurl.com/49t4e4uk	39
Diller, Why do Cities Innovate in Public Health? Implications of Scale and Structure, 91 Wash. U. L. Rev. 1219 (2014)	10
FDA, Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Menthol in Cigarettes, Docket No. FDA-2021-N-1349, https://tinyurl.com/yckx2zpt	40

P	age
FDA, Stmt. from Commissioner Gottlieb on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), https://tinyurl.com/ks7p6xxy	8
H.R. Rep. No. 111-58 pt. 1 (2009), 2009 U.S.C.C.A.N. 468	7
Inst. of Med., Nat'l Acads. of Sci., Ending the Tobacco Problem (2007), https://tinyurl.com/msn6sbuy	. 3, 4
Inst. of Med., Nat'l Acads. of Sci., State Programs Can Reduce Tobacco Use (2000), https://tinyurl.com/4j6sh4p5	8
Janofsky, Mississippi Seeks Damages from Tobacco Companies, N.Y. Times, May 24, 1994	4
LeMee, Track the Money Flowing Into Prop. 31: Flavored Tobacco, Los Angeles Times (updated Dec. 6, 2022), https://tinyurl.com/2ap9kcwp	13
Nat'l Ass'n for the Advancement of Colored People, Letter to the FDA (Apr. 20, 2022), https://tinyurl.com/2ndc6mbj	41
Park-Lee, Tobacco Product Use Among Middle and High School Students-United States, 2022, 71 Morb. Mortal Wkly. Rep 1429 (2022), https://tinyurl.com/mu9dys77	9
Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health & the Env't, 103d Cong. (1994)	4
Shapiro et al., Supreme Court Practice (11th ed. 2019)	16
U.S. Dep't of Health & Human Servs., Office of the Surgeon Gen., The Health Consequences of Smoking—50 Years of Progress (2012) https://tinyurl.com/3r799873	39

INTRODUCTION

For more than a century, States have carried out their authority to "guard the health" of their citizens by enacting laws that restrict how tobacco products "may be sold," and sometimes that "prohibit their sale entirely." *Austin v. Tennessee*, 179 U.S. 343, 348-349 (1900). Voters in California recently joined other States and local jurisdictions in banning the retail sale of flavored tobacco products. Those laws respond to the manifest threat that flavored tobacco products present to public health: As the federal government has acknowledged, flavored tobacco products are the central cause of unfavorable trends in youth addiction to tobacco. And young people who are initiated into tobacco use through flavored tobacco products are more likely to become long-term users and suffer grievous health effects as a result.

The tobacco industry, including some of the applicants here, spent tens of millions of dollars trying to persuade voters to defeat California's ban on the sale of flavored tobacco products. Having failed in that effort by an overwhelming margin, R.J. Reynolds Tobacco Co. and the other applicants (collectively, "R.J. Reynolds") now ask this Court to enjoin that statute, in order "to preserve the status quo" (Appl. 38) under which they profit by selling addictive products that are indisputably harmful to public health and the public fisc. ¹ But they

¹ "Appl." refers to the Emergency Application for Writ of Injunction filed in this Court. "App'x" refers to the appendix filed in connection with that Emergency Application. "ER" refers to the excerpts of record filed in the court of appeals.

cannot satisfy the demanding standard that governs their request for emergency injunctive relief from this Court.

R.J. Reynolds claims that California's sales ban is expressly preempted by the Family Smoking Prevention and Tobacco Control Act (TCA). When Congress enacted that statute in 2009, however, it protected the pre-existing authority of States and local governments with respect to the sale of tobacco products. In a section of the Act titled "Preservation of State and local authority," Congress expressly preserved state authority to restrict or prohibit the sale of tobacco products, 21 U.S.C. § 387p(a)(1), and expressly excepted that authority from the scope of the Act's narrow preemption provision, *id.* § 387p(a)(2)(B). Nonetheless, in the years since Congress enacted the TCA, the tobacco industry has filed lawsuits across the country taking the position that laws restricting or prohibiting the sale of flavored tobacco products were expressly preempted by that Act. In all those years, not a single court has agreed with that position.

That body of precedent underscores the lack of merit in R.J. Reynolds' preemption claims. And R.J. Reynolds fails to identify any other persuasive argument why this case might warrant further review by this Court. In particular, the decision of the court of appeals below does not conflict with any of the cited precedents from this Court—none of which construed a preemption clause that was remotely similar to Section 387p of the TCA—or any other circuit decision. Finally, the equitable considerations overwhelmingly favor

allowing the will of the voters to take effect, as opposed to preserving a status quo that imperils the health of more young people in California with each passing day. The application for writ of injunction should be denied.

STATEMENT

A. Historical and Legal Background

1. Tradition of state tobacco regulation

"Until just over a decade ago, tobacco products were regulated almost exclusively by the states and local governments, with little federal involvement." R.J. Reynolds Tobacco Co. v. County of Los Angeles, 29 F.4th 542, 547 (9th Cir. 2022), petition for cert. pending No. 22-338 (filed Oct. 7, 2022). Early regulations of tobacco "includ[ed] the passage of laws in several states that prohibited tobacco use by both adults and minors." Inst. of Med., Nat'l Acads. of Sci., Ending the Tobacco Problem 107 (2007). This Court long ago recognized the broad authority of the States to regulate in that way. In upholding a Tennessee law that categorically banned the sale of cigarettes, the Court concluded that it is "within the province of the legislature to say how far [cigarettes] may be sold, or to prohibit their sale entirely." Austin v. Tennessee, 179 U.S. 343, 348-349 (1900). The Tennessee law was "a bona fide exercise of [the State's] police power" and was "dictated by a genuine regard for the preservation of public

_

² https://tinyurl.com/msn6sbuy.

health"—including widespread concerns about the "deleterious effects" of cigarettes, "particularly upon young people." *Id.* at 348-349.

State and local regulation of tobacco products continued throughout the twentieth century, becoming even more prevalent as scientific evidence confirmed that the use of cigarettes and other tobacco products caused disease and death. See generally Ending the Tobacco Problem, supra, at 109-121. After the leaders of major tobacco companies denied under oath to Congress that nicotine was addictive, Mississippi and other States sued those companies, alleging a conspiracy to conceal the health harms of cigarettes and other tobacco products.³ That litigation culminated in a "landmark agreement," placing extensive restrictions on manufacturers' sales and marketing practices and providing for annual payments to the States. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 533 (2001).

In the early 1990s, Congress considered but ultimately failed to enact legislation giving the Food and Drug Administration explicit authority to regulate tobacco. The FDA nonetheless promulgated regulations in 1996 to assert jurisdiction over tobacco products—focusing in substantial part on the products' "accessibility to children and adolescents"—but this Court struck them down as exceeding the agency's authority. See FDA v. Brown & Williamson Tobacco

³ See Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health & the Env't, 103d Cong. 628 (1994); Janofsky, Mississippi Seeks Damages from Tobacco Companies, N.Y. Times, May 24, 1994.

Corp., 529 U.S. 120, 128, 161 (2000). Meanwhile, States and local governments continued to enact laws restricting the sale and use of cigarettes and tobacco products. Those laws included, for example, bans on the retail sale of certain tobacco products; fire safety standards for cigarettes; laws restricting sales of tobacco products that are not face-to-face; and licensing requirements applying up and down the distribution chain, from manufacturers to retailers.⁴

2. The Tobacco Control Act

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009), codified at 21 U.S.C. §§ 387, et seq. The text and structure of the TCA reflect Congress's dual objectives of granting the FDA certain authority "to regulate tobacco products," while at the same "expressly preserving and saving from preemption" much of the pre-existing "state and local regulatory authority over tobacco." County of Los Angeles, 29 F.4th at 547-548; see, e.g., 21 U.S.C. § 387a ("FDA authority over tobacco products"); id. § 387p ("Preservation of State and local authority"). In its legislative findings supporting that approach, Congress determined

⁴ See, e.g., Vt. Stat. Ann. tit. 7, § 1003(d) (2000) (prohibiting sale of "bidi" cigarettes); 720 Ill. Comp. Stat. 685/4 (a-5), (b-5) & 685/5 (2001) (same); W. Va. Code § 16-9A-9 (2001) (same); N.D. Cent. Code § 12.1-31-10 (2003) (same); N.M. Stat. § 57-2-14 (2000) (prohibiting sale of clove cigarettes); Utah Code Ann. § 76-10-105.3 (2003) (same); N.J. Stat. Ann. § 2A:170-51.6 (2008) (prohibiting sale of certain flavored cigarettes); Bonander, 24 Injury Prevention 193, 194 (2018), https://tinyurl.com/3vyxxx95 (discussing fire safety standards adopted by "all 50 states"); Cal. Bus. & Prof. Code § 22963 (restricting sales through public or private delivery services); id. §§ 22970-22995 (licensing requirements).

(among other things) that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults"; that a "consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects"; and that "[r]educing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease" and resulting in "\$75,000,000,000 in savings attributable to reduced health care costs." TCA §§ 2(1), (2), (14), Pub. L. No. 111-31, 123 Stat. 1776, Congressional Findings (2009), note following 21 U.S.C. § 387 (hereinafter TCA Findings).

The legal claim advanced by R.J. Reynolds in this case turns on 21 U.S.C. § 387p, the section of the TCA titled "Preservation of State and local authority." That section contains "a unique three-layered preservation provision," *County of Los Angeles*, 29 F.4th at 550, reflecting "Congress's explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products," *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013).

The first of the three layers is a clause titled "Preservation," 21 U.S.C. § 387p(a)(1), which states that,

[e]xcept as provided in paragraph (2)(A), nothing in [the TCA], or rules promulgated under [the TCA], shall be construed to limit the

authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe 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], including a law . . . relating to or prohibiting the sale . . . of tobacco products by individuals of any age.

Id. § 387p(a)(1) (emphasis added). As the House committee report observed, the preservation clause ensures "that state authority is preserved, with no federal preemption, with regard to enacting . . . any law . . . in critical areas with respect to tobacco products that is in addition to or more stringent than required under [the TCA]." H.R. Rep. No. 111-58 pt. 1, at 45 (2009), 2009 U.S.C.C.A.N. 468 (H.R. Rep.) (emphasis added). That preserved authority expressly "includ[es] measures relating to or prohibiting the sale" of tobacco products. Id.

The second layer, the preemption clause in 21 U.S.C. § 387p(a)(2)(A), directs that

[n]o State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of [the TCA] relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Id. § 387p(a)(2)(A). As the House committee explained, that text restricts the scope of preemption to state laws that conflict with or exceed certain FDA requirements "relating to specified and limited areas." H.R. Rep., supra, at 45.

The third and final layer, 21 U.S.C. § 387p(a)(2)(B), styled as an "Exception" to the preemption clause, is commonly referred to as the savings clause.

It directs that the preemption clause "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." Id. § 387p(a)(2)(B) (emphasis added). Thus, in enacting the unique, three-part "Preservation" provision contained in 21 U.S.C. § 387p, Congress "sandwiched the[] preemption clause between preservation and savings clauses that explicitly and repeatedly reiterated local authority over product sales." County of Los Angeles, 29 F.4th at 558.

3. State and local response to flavored tobacco products

State and local tobacco regulations contributed to "years of favorable trends in our nation's fight to prevent youth addiction to tobacco products"; but recent developments have "revers[ed]" those trends.⁵ The "central problems" causing that reversal are "youth appeal and youth access to flavored tobacco products." Indeed, "[f]ueled by kid friendly flavors like cotton candy and bubblegum," "youth usage of flavored tobacco products has exploded recently." In

⁵ FDA, Stmt. from Commissioner Gottlieb on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), https://tinyurl.com/ks7p6xxy; see also Inst. of Med., Nat'l Acads. of Sci., State Programs Can Reduce Tobacco Use 6, 8-9 (2000), https://tinyurl.com/4j6sh4p5; Diller, Why do Cities Innovate in Public Health? Implications of Scale and Structure, 91 Wash. U. L. Rev. 1219, 1225-1226 (2014).

⁶ Stmt. From FDA Commissioner Gottlieb, supra.

⁷ Cal. Senate Comm. on Health, Report on Flavored Tobacco Products 2

2018, 27.1 percent of high school students (4.9 million) reported tobacco use within the last 30 days.⁸ The Centers for Disease Control has reported that 80 percent of young people who have used tobacco acknowledge that they started with a flavored product.⁹

Nicotine use is especially harmful to youth and young adults, affecting their brain development. ¹⁰ Moreover, young people who are initiated into tobacco use through flavored tobacco products have an increased likelihood of further tobacco use compared to those who initiate with an unflavored tobacco product, and flavored products "can lead to long-term addiction, as well as tobacco-related disease and death." ¹¹ The harmful health effects of long-term tobacco use is undeniable. Cigarette use alone causes more than 480,000 deaths a year in the United States and is responsible for 90 percent of all lung

⁽May 11, 2020), https://tinyurl.com/bmu8e885.

⁸ See CDC, Tobacco Use by Youth is Rising (Feb. 21, 2019), https://tinyurl.com/4ak9ezzt; see also See Park-Lee, Tobacco Product Use Among Middle and High School Students—United States, 2022, 71 Morb. Mortal Wkly. Rep 1429 (2022), https://tinyurl.com/mu9dys77 (describing results of 2022 National Youth Tobacco Survey showing that over 2.5 million of high school students admitted tobacco use).

⁹ See Cal. Senate Comm. on Health, supra, at 6; CDC, Youth and Tobacco Use (Nov. 10, 2022), https://tinyurl.com/mr3rnxey; Ambrose, Flavored Tobacco Product Use Among US Youth Aged 12-17 years, 2013-2014, 314 J. Am. Med. Ass'n 1871, 1872 (2015).

¹⁰ See CDC, Office on Smoking and Health, Summary of Scientific Evidence: Flavored Tobacco Products, Including Menthol 2 (Feb. 2021), https://tinyurl.com/zysfta3p.

¹¹ CDC, Summary of Scientific Evidence, supra, at 2-5.

cancer deaths and 80 percent of all deaths from chronic obstructive pulmonary disease. 12

In response to these concerns, state and local jurisdictions across the country have enacted laws prohibiting the sale of flavored tobacco products. See County of Los Angeles, 29 F.4th at 551.¹³ Some of those laws pre-date the TCA, including a 2007 Maine ban on the sale of flavored cigars and other products, and a 2008 New Jersey prohibition on the sale of certain flavored cigarettes. ¹⁴ Municipalities adopted similar laws, both before and after the enactment of the TCA. ¹⁵ More recently, Massachusetts restricted the sale of all flavored tobacco products, and New York, New Jersey, and Rhode Island enacted bans on the sale of flavored e-cigarettes. ¹⁶

 12 See CDC, Health Effects of Cigarette Smoking (Oct. 29, 2021), https://tinyurl.com/3zbj4kwe.

¹³ See also Campaign for Tobacco-Free Kids, States and Localities That Have Restricted the Sale of Flavored Tobacco Products (Oct. 18, 2022), https://tinyurl.com/my9uupux (collecting statutes and ordinances).

¹⁴ See 22 Me. Rev. Stat. §1560-D (2007); N.J. Stat. Ann. § 2A:170-51.6 (2008).

¹⁵ See Diller, supra, 91 Wash. U. L. Rev. at 1234-1235 (describing municipal bans in Chicago, New York, Providence, and elsewhere).

¹⁶ See Campaign for Tobacco-Free Kids, States and Localities That Have Restricted the Sale of Flavored Tobacco Products, supra; see Mass. Gen. Laws ch. 270, § 28 (2019); N.Y. Pub. Health Law § 1399-mm-1 (2020); N.J. Stat. Ann. § 2A:170-51.12 (2020); 216 R.I. Admin. Code 50-15-6.10 (2020).

4. California's S.B. 793 and Proposition 31

The California Legislature considered this emerging public health problem in 2020. It heard from industry officials, medical experts, public health organizations, and parents. And it reviewed the mounting evidence that flavored tobacco products facilitate the initiation of tobacco use—especially among youth. In August 2020, the Legislature enacted S.B. 793, which prohibits the retail sale of flavored tobacco products on a statewide basis. See S.B. 793, Act of Aug. 28, 2020, ch. 34, 2020 Cal. Stat. 1743 (codified at Cal. Health & Safety Code § 104559.5). The statute was initially scheduled to take effect on January 1, 2021. See Cal. Gov't Code § 9600(a).

S.B. 793 provides that a tobacco retailer may not sell a "flavored tobacco product" or a "tobacco product flavor enhancer." Cal. Health & Safety Code § 104559.5(b)(1). It defines a "flavored tobacco product" as a tobacco product "that contains a constituent that imparts a characterizing flavor." *Id.* § 104559.5(a)(4). A "characterizing flavor" is a "distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product." *Id.* § 104559.5(a)(1). Significantly, the statute directs that a "tobacco product shall not be determined

¹⁷ See Cal. Assembly Health Comm., Standing Comm. Health, S.B. 793 (Aug. 4, 2020) at 1:50:49–5:15:56, https://tinyurl.com/36md5w4f.

^{1, 2020)} at 1.80.10 0.10.80, https://tilly.att.com/8011140

 $^{^{18}}$ See Cal. Senate Comm. on Health, supra, at 2.

to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information." *Id.* "Rather, it is the presence of a distinguishable taste or aroma, or both, as described in the first sentence of [subsection (a)(1)], that constitutes a characterizing flavor." *Id.*

In a prior lawsuit, filed shortly after the enactment of S.B. 793 in 2020, R.J. Reynolds and other industry plaintiffs challenged the statute on express preemption grounds. See Compl., R.J. Reynolds Tobacco Co. v. Becerra, No. 20-cv-01990, Dkt. 1 (S.D. Cal. Oct. 9, 2020). One month later, a coalition of manufacturers and sellers of tobacco products—including R.J. Reynolds—filed a referendum petition to place S.B. 793 on the next statewide ballot. See Order, Agenbroad v. Padilla, Case No. 34-2020-80003542 (Sacramento Super. Ct. Dec. 10, 2020). In January 2021, the referendum was certified for the November 2022 election as Proposition 31. That had the effect of suspending operation of S.B. 793 until the referendum was approved by a majority of voters. See Wilde v. City of Dunsmuir, 9 Cal. 5th 1105, 1111 (2020); Cal. Const. art. II, § 9(a). In light of those developments, the district court dismissed the prior lawsuit challenging S.B. 793 for want of jurisdiction. Order, R.J. Reynolds Tobacco Co. v. Becerra, No. 20-cv-01990, Dkt. 57 (S.D. Cal. Aug. 6, 2021).

R.J. Reynolds and other tobacco companies invested heavily in a campaign to defeat Proposition 31 and prevent S.B. 793 from taking effect: committees opposing Proposition 31 collectively spent over \$20 million, with R.J.

Reynolds alone contributing more than \$8.1 million.¹⁹ The ballot arguments against Proposition 31 advanced many of the policy objections that R.J. Reynolds now asserts in its pending application in this Court, *see* Appl. 38-40 & n.8, including that "[p]rohibition has never worked"; that S.B. 793 would adversely "impact minority neighborhoods"; and that it would "drive" sales of flavored tobacco products "underground."²⁰ On November 8, 2022, 63.4 percent of California voters approved Proposition 31, allowing S.B. 793 to take effect.²¹ By operation of state law, S.B. 793 will go into effect no later than December 21, 2022. *See* Cal. Const. art. II, § 10(a); Cal. Elec. Code § 15501(b).

B. Proceedings Below

The applicants here (collectively, "R.J. Reynolds") are R.J. Reynolds Tobacco Company and other members of the tobacco industry. The day after the voters approved Proposition 31, R.J. Reynolds filed a complaint alleging that the TCA expressly preempts S.B. 793's ban on the sale of flavored tobacco products. ER 5-22. It also filed a motion for a preliminary injunction and an injunction pending appeal. App'x 4a-31a. But it acknowledged that the district court was "bound by Ninth Circuit precedent" to deny that motion. *Id.* at 13a.

¹⁹ See LeMee, Track the Money Flowing Into Prop. 31: Flavored Tobacco, Los Angeles Times (updated Dec. 6, 2022), https://tinyurl.com/2ap9kcwp.

²⁰ Cal. Official Voter Information Guide, Gen. Elec. Nov. 8, 2022, Proposition 31, Arguments and Rebuttals, https://tinyurl.com/3ry55wja.

²¹ See Cal. Sec'y of State, Unofficial Election Results, Proposition 31 (Dec. 2, 2022), https://tinyurl.com/tm2p8ve8.

On that basis, R.J. Reynolds "acquiesce[d] in the denial" of the preliminary injunction and the injunction pending appeal, and requested a ruling from the district court by November 23, 2022. *Id.* at 14a.

The binding precedent to which the motion referred was R.J. Reynolds Tobacco Co. v. County of Los Angeles, 29 F.4th 542 (9th Cir. 2022), petition for cert. pending No. 22-338 (filed Oct. 7, 2022), which involved a similar preemption challenge to a Los Angeles ordinance banning flavored tobacco products. In an opinion authored by Judge VanDyke, the court of appeals examined the "unique tripartite preemption structure" of the TCA, and held that "[t]he TCA's text, structure, and historical context precludes express preemption in this case" for two reasons. Id. at 548, 552. First, "the phrase 'tobacco product standards' in the TCA's preemption clause does not encompass the County's sales ban." Id. at 553. Instead, considering the phrase in light of the "surrounding categories" and the "historical backdrop against which Congress' acted," the court concluded that "it makes sense to view 'tobacco product standards' in the TCA's preemption clause as most naturally referring to standards pertaining to the production or marketing stages up until the actual point of sale." Id. at 554, 555. Understood in that way, the preemption clause was consistent with the "careful balance of power between federal authority and state, local, and tribal authority" struck in the TCA, "whereby Congress has allowed the federal government to set the standards regarding how a product would be manufactured and marketed, but has left states, localities, and tribal

entities the ability to restrict or opt out of that market altogether." *Id.* at 555. Second, and "[a]lternatively," even if a sales ban on flavored tobacco products could be said to relate to a "tobacco product standard" under the TCA's preemption clause, it would nonetheless "be 'except[ed]' from preemption by the TCA's savings clause." *Id.* at 558. "A ban on the sale of flavored tobacco products is, simply put, a requirement that tobacco retailers or licensees throughout the County not sell flavored tobacco products." *Id.* "It therefore fits within the savings clause as a 'requirement[] relating to the sale . . . of[] tobacco products [to] individuals of any age." *Id.* (alterations in original) (quoting 21 U.S.C. § 387p(a)(2)(B)). Judge Nelson dissented, *id.* at 567, but the court of appeals later denied rehearing en banc without any judge requesting a vote, Order, *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, C.A. No. 20-55930, Dkt. 59 (9th Cir. May 11, 2022).

In this case, the district court below entered an order on November 15 denying a preliminary injunction and denying an injunction pending appeal. App'x 2a-3a. It reasoned that the "Ninth Circuit's decision in *County of Los Angeles* currently forecloses Plaintiffs' express preemption claim." *Id.* at 3a. R.J. Reynolds appealed, ER 112-114, and filed an emergency motion in the court of appeals seeking an injunction pending appeal, which again "acquiesc[ed] in the denial of [the motion] because binding Ninth Circuit precedent currently forecloses the express preemption claim." C.A. No. 22-56052, Dkt. 14

(9th Cir. Nov. 18, 2022). After ordering and receiving a response, *id.*, Dkt. 21, the court of appeals denied the motion, App'x 1a.

ARGUMENT

R.J. Reynolds seeks an emergency injunction under the All Writs Act "prohibiting enforcement of [S.B. 793] pending the appeal, and the filing and disposition of a petition for certiorari seeking review of [its] federal-preemption challenge to SB793." Appl. 1. Injunctive relief under the All Writs Act is to be used "sparingly and only in the most critical and exigent circumstances." Brown v. Gilmore, 533 U.S. 1301, 1303 (2001) (Rehnquist, J., in chambers) (internal quotation marks omitted). And a request for injunctive relief from this Court in the first instance "demands a significantly higher justification' than a request for a stay, because unlike a stay, an injunction 'does not simply suspend judicial alteration of the status quo but grants judicial intervention that has been withheld by lower courts." Respect Maine PAC v. McKee, 562 U.S. 996 (2010). The "applicant must demonstrate that the 'legal rights at issue are "indisputably clear,"" Lux v. Rodrigues, 561 U.S. 1306, 1307 (2010) (Roberts, C.J., in chambers); see Brown, 533 U.S. at 1303 (Rehnquist, C.J., in chambers), and that the Court is likely to grant certiorari and reverse, see Shapiro et al., Supreme Court Practice § 17.13(b), p. 17-38 (11th ed. 2019). As with injunctive relief generally, the applicant must also show "that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." Winter v.

Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008); see Roman Catholic Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 66 (2020) (per curiam).

R.J. Reynolds cannot satisfy those standards here. As to the merits, in the dozen years since Congress enacted the TCA, courts have universally rejected the tobacco industry's arguments that state and local laws restricting or prohibiting the sale of flavored tobacco products are expressly preempted by that Act. The TCA expressly *preserves* the authority of state and local governments to enact that type of law; the preemption clause does not encompass that type of law; and, if there were any remaining doubt, Congress included a savings clause that expressly excepts that type of law from preemption. The decision of the court of appeals below is consistent with this Court's precedents and does not create any circuit conflict. As to the equities, any economic losses that R.J. Reynolds might sustain from allowing the voters' decision to ban the sale of flavored tobacco products to take effect pale in comparison to the devastating harms that the continued sale of those products would cause to the public health and the public fisc.

I. R.J. REYNOLDS' MERITS ARGUMENTS CANNOT ESTABLISH A CLEAR RIGHT TO RELIEF

R.J. Reynolds contends that 21 U.S.C. § 387p, which Congress enacted to "Preserv[e] State and local authority," *id.*, forbids States and local governments from banning flavored tobacco products, *see*, *e.g.*, Appl. 28. But R.J. Reynolds has not established that it is "likely correct on the merits of [its] express-preemption claim" (Appl. 15)—let alone that it has an indisputably clear

right to relief. Despite litigating this issue in federal courts across the Nation since shortly after the enactment of the TCA, R.J. Reynolds and its allies have failed to persuade a single court to adopt their sweeping understanding of the TCA's three-layer "Preservation" provision. Their interpretation of the preemption clause (Section 387p(a)(2)(A)) has been squarely rejected by both the Second Circuit and the court of appeals below. And even if that interpretation were correct, lower court authority persuasively establishes that the type of ban challenged here would still be permissible under the savings clause (Section 387p(a)(2)(B)). The decision of the court of appeals below does not "directly conflict[] with this Court's precedents" (Appl. 14): none of those precedents considered anything similar to the unique, three-part preservation provision in the TCA. Nor does this case implicate any genuine conflict between the lower courts of a type that might warrant further review by this Court or cast doubt on the lower courts' denial of injunctive relief.

A. Text, Structure, and History Establish That the TCA Does Not Preempt S.B. 793

Any analysis of "the scope of a statute's pre-emptive effect is guided by the rule that the purpose of Congress is the ultimate touchstone in every pre-emption case." *Altria Grp., Inc. v. Good,* 555 U.S. 70, 76 (2008) (internal quotation marks and alteration omitted). Regardless of whether the question is one "of express or implied pre-emption," the analysis begins "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress"—

an assumption that "applies with particular force when Congress has legislated in a field traditionally occupied by the States," as it has done here. *Id.* at 77. Where Congress adopts an express preemption clause, the "task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002). If the language of an express preemption clause "is plain," then that is "where the inquiry should end." *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 579 U.S. 115, 125 (2016) (internal quotation marks omitted). But if "the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption." *Altria Grp., Inc.*, 555 U.S. at 77 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

In this case, for R.J. Reynolds to succeed on its claim that S.B. 793 is preempted by the TCA, it must establish *both* that S.B. 793 falls within the scope of the preemption clause in Section 387p(a)(2)(A) *and* that it is not saved by the savings clause in Section 387p(a)(2)(B). As the lower courts have recognized, the text of those clauses, the structure of Section 387p, and the history of the TCA foreclose R.J. Reynolds' express preemption claim.

1. Preemption clause

R.J. Reynolds first contends that S.B. 793's ban on the sale of flavored tobacco products enacted a "requirement which is different from, or in addition to," federal "tobacco product standards" under the TCA's preemption clause.

21 U.S.C. § 387p(a)(2)(A); see, e.g., Appl. 14. In rejecting the same argument with respect to the ordinance in the County of Los Angeles case, the court of appeals recognized the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." R.J. Reynolds Tobacco Co. v. County of Los Angeles, 29 F.4th 542, 553 (9th Cir. 2022), petition for cert. pending No. 22-338 (filed Oct. 7, 2022) (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000)); see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428, 432 (2d Cir. 2013). Accordingly, it began by examining the text of "all three adjacent clauses" in Section 387p, "considered together." County of Los Angeles, 29 F.4th at 553; see also U.S. Smokeless, 708 F.3d at 433-434.

The "initial preservation clause," Section 387p(a)(1), "broadly preserves" state and local authority "to enact a variety of regulations that are in 'addition to, or more stringent than' the TCA's requirements," including laws "prohibiting the sale . . . of tobacco products [to] individuals of any age." County of Los Angeles, 29 F.4th at 553 (emphasis and alterations in court of appeals' opinion). The preemption clause in Section 387p(a)(2)(A) then "carves out eight limited exceptions to the preservation clause," id., for state or local "requirement[s] . . . relating to" federal "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or

modified risk tobacco products," 21 U.S.C. § 387p(a)(2)(A). As the court of appeals observed, each of those exceptions "relates most obviously to the production or marketing stages—and not the retail sale—of tobacco products." County of Los Angeles, 29 F.4th at 553-554.²² Finally, the "savings clause immediately follows the preemption clause and 'except[s]' broad categories from preemption, including 'requirements relating to the sale . . . of[] tobacco products [to] individuals of any age." Id. at 555 (quoting 21 U.S.C. § 387p(a)(2)(B)) (alterations in court of appeals' opinion). It "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." Id.

Considered in light of each of its component parts, the TCA's unique "Preservation" provision "sandwiches limited production and marketing categories of preemption between clauses broadly preserving and saving local authority, including any 'requirements relating to the sale' of tobacco products." County of Los Angeles, 29 F.4th at 555. It creates "a careful balance of power

²² To take several examples, "the TCA describes 'adulteration' in terms of various issues that could arise during the manufacturing or marketing stages," *County of Los Angeles*, 29 F.4th at 554 (citing 21 U.S.C. § 387b); the Act's "registration" provision "requires that 'every person who owns or operates any establishment in any State engaged in the *manufacture*, *preparation*, *compounding*, *or processing* of a tobacco product . . . register with the Secretary the name, places of business, and all such establishments of that person, *id*. (quoting 21 U.S.C. § 387e(b)); and "to qualify as a 'modified risk tobacco product" under the Act, "details about the manufacturing and marketing processes must be provided," *id*. (citing 21 U.S.C. § 387k(d)).

between federal authority and state, local, and tribal authority," under which "Congress has allowed the federal government to set the standards regarding how a product would be manufactured and marketed, but has left states, localities, and tribal entities the ability to restrict or opt out of that market altogether." *Id.*; see also U.S. Smokeless, 708 F.3d at 432, 434 (considering the provision "as a whole," Section 387p "distinguishes between manufacturing and the retail sale of finished products; it reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry in the absence of conflicting federal regulation").

Turning to the particular phrase in the preemption clause that R.J. Reynolds invokes, the court of appeals noted that "the TCA does not explicitly define 'tobacco product standards." County of Los Angeles, 29 F.4th at 554; see 21 U.S.C. § 387 (listing definitions for other terms but not "tobacco product standard"). But certain other provisions of the Act "describe[] that phrase in terms of the manufacturing and marketing stages." County of Los Angeles, 29 F.4th at 554 (citing 21 U.S.C. § 387g(a)(4)(B)(i)); cf. 21 U.S.C. § 387g(a)(1)(A) (special rule prohibiting manufacturers from using certain flavors in cigarettes). And "[c]onsistent with its surrounding categories" of expressly preempted requirements in Section 387p(a)(2)(A), "it makes sense to view 'tobacco product standards' in the TCA's preemption clause as most naturally referring to standards pertaining to the production or marketing stages up until the actual point of

sale." *Id.* Accordingly, the type of sales ban at issue here does not impose a "requirement which is different from, or in addition to" a "requirement . . . relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A); *see also County of Los Angeles*, 29 F.4th at 553; *U.S. Smokeless*, 708 F.3d at 434.

R.J. Reynolds contends that the phrase "tobacco product standards" in the preemption clause should be read far more broadly, to include requirements addressing what tobacco products may be sold to the public, not just standards governing "how [tobacco products] may be produced." Appl. 17; see id. at 17-18 (reasoning based on language in a separate provision, 21 U.S.C. § 387g, and non-final proposals to exercise regulatory authority granted by that provision). As the court of appeals acknowledged, the phrase is not "incapable of being read more broadly," and could "conceivably encompass essentially anything and everything related to tobacco products," such as "labeling" and other categories of requirements described by Section 387g. County of Los Angeles, 29 F.4th at 554 (discussing 21 U.S.C. § 387g(a)(4)(C)). But such a "capacious[]" reading of the preemption clause, giving the phrase "tobacco product standards" its "broadest possible interpretation," would render redundant other categories of requirements that are expressly preempted by that clause—including, for example, "labeling" requirements. *Id.* at 555.

More fundamentally, reading "tobacco product standards" in the preemption clause to encompass sales restrictions would be at odds with the text of the surrounding clauses that recognize and preserve the States' authority to

impose requirements "relating to the sale" of tobacco products. 21 U.S.C. § 387p(a)(2)(B); see id. § 387p(a)(1). The "narrower interpretation" thus harmonizes the preemption clause with Congress's intent—twice expressed—that States should retain the authority to "restrict or opt out of" the market for particular tobacco products altogether. County of Los Angeles, 29 F.4th at 555; see also U.S. Smokeless 708 F.3d at 434 (broader reading "would render superfluous [Section 387's] three-part structure, and in particular would vitiate the preservation clause's instruction" regarding sales restrictions); see generally Geier v. Am. Honda Motor Co., 529 U.S. 861, 868 (2000) (construing preemption provision in light of the "presence of the saving clause"); Sprietsma, 537 U.S. at 63 (same). That interpretation is also "consistent with the historical 'backdrop against which Congress' acted in enacting the TCA": "the states and localities have historically played a primary role in regulating the sale of tobacco products," a role that "Congress clearly preserved" in Section 387p. County of Los Angeles, 29 F.4th at 555.23

_

 $^{^{23}}$ In a footnote, R.J. Reynolds argues that "even under the Ninth Circuit's reasoning, SB793 is directed 'at the manufacturing stage" because it defines "constituent" to include "any ingredient . . . added by the manufacturer . . . during the . . . manufacture . . . of the tobacco product." Appl. 20 n.6. What that argument ignores is that S.B. 793 applies only to "tobacco retailers," and whether a product is a "flavored tobacco product" is determined by examination of the finished product sold by tobacco retailers. See Cal. Health & Safety Code § 104559.5(a)(1), (4), (b)(1). The definition of a "flavored tobacco product" turns on whether a constituent in the finished product "imparts a characterizing flavor," id. § 104559.5(a)(4), and a product "shall not be determined to have a characterizing flavor solely because of the use of additives or flavorings" during the manufacturing process, id. § 104559.5(a)(1).

2. Savings clause

R.J. Reynolds' merits arguments also fail for a second and independent reason: even assuming that its broad reading of "tobacco product standards" in the preemption clause is correct, S.B. 793 "would still be 'except[ed]' from preemption by the TCA's savings clause." County of Los Angeles, 29 F.4th at 558; see Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71, 82 (1st Cir. 2013); R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 880-882 (D. Minn. 2020), appeal docketed, No. 20-2852 (8th Cir. Sept. 4, 2020). S.B. 793 prohibits "tobacco retailer[s]" from "sell[ing]" a "flavored tobacco product or a tobacco product flavor enhancer." Cal. Health & Safety Code § 104559.5(b)(1). That "ban on the sale of flavored tobacco products is, simply put, a requirement that tobacco retailers . . . not sell flavored tobacco products." County of Los Angeles, 29 F.4th at 558. Whatever the scope of the TCA's preemption clause, the savings clause expressly carved out that kind of "requirement[] relating to the sale ... of[] tobacco products." 21 U.S.C. $\S 387p(a)(2)(B)$.

Again, that straightforward reading of the text is supported by the context surrounding the enactment of the TCA. States and localities have a "longstanding role as the primary regulators of tobacco products," dating back to more than a century before Congress enacted the TCA. County of Los Angeles, 29 F.4th at 548. That tradition has included laws that "prohibit the[] sale entirely" of certain products. Austin v. Tennessee, 179 U.S. 343, 348-349

(1900); see also supra pp. 3-5.²⁴ In light of that "extensive background of state and local tobacco regulation, it would have been surprising if Congress had broadly jettisoned" State authority to prohibit the sales of particular tobacco products that legislatures or voters view as harmful. County of Los Angeles, 29 F.4th at 549-550. That is especially so given that the express purpose of Congress in enacting the TCA was "to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products," TCA Findings § 3(3) (emphasis added), not to displace longstanding state authority over tobacco sales restrictions.

R.J. Reynolds advances two theories in support of its position that a ban on the sale of flavored tobacco products is not a "requirement[] relating to the sale . . . of[] tobacco products," 21 U.S.C. § 387p(a)(2)(B), but neither one is persuasive. First, it argues that while "the savings clause saves 'requirements relating to . . . sale[s]," it does not save any "requirements prohibiting sales." Appl. 22 (emphasis added). In support of that argument, R.J. Reynolds principally relies on Ysleta Del Sur Pueblo v. Texas, 142 S. Ct. 1929 (2022). See Appl. 24-26.

²⁴ Indeed, for the first 233 years following the founding, the tobacco industry operated without any "comprehensive scheme to regulate tobacco products nationwide." Appl. 32. That history belies any contention that adhering to the TCA's express preservation of state and local authority to "ban the[] sale" of certain products would lead to "regulatory chaos" that would "threaten[] the stable conditions that are necessary for the tobacco industry." *Id.* at 33.

But Ysleta construed a different kind of statute (the Ysleta del Sur and Alabama and Coushatta Indian Tribes of Texas Restoration Act) containing a materially different provision. 142 S. Ct. at 1935. The terms of that provision recognized a "dichotomy between prohibition and regulation" of gaming activities: "subsection (a) says that gaming activities prohibited by state law are also prohibited as a matter of federal law"; "subsection (b) insists that the statute does not grant Texas civil or criminal regulatory jurisdiction with respect to" matters related to gaming. Id. at 1938 (describing Section 107 of the Restoration Act). In that particular context, the Court concluded that Congress meant to incorporate a distinction—recognized in California v. Cabazon Band of Mission Indians, 480 U.S. 202 (1987), just six months before the Restoration Act was enacted—which allowed "prohibitory' state gaming laws [to] be applied on the Indian lands" but "not state 'regulatory' gaming laws." Ysleta, 142 S. Ct. at 1940. The Court emphasized, however, that the same analysis would not necessarily apply "in another context." *Id.* at 1938.

Turning to the context of the TCA: R.J. Reynolds argues that "Congress deliberately excluded sales prohibitions from the class of non-preempted laws in the savings clause," Appl. 28, because the savings clause refers to "requirements relating to the sale" of tobacco products, 21 U.S.C. § 387p(a)(2)(B), whereas the earlier preservation clause refers to laws "relating to or prohibiting the sale," *id.* § 387p(a)(1). Although the phrase "relating to . . . sale[s]" is surely capacious enough to include a prohibition on sales, *cf. Morales v. Trans*

World Airlines, Inc., 504 U.S. 374, 383-384 (1992), it is not at all surprising that Congress expressly referred to sales prohibitions in the context of the initial preservation clause: the States already had authority to enact that type of law, see supra pp. 3-5, 20-21; Congress chose not to grant similar regulatory authority to the FDA, see U.S. Smokeless, 708 F.3d at 433 (citing 21 U.S.C. § 387g(d)(3)); and preserving the States' pre-existing authority with respect to sales "prohibit[ions]" was an important and explicit congressional objective, 21 U.S.C. § 387p(a)(1); see generally Ali v. Fed. Bureau of Prisons, 552 U.S. 214, 226 (2008) ("Congress may have simply intended to remove any doubt[.]"). What would be surprising is if Congress had intended to countermand that explicit statement—and "exclude[] sales prohibitions" from the States' legislative toolbox, Appl. 28—via the circuitous means of an omission from the savings clause. The more likely explanation for that omission is that Congress thought it unnecessary to repeat the word "prohibition" in the savings clause, given the broad scope of the phrase "relating to ... sale[s]," 21 U.S.C. § 387p(a)(2)(B), and the fact that the preemption clause itself does not contain any express reference to preempting sales "prohibitions," $\S 387p(a)(2)(A).^{25}$

²⁵ See also County of Los Angeles, 289 F.4th at 559 ("[I]f Appellants are correct that § 387p draws a sharp distinction between 'prohibitions' versus mere 'requirements relating to the sale . . . of[] tobacco products,' then the plain text of the preemption clause itself doesn't preempt any tobacco product 'prohibitions."); City of Edina, 482 F. Supp. 3d at 882 ("[A]s the Preemption Clause is

Next, R.J. Reynolds argues that the court of appeals' common-sense interpretation of the savings clause leaves "nothing for the preemption clause to do." Appl. 23. That is simply incorrect. The preemption clause retains an important role. *Cf. Bates*, 544 U.S. at 452. Under the court of appeals' interpretation, a State may not "require tobacco companies to make their products according to any particular standard—only the federal government can do that." *County of Los Angeles*, 29 F.4th at 560. "But a state can place restrictions on the retail sale of a tobacco product, including banning its sale altogether." *Id.* The "balance of power struck by" Congress thus "allows state and local governments to opt out of the market"; it does not, however, "allow them to otherwise set parameters for that market that conflict with the federal government's tobacco product standards." *Id.*

Nor would the court of appeals' interpretation allow a State to "circumvent the preemption clause and establish its own good manufacturing standards," as R.J. Reynolds contends. Appl. 23; see id. at 23-24 (discussing a hypothetical state "requirement that manufacturers use certain equipment" or follow certain "labeling standards"). Again, existing circuit precedent holds that "only the federal government" may "require tobacco companies to make their products according to any particular standard." County of Los Angeles,

itself silent regarding sales prohibitions, it seems far more likely that prohibitions are preserved and never preempted, and therefore need never be saved.") (quoting *U.S. Smokeless Tobacco Mfg. v. City of New York*, 2011 WL 5569431, at *7 (S.D.N.Y. Nov. 15, 2011), *aff'd*, 708 F.3d 428).

29 F.4th at 560 (emphasis added); see also U.S. Smokeless, 708 F.3d at 434 (Section 387p "reserves regulation at the manufacturing stage exclusively to the federal government"). And if a state or local sales restriction somehow created "an obstacle to the accomplishment or execution of the full purposes and objectives" of Congress, with respect to tobacco product standards or other nationwide manufacturing requirements addressed by the TCA, the restriction could be challenged under a theory of implied preemption. Lamps Plus, Inc. v. Varela, 139 S. Ct. 1407, 1415 (2019); see also City of Edina, 482 F. Supp. 3d at 882 ("[T]his argument raises a concern that may be addressed by the application of ordinary principles of implied preemption."). 26

Indeed, it is R.J. Reynolds' interpretation of the savings clause that would create problems of administrability. In *City of Edina*—a decision that applicants cite approvingly, *see* Appl. 18, 20—the court explained that "plaintiffs' theory" would make it "nearly impossible to distinguish a permissible 'restriction' from an impermissible 'prohibition." 482 F. Supp. 3d at 881 n.4. "Nearly any regulation can be characterized as a 'prohibition." *Id.* (for example, "an ordinance that permitted sales of tobacco products only between 10:00 p.m. and 6:00 a.m. could easily be characterized as a 'prohibition' on sales between 6:00 a.m. and 10:00 p.m."); *see also County of Los Angeles*, 29 F.4th at

 $^{^{26}}$ R.J. Reynolds has abandoned that type of claim here. See App'x 18a.

559.²⁷ R.J. Reynolds appears to acknowledge these difficulties. *See* Appl. 28-29. Its only response is to cite *Ysleta* and characterize administrability concerns as an improper "appeal to public policy." *Id.* at 28 (quoting *Ysleta*, 142 S. Ct. at 1943-1944). But the administrability concerns raised by Texas in *Ysleta* were "irrelevant" because Congress wrote a statute adopting the "prohibitory/regulatory framework" that purportedly gave rise to those concerns. *Ysleta*, 142 S. Ct. at 1938, 1943-1944; *see supra* p. 27. Here, in contrast, the administrability concerns identified by the court in *City of Edina* arise only if one ignores the abundant textual and contextual evidence demonstrating that Congress intended the TCA to preserve States' pre-existing authority to ban the sales of certain tobacco products.

Finally, R.J. Reynolds advances a second theory for why a ban on flavored tobacco products falls outside the savings clause, which has also been roundly rejected by the federal courts: it posits that the clause *only* saves the authority to enact age-based sales restrictions because of the presence of the phrase "of any age." *See* Appl. 29 (describing the clause's "limitation to 'requirements relating to the sale . . . of[] tobacco products [to] *individuals of any age*"). That "interpretation turns the plain meaning of this phrase on its head." *City of Edina*, 482 F. Supp. 3d at 880. The text "reveals the opposite of [R.J. Reynolds']

²⁷ Similarly, a ban on the retail sales of flavored cigarettes could be framed as a "restriction" on the sale of cigarettes, but not a "prohibition" on the sale of all cigarettes.

interpretation": "[o]f any age' suggests that state and local governments are not limited to enacting only age-based rules, but rather can enact regulations for people 'of any age'—in other words, for everyone." *County of Los Angeles*, 29 F.4th at 560. And the presence of that clarifying language makes sense in the context of the TCA, which was enacted after unsuccessful federal attempts to impose age-specific tobacco regulations. *See id.* (discussing *Brown & Williamson*, 529 U.S. at 125-126); *City of Edina*, 482 F. Supp. 3d at 880-881 (same).²⁸

B. The Court of Appeals' Decision Is Consistent with This Court's Precedents

R.J. Reynolds also asserts (Appl. 2) that the court of appeals' decision "directly conflicts with numerous decisions from this Court," specifically *Engine Manufacturers Ass'n v. South Coast Air Quality Management District*, 541 U.S. 246 (2004), and *National Meat Ass'n v. Harris*, 565 U.S. 452 (2012). It contends that those decisions establish a rule that States "cannot evade preemption by simply enforcing their standards at the point of sale." Appl. 16. But neither decision establishes any sort of categorical rule barring state sales restrictions

²⁸ The court of appeals and R.J. Reynolds resolve the preposition mismatch in the savings clause by replacing "sale . . . by individuals of any age" with "sale . . . [to] individuals of any age." *See County of Los Angeles*, 29 F.4th at 550 n.5; Appl. 29. Another way to "resolve this oddity would be to interpret 'by individuals of any age' to apply only to 'use of' tobacco products (the last item in the list)"—and not to the other items on the list, including the "sale" of tobacco products. *City of Edina*, 482 F. Supp. 3d at 880 n.3. Under either interpretation, R.J. Reynolds' argument fails.

of the type R.J. Reynolds suggests. What they establish, instead, is that preemption analysis—like any kind of statutory construction—"must begin with the language employed by Congress" and consider the text and structure of the particular statute at issue. *Engine Mfrs.*, 541 U.S. at 252-253.²⁹ And the preemption provisions examined in those cases were not "anything like" Section 387p of the TCA. *County of Los* Angeles, 29 F.4th at 557; *see id.* at 558 ("Unlike the preemption provisions considered in those cases . . . the TCA's plain text distinguishes between tobacco product standards and state or local regulation of the final sale of tobacco products.").

Engine Manufacturers considered a Clean Air Act provision directing that "No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part." 541 U.S. at 252 (quoting 42 U.S.C. § 7543(a)). The question was whether that provision preempted rules adopted by a local air quality district, which prohibited certain fleet operators from purchasing vehicles that did not comply with stringent emissions requirements. See id. at 248-249. The Court rejected the district's theory that its rules were not preempted because the preemption provision only covered state

²⁹ See also Altria Grp., 555 U.S. at 85 (preemption decision invoked by petitioners was "inapposite . . . because it involved a pre-emption provision much broader than the" statute at issue in Altria Group); Bates, 544 U.S. at 446 (lower courts erred in applying holding of preemption case "without paying attention to the rather obvious textual differences between the two pre-emption clauses").

"production mandate[s] that require[d] manufacturers" to comply with emissions standards. *Id.* at 253 (alterations omitted). As the Court explained, that interpretation "confuse[d] standards with the means of enforcing standards"—a "distinction" that was evident in multiple provisions immediately following the preemption provision. *Id.* at 253-254 (discussing 42 U.S.C. §§ 7522(a), 7523-7524, 7525). The text and structure of the Clean Air Act established that Congress "[c]learly" contemplated "enforcement of emission standards through purchase requirements," *id.* at 254, thus bringing the district's purchase requirements within the bar on State "attempt[s] to enforce any standard relating to the control of emissions," 42 U.S.C. § 7543(a). That text and structure differ markedly from what Congress enacted in the TCA, which expressly preserves the authority of state and local governments to impose requirements relating to the sale of tobacco products. *See* 21 U.S.C. § 387p.

National Meat likewise addressed "a fundamentally different preemption provision," County of Los Angeles, 29 F.4th at 557-558, which "did not contain a savings clause that expressly exempted regulations 'relating to the sale' of" products. Nat'l Ass'n of Tobacco Outlets, 731 F.3d at 82. That provision preempted state requirements that differed from any Federal Meat Inspection Act (FMIA) requirements "with respect to premises, facilities and operations of any establishment at which inspection is provided under . . . this Act." Nat'l Meat, 565 U.S. at 458 (quoting 21 U.S.C. § 678). The Court held that the pro-

vision preempted a state sales ban that "function[ed] as a command to slaughterhouses to structure their operations in the exact way the [state law] mandates." Id. at 464. The sales ban was "a criminal proscription calculated to help implement and enforce . . . other regulations" setting state requirements for the "receipt and purchase" of animals by slaughterhouses, barring the "butchering and processing" of nonambulatory animals, and "mandat[ing] . . . immediate euthanasia" for such animals. *Id.* at 463-464. Those requirements were different from the requirements in the FMIA. See, e.g., id. at 462 (noting, for example, that the state law and the FMIA "require[d] different things of a slaughterhouse confronted with a delivery truck containing nonambulatory swine"). Even setting aside the material differences between the text of the FMIA and TCA preemption provisions, the state law at issue here is not comparable to the statute held preempted in *National Meat*. It does not "function[] as a command" to manufacturers "to structure their operations in" any particular way, and it does not implement or enforce any substantive requirements relating to manufacturing. Nat'l Meat, 565 U.S. at 464. It leaves manufacturers free to produce flavored tobacco products however they see fit. It just provides that tobacco retailers in California may not sell those products.³⁰

³⁰ R.J. Reynolds' assertion that the court of appeals' decision "conflicts with this Court's recent decision in *Ysleta*" (Appl. 23) is also unfounded, as discussed above, *see supra* pp. 26-27, 31.

R.J. Reynolds cannot establish any "conflict with this Court's precedents." Appl. 15. "Rather than following precedent interpreting very different federal statutory language," the analysis here should "be guided by the TCA's unique text, framework, and history," which foreclose R.J. Reynolds' preemption theories. *County of Los Angeles*, 29 F.4th at 558.

C. The Circuit Conflict Alleged by R.J. Reynolds Is Illusory

R.J. Reynolds also asserts that the Ninth Circuit's decision in County of Los Angeles created a "conflict[]" with the Second Circuit's decision in U.S. Smokeless and the First Circuit's decision in National Ass'n of Tobacco Outlets. Appl. 30. That is plainly incorrect. Both of those cases "upheld local restrictions" on the sale of "flavored tobacco products"; and neither case establishes that "the First [or] Second Circuits . . . would not permit a blanket prohibition" on sales of tobacco products. Id. The Second Circuit expressly reserved the question whether the savings clause could be read to cover "an outright ban on the sale of flavored tobacco." U.S. Smokeless, 708 F.3d at 435 ("We need not determine whether this reading of the saving clause is correct."). 31 The First Circuit similarly had no occasion to address whether a sales ban would fall within the scope of the savings clause: the ordinance challenged in that case did not impose a "blanket prohibition because it allow[ed] the sale

³¹ In other respects, that decision aligns with the precedent of the court of appeals below. *See County of Los Angeles*, 29 F.4th at 555 (citing *U.S. Smokeless* as evidence that "[w]e are not alone in reaching this interpretation of the TCA's unique preemption structure").

of flavored tobacco products in smoking bars." Nat'l Ass'n of Tobacco Outlets, 731 F.3d at 82.

Indeed, in the 13 years since Congress enacted the TCA, no court has agreed with the tobacco industry position that the Act preempts restrictions and prohibitions on the sale of flavored tobacco products. See County of Los Angeles, 29 F.4th at 561; U.S. Smokeless, 708 F.3d at 436; Nat'l Ass'n of Tobacco Outlets, 731 F.3d at 82-83; Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015); City of Edina, 482 F. Supp. 3d at 886.

* * *

That substantial body of precedent underscores that the preemption theories advanced by R.J. Reynolds lack merit—and do not establish an entitlement to relief that is "indisputably clear," *Lux*, 561 U.S. at 1307 (Roberts, C.J., in chambers), or create a likelihood that this Court will grant certiorari and reverse. R.J. Reynolds' oft-rejected merits arguments provide no basis for this Court to grant extraordinary injunctive relief or certiorari before judgement.

II. THE EQUITABLE CONSIDERATIONS DO NOT SUPPORT R.J. REYNOLDS' REQUEST FOR EXTRAORDINARY INJUNCTIVE RELIEF

With respect to equitable considerations, R.J. Reynolds principally contends that the applicants will suffer irreparable harm absent an immediate injunction "because they will be unable to sell their products in one of the Na-

tion's largest markets." Appl. 1. That will cause them to lose "millions of dollars in gross revenue per year" on the sales of flavored tobacco products, *id.* at 13, and it may lead some of their customers who previously used "Reynolds' flavored tobacco products" to "resort to using other, non-Reynolds tobacco products," *id.*, or perhaps to stop using tobacco products altogether. Of course, whenever a law bans the sale of dangerous or unhealthy products, the industry that produces and sells those products will experience similar "financial losses," *id.* at 13—especially if it has invested enormous sums to aggressively market those harmful products, including to youth and vulnerable communities, *see*, *e.g.*, TCA Findings § 2(15). But while tobacco companies may experience irreparable financial losses when States "prohibit the[] sale" of tobacco products with "deleterious effects" (*Austin*, 179 U.S. at 348, 349), such losses pale in comparison to the powerful government and public interest in preventing the devastation caused by those products. 32

When the California Legislature deliberated on S.B. 793, it considered evidence that 80 percent of young people who have used tobacco started with

³² R.J. Reynolds also asserts that "being forced to comply with a law that violates the Supremacy Clause constitutes irreparable harm per se," Appl. 12 (citing *Morales v. Trans World Airlines*, 504 U.S. 374, 381 (1992)), and that "there is no doubt that California's law is unconstitutional," *id. Morales* did not state any such "per se" rule; its analysis turned on the particular facts of that case. *See* 504 U.S. at 381. In any event, the unbroken line of precedent rejecting R.J. Reynolds' preemption claims against flavored tobacco sales restrictions is evidence that there is—at the very least—substantial doubt about the merits of those claims. *See supra* pp. 36-37.

a flavored product.³³ Many of those who begin using tobacco in their youth continue to do so into adulthood.³⁴ For example, the CDC reports that over 30 million adults in the United States currently smoke cigarettes on a daily basis and that nearly 90 percent of them started using tobacco before the age of 18.³⁵ The sustained use of tobacco products can grievously harm individual health and impose massive burdens on our healthcare system. Nationwide, nearly half a million deaths each year are caused by cigarette smoking: smoking causes 90 percent of all lung cancer deaths; it causes 80 percent of all deaths from chronic obstructive pulmonary disease; it increases the risk of coronary heart disease and stroke by two to four times; and it leads to tens of billions of dollars in increased health care costs.³⁶ In California alone, a study predicted that more than 440,000 residents who were under age 18 in 2012 would ultimately die prematurely as a result of tobacco use.³⁷ S.B. 793 was enacted to

_

 $^{^{33}}$ See Cal. Senate Comm. on Health, supra, at 6; CDC, Youth and Tobacco Use, supra.

³⁴ See Cal. Senate Comm. on Health, supra, at 3; CDC, Youth and Tobacco Use, supra.

³⁵ See Cornelius, Tobacco Product Use Among Adults—United States 2020, 71 Morb. Mortal. Wkly. Rep. 397, 397, 402 (2022), https://tinyurl.com/49t4e4uk; CDC, Youth and Tobacco Use, supra.

³⁶ See Cal. Senate Comm. on Health, supra, at 3; CDC, Health Effects of Cigarette Smoking (Oct. 29, 2021), https://tinyurl.com/3zbj4kwe; TCA Findings § 2(14) (legislative finding that a 50 percent reduction in tobacco use among young smokers in 2009 would have resulted in "\$75,000,000,000 in savings attributable to reduced health care costs").

³⁷ See Cal. Senate Comm. on Health, supra, at 3; U.S. Dep't of Health & Human Servs., Office of the Surgeon Gen., The Health Consequences of Smoking—50

address the patent harms to public health and the public interest caused by the sale of flavored tobacco products.³⁸

R.J. Reynolds views the public interest differently. Appl. 38-39. Its arguments are unpersuasive. It expresses concern for the well-being of consumers who will no longer be able to purchase flavored tobacco products, *see id.* at 38-39, but ignores the overwhelming consensus "within the scientific and medical communities" that those products "are inherently dangerous," *e.g.*, TCA Findings § 2(2).³⁹ It points to "[s]cientific studies" purporting to demonstrate that bans on flavored tobacco products "lead to an increase in associated crimes," Appl. 39, but the "study" it cites is a report prepared by its own corporate affiliate, *id.*, and it overlooks evidence demonstrating that flavored-tobacco bans have not materially contributed to any illicit trade.⁴⁰ It also warns of "significant negative consequences for communities of color, including African Americans" who "disproportionately prefer menthol cigarettes," *id.* at 39 n.8, but ignores that the "high prevalence of menthol cigarette use among

-

Years of Progress 693 (2012), https://tinyurl.com/3r799873.

 $^{^{38}}$ See Cal. Senate Comm. on Health, supra at 1-16.

³⁹ See also CDC, Summary of Scientific Evidence, supra, at 2 (flavored tobacco products "can lead to long-term addiction, as well as tobacco-related disease and death").

⁴⁰ See, e.g., FDA, Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Menthol in Cigarettes, Docket No. FDA-2021-N-1349, at 212, https://tinyurl.com/yckx2zpt.

Black Americans is . . . the result of decades of targeted and insidious marketing campaigns by the tobacco industry."⁴¹

Finally, R.J. Reynolds contends that a "small delay" in implementing S.B. 793 "will not cause the State any harm." Appl. 38. That is not true. The unsuccessful referendum campaign has already delayed the implementation of S.B. 793 for nearly two years, allowing children and teenagers across the State to be initiated into the deadly habit of tobacco use via flavored tobacco products throughout that period. The voters have now spoken, rejecting the tobacco industry's policy arguments and approving the ban on retail sales of flavored tobacco products "by a margin of 63.5% to 36.5%." Appl. 6. The equitable balance tips decisively in favor of allowing the will of the voters to take effect now—rather than "preserv[ing] the status quo" (Appl. 38) that imperils the health of more young people with each passing day.

⁴¹ Comment, Docket No. FDA-2021-N-1349, Tobacco Product Standard for Menthol in Cigarettes 17 (Aug. 2, 2022), https://tinyurl.com/37tv2hbv (comment submitted by over 100 public health, medical, and civil rights organizations, including the African American Tobacco Control Leadership Council, the American Cancer Society Cancer Action Network, the American Medical Association, and the Association of Black Cardiologists,); see also Nat'l Ass'n for the Advancement of Colored People, Letter to the FDA (Apr. 20, 2022), https://tinyurl.com/2ndc6mbj (describing the tobacco industry's "[e]gregious marketing practices" and noting that "African Americans suffer disproportionately from being addicted to cigarettes and the effects of long-term tobacco use").

CONCLUSION

The Court should deny the application.

Respectfully submitted,

ROB BONTA

Attorney General of California

MICHAEL J. MONGAN

Solicitor General

RENU R. GEORGE

Special Assistant Attorney General

HELEN H. HONG

Deputy Solicitor General

JAMES V. HART

Supervising Deputy Attorney General

PETER F. NASCENZI

TAYLOR ANN WHITTEMORE

Deputy Attorneys General

Counsel for the Attorney General

CLAUDIA G. SILVA
County Counsel, County of San Diego
JOSHUA M. HEINLEIN
Senior Deputy County Counsel
Counsel for the District Attorney

December 6, 2022