

No. 22A474

IN THE
Supreme Court of the United States

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

Applicants,

v.

ROBERT BONTA, IN HIS OFFICIAL CAPACITY AS
ATTORNEY GENERAL OF CALIFORNIA; AND SUMMER
STEPHAN, IN HER OFFICIAL CAPACITY AS DISTRICT
ATTORNEY FOR THE COUNTY OF SAN DIEGO,

Respondents.

**MOTION FOR LEAVE TO FILE BRIEF AS
AMICI CURIAE AND BRIEF OF PUBLIC
HEALTH, MEDICAL, AND COMMUNITY
GROUPS AS AMICI CURIAE IN OPPOSITION
TO THE EMERGENCY APPLICATION FOR
WRIT OF INJUNCTION**

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December 6, 2022

**MOTION FOR LEAVE TO FILE BRIEF AS
*AMICI CURIAE***

The following national and California medical, public health, and community organizations respectfully move this Court for leave to file the enclosed brief as *Amici Curiae* in opposition to Applicants' Emergency Application for Writ of Injunction ("Application") against California Senate Bill 793 ("SB 793"), which prohibits the retail sale of flavored tobacco products: African American Tobacco Control Leadership Council; American Academy of Pediatrics; Americans Academy of Pediatrics California; American Cancer Society Cancer Action Network; American College of Physicians, California Services Chapter; American Heart Association; American Lung Association; American Medical Association; American Public Health Association; American Thoracic Society; Americans for Nonsmokers' Rights; Asian Pacific Partners for Empowerment, Advocacy, and Leadership (APPEAL); Association of Black Women Physicians; Association of Northern California Oncologists (ANCO); Breathe California of the Bay Area, Golden Gate, and Central Coast; California Academy of Family Physicians; California Medical Association; Campaign for Tobacco-Free Kids; Kaiser Permanente; LGBT Cancer Network; Parents Against Vaping E-cigarettes (PAVe); Public Health Institute; Truth Initiative.

Each of these groups works, on a daily basis, to reduce the devastating health harms of tobacco products. *Amici* include physicians, including pediatricians, who counsel their young patients and their parents about the hazards of tobacco use,

organizations with formal programs to urge users to quit, and groups representing parents and families struggling to free young people from nicotine addiction. Each of these organizations has a direct and immediate interest in curbing the sale of flavored tobacco products, as well as substantial expertise in the role those products play in enticing young people to use tobacco. Thus, *Amici* are particularly well suited to inform the Court of the substantial public health benefits that SB 793 would provide to the residents of California, as well as the devastating harm to the public interest that would result if the Court were to grant the Application and to enjoin SB 793 for any period of time. The impact of an injunction on the public interest is a required factor in determining whether such relief should be granted. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

Amici have a strong interest in ensuring the timely implementation of SB 793 because, as detailed in the enclosed brief, it is necessary to curb youth usage of flavored tobacco products in California, which threatens to addict a new generation of young people to nicotine and to undermine the progress made over decades in curbing tobacco use by adolescents in California and elsewhere. SB 793 also is necessary to reduce the disproportionate harm of flavored tobacco products, particularly menthol cigarettes, on the African American community in California.

Collectively, *Amici* possess expertise on issues relating to youth usage of tobacco products, as well as experience developing, and advocating for, policies to curb tobacco use, particularly among youth and other vulnerable populations. *Amici's* analysis is also directly

relevant to the issues raised by the Application, particularly whether the balance of equities and the public interest weigh in favor of, or against, entry of an injunction.

Additionally, many of the *Amici* have previously participated in other cases in federal courts that have raised the issue of federal preemption of state and local restrictions on flavored tobacco products under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776. *E.g.*, Brief of Public Health and Medical Organizations as *Amici Curiae* in Support of Appellees, *R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, 29 F.4th 542 (9th Cir. 2022) (No. 20-55390), ECF No. 29; Brief of Public Health Law Center et al., *R.J. Reynolds Tobacco Co. v. City of Edina*, No. 20-2852 (8th Cir. Dec. 2, 2020); *Amici Curiae* Brief in Support of Appellees City of Providence et al., in Support of Affirmance of District Court Order, and Against Preemption, *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013) (No. 13-1053). Indeed, many of the *Amici* filed briefs opposing motions to preliminarily enjoin SB 793, the law at issue here. Brief of *Amici Curiae* in Opposition to Plaintiffs' Motion for Preliminary Injunction, *R.J. Reynolds Tobacco Co. v. Becerra*, No.20-cv-01990 (S.D. Cal. Nov. 16, 2020), ECF No. 31; Brief of *Amici Curiae* in Opposition to Plaintiffs' Motion for Preliminary Injunction, *R.J. Reynolds Tobacco Co. v. Cnty. of San Diego*, No. 20-cv-01290 (S.D. Cal. Aug. 31, 2020), ECF No. 23.

All parties have consented to the filing of the enclosed *amicus* brief. Given the time-press of the Emergency Application, *Amici* also move to file the

brief without the ten days' notice to the parties of their intent to file as ordinarily required by Sup. Ct. R. 37(2)(a).

Respectfully submitted,

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Amici national and California public health, medical, and community organizations submit this brief urging the Court to deny the Emergency Application for Writ of Injunction (“Application”) preventing implementation of California’s statute barring retailers from selling flavored tobacco products (“Flavors Statute”). This brief is filed with the consent of the parties.¹

**STATEMENT OF INTEREST OF *AMICI*
*CURIAE***

Amici here include the following national, state, and local public health, medical, and community organizations: African American Tobacco Control Leadership Council; American Academy of Pediatrics; Americans Academy of Pediatrics California; American Cancer Society Cancer Action Network; American College of Physicians, California Services Chapter; American Heart Association; American Lung Association; American Medical Association; American Public Health Association; American Thoracic Society; Americans for Nonsmokers’ Rights; Asian Pacific Partners for Empowerment, Advocacy, and Leadership (APPEAL); Association of Black Women Physicians; Association of Northern California Oncologists (ANCO); Breathe California of the Bay Area, Golden Gate, and Central Coast; California Academy of Family Physicians; California Medical Association; Campaign for Tobacco-Free Kids; Kaiser Permanente; LGBT

¹ No counsel for a party authored this brief in whole or in part, and no person other than *Amici Curiae*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Cancer Network; Parents Against Vaping E-cigarettes (PAVe); Public Health Institute; Truth Initiative.

Each of these groups works, on a daily basis, to reduce the devastating health harms of tobacco products. *Amici* include physicians, including pediatricians, who counsel their young patients and their parents about the hazards of tobacco use, organizations with formal programs to urge users to quit, and groups representing parents and families struggling to free young people from nicotine addiction. Each of these organizations has a direct and immediate interest in curbing the sale of flavored tobacco products, as well as substantial expertise in the role those products play in enticing young people to use tobacco. Thus, *Amici* are particularly well suited to inform the Court of the substantial public health benefits to residents of California provided by the Flavors Statute. These benefits are a direct result of the Family Smoking Prevention and Tobacco Control Act's ("Tobacco Control Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) broad protection for state and local authorities to prohibit and regulate the retail sale of dangerous and addictive tobacco products, as California has done.

INTRODUCTION AND SUMMARY OF ARGUMENT

In *FDA v. Brown & Williamson Tobacco Corp.* 529 U.S. 120, 125 (2000), this Court recognized that “the thousands of premature deaths that occur each year because of tobacco use” constitute “one of the most troubling public health problems facing our Nation” Indeed, today use of tobacco products is the leading cause of preventable death in the United States, resulting in 480,000 deaths per year.² Ninety percent of adult smokers begin smoking in their teens,³ a fact the tobacco industry has long understood. As the D.C. Circuit recently noted, “[b]usinesses seeking to make a profit selling tobacco products . . . face powerful economic incentives to reach younger customers.” *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 12 (D.C. Cir. 2022).

The tobacco industry also knows that to successfully market its products to young people, flavors are essential. For all tobacco products, including cigarettes, e-cigarettes, and cigars, flavors significantly increase the appeal of tobacco products to youth. Data from the U.S. Food and Drug Administration (“FDA”)/National Institutes of Health

² Office of the Surgeon General (“OSG”), U.S. Department of Health and Human Services (“HHS”), *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, Executive Summary* 2 (2014), <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf> (“*50 Years of Progress, Executive Summary*”).

³ OSG, HHS, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* 708 (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf (“*50 Years of Progress*”).

(“NIH”) Population Assessment of Tobacco and Health (“PATH”) study found that almost 80% of 12-to-17 year-olds who had ever used a tobacco product initiated their use with a flavored product.⁴ As the FDA has found, “the availability of tobacco products with flavors at these developmental stages attracts youth to initiate use of tobacco products and may result in lifelong use.”⁵

By enacting the Flavors Statute, California has sought to protect its residents – and particularly its young people – from the continuing scourge of flavored tobacco products that lure millions into a lifetime of addiction and contribute so significantly to disease and death. That the Flavors Statute, enacted by the California Legislature in 2020 as S.B. 793,⁶ was recently approved by nearly two-thirds of California voters in Proposition 31,⁷ demonstrates that Californians understand that protection from flavored tobacco products is critical to their health and well-being.

⁴ Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. AM. MED. ASS'N 17, 1871-3, 1872 (2015), <https://jamanetwork.com/journals/jama/fullarticle/2464690>.

⁵ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,295 (proposed Mar. 21, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) (“Flavors Advance Notice of Proposed Rulemaking”).

⁶ S.B. 793, Act of Aug. 28, 2020, ch. 34, 2020 Cal. Stat. 1743 (codified at Cal. Health & Safety Code Sec. 104559.5).

⁷ Cal. Sec’y of State, Unofficial Election Results, Proposition 31 (Dec. 1, 2022), <https://electionresults.sos.ca.gov/returns/maps/ballot-measures/prop/31>.

The Flavors Statute does not, as Applicants allege, interfere with the statutory scheme under the Tobacco Control Act. To the contrary, the preservation of state and local authority to enact laws like the Flavors Statute is embedded in the federal scheme. The Tobacco Control Act both provides for exclusive federal authority over the regulation of activities engaged in by tobacco product manufacturers and others *before* a product is introduced into commerce, and preserves to states and localities the authority to determine whether a tobacco product will be permitted to be sold to persons residing within their borders. The First, Second and Ninth Circuits reached this conclusion in rejecting challenges to local restrictions on the sale of flavored tobacco products based on the alleged preemptive impact of the Tobacco Control Act. *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022), *petition for cert. filed* (Oct. 7, 2022) (No. 22-338); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428 (2d Cir. 2013); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013). Indeed, no court has struck down a state or local restriction on the sale of flavored tobacco products as having been preempted by the TCA. By broadly preserving state and local authority over tobacco product sales, the Tobacco Control Act provides states and localities the capacity to protect the health of their residents to a greater degree than may be afforded by federal regulation over manufacturer activities alone.⁸

⁸ Applicants misleadingly assert that “Congress and FDA have allowed” the products affected by the Flavors Statute to “remain on the market,” Appl. 39, without informing the Court that the FDA has issued proposed rules to create product standards to prohibit menthol as a characterizing flavor in

In this brief, *Amici* focus on the significant public health benefits afforded by the Flavors Statute – precisely the kinds of benefits Congress intended to confer by its decree that state and local authority over the sale of tobacco products be broadly preserved to protect the public health. As explained in detail below, these benefits include protection against the public health harms of (1) menthol cigarettes; (2) flavored e-cigarettes; and (3) flavored cigars.

Applicants recognize that where, as here, “the Government is the opposing party,” the “balance of the equities” merges with the “public interest” factor in determining whether an injunction should issue. *See* Appl. 38 (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). Here the public interest overwhelmingly favors denial of an injunction because it would deny Californians the public health protection afforded by the Flavors Statute. Applicants’ claims of irreparable harm are either dependent on the validity of their preemption argument, which has no merit, or the financial loss of being deprived of the ability to sell tobacco products that, as the discussion *infra* shows, cause significant harm to public health. Applicants’ alleged financial harm is far outweighed by the health

cigarettes (the only cigarette flavor not prohibited outright by the TCA) and to prohibit all flavors in cigars. *See* Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (proposed May 4, 2022) (“Menthol proposed rule”); Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396 (proposed May 4, 2022) (“Flavored cigar proposed rule”). FDA also has used its premarket review authority under the TCA to prohibit the manufacture and sale of various flavored e-cigarettes that do not meet the statutory standard of being “appropriate for the protection of the public health.” *See, e.g., Prohibition Juice Co.*, 45 F.4th 8.

harms long suffered by Californians due to flavored tobacco products.

Applicants seek to minimize the public health stakes here by arguing that “[e]njoining SB793 will preserve the status quo that has existed for decades.” Appl. 38. But, as discussed below, that status quo is one in which companies like R.J. Reynolds have been allowed to market their deadly and addictive products to young people, using flavors as the lure, with devastating consequences for the health of millions. In the Tobacco Control Act, Congress sought to preserve to states and localities the authority to alter that status quo to protect the public health. Applicants seek what they characterize as a “small delay” in implementation of the Flavors Statute, Appl. 38, but Californians have already suffered the health harms of two years of delay since SB 793 was enacted, including an unsuccessful industry-sponsored referendum campaign. The cost of *any* further delay will be measured in disease and death from tobacco products that could have been avoided.

ARGUMENT

I. The Flavors Statute Affords California Residents Greater Protection Against the Public Health Harms of Menthol Cigarettes.

Menthol cigarettes are a substantial threat to public health because they increase the risk of youth initiation of smoking, increase addiction, and disproportionately harm the African American community, thus exacerbating serious existing health disparities.

A. Menthol Cigarettes Increase Youth Initiation of Smoking.

Although the tobacco companies are well aware that almost all new tobacco users begin their addiction as kids, they also know that, to novice smokers, tobacco smoke can be harsh and unappealing. As FDA has found, “[m]enthol’s flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users, particularly youth and young adults, to continue experimenting and progress to regular use.”⁹ Thus, young smokers are more likely to use menthol cigarettes than any other age group. As the FDA has stated, “[t]he disproportionate use of menthol cigarettes by youth and young adult smokers compared to older adults has been consistent over time and across multiple studies with nationally representative populations.”¹⁰ The FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”), after an extensive study of the public health impact of menthol cigarettes, concluded in a 2011 Report that they increase the number of children who experiment with cigarettes and that young people who initiate using menthol cigarettes are more likely to become addicted and long-term daily smokers.¹¹ Since 90% of adult smokers begin smoking in their teens,¹² menthol

⁹ Menthol proposed rule, 87 Fed. Reg. at 26,455.

¹⁰ *Id.* at 26,462.

¹¹ TPSAC, FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* 136, 199-202 (2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (“TPSAC Menthol Report”).

¹² OSG, *50 Years of Progress*, *supra* note 3, at 708.

cigarettes function as a starter product for the young and are critical to the tobacco industry's efforts to recruit "replacement smokers" for the one-half of long-term smokers who eventually die from tobacco-related disease.¹³

Recent research continues to demonstrate the popularity of menthol cigarettes among youth and menthol's role in smoking initiation. According to the 2021 National Youth Tobacco Survey ("NYTS"), 41.1% of current high school smokers use menthol cigarettes.¹⁴ Another government survey, the National Survey of Drug Use and Health, found that preference for menthol among cigarette smokers is inversely correlated with age.¹⁵ Data from Truth Initiative's Young Adult Cohort Study, a national study of 18-34 year olds, likewise showed that 52% of new young adult smokers initiated with menthol cigarettes.¹⁶ Initiation with menthol cigarettes was much higher among

¹³ OSG, *50 Years of Progress, Executive Summary*, supra note 2, at 15.

¹⁴ Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1, 21 tbl.5 (2022), <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

¹⁵ Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, 22 NICOTINE & TOBACCO RES. 1673, 1673 (2020), <https://academic.oup.com/ntr/article/22/10/1673/5906409>.

¹⁶ Joanne D'Silva et al., *Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, 20 NICOTINE & TOBACCO RES. 1062, 1064 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6093322/>.

African American smokers (93.1%) compared to white smokers (43.9%).¹⁷

The devastating health impact of menthol cigarettes is most dramatically shown by a more recent study by researchers from the University of Michigan. With the same methodology used by TPSAC, the study estimates that during the 38-year period from 1980-2018, menthol cigarettes were responsible for 10.1 million extra smokers, or approximately 266,000 additional smokers every year.¹⁸ The study also found that menthol cigarettes were responsible for 378,000 additional smoking-related deaths during that period, or almost 10,000 deaths per year.¹⁹

B. Menthol Cigarettes Increase Addiction and Reduce Cessation.

The 2020 Surgeon General's Report on smoking cessation cited numerous studies finding an association between menthol use and lower cessation rates.²⁰ Research analyzing four waves of data from the government's PATH study shows that among daily smokers, menthol cigarette smokers have a 24% lower likelihood of quitting as compared to non-menthol

¹⁷ *Id.*

¹⁸ Thuy T.T. Le & David Mendez, *An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018*, 31 TOBACCO CONTROL 564, 566 (2022), <https://tobaccocontrol.bmj.com/content/early/2021/02/09/tobaccocontrol-2020-056256.info>.

¹⁹ *Id.*

²⁰ OSG, HHS, *Smoking Cessation: A Report of the Surgeon General* 16-17 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf> ("OSG Smoking Cessation").

smokers.²¹ Among daily smokers, African American menthol smokers had a 53% lower chance of quitting compared to African American non-menthol smokers, while white menthol smokers had 22% lower odds of quitting compared to white non-menthol smokers.²²

Data show that among middle and high school students, menthol smoking was associated with greater smoking frequency and intention to continue smoking, compared to non-menthol smoking.²³ Data from the government PATH study show that youth menthol smokers have significantly higher levels of certain measures of dependence,²⁴ and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.²⁵ In proposing a product standard to prohibit menthol as a

²¹ Sarah D. Mills et al., *The Relationship Between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study*, 23 *NICOTINE & TOBACCO RES.* 966, 970 (2020), <https://doi.org/10.1093/ntr/ntaa212>.

²² *Id.*

²³ Sunday Azagba et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent Smokers*, 66 *J. ADOLESCENT HEALTH* 545, 549 (2020), <https://pubmed.ncbi.nlm.nih.gov/31964612/>.

²⁴ Sam N. Cwalina et al., *Adolescent Menthol Cigarette Use and Risk of Nicotine Dependence: Findings from the National Population Assessment on Tobacco and Health (PATH) Study*, 206 *DRUG & ALCOHOL DEPENDENCE* 1, 3 (2019), <https://www.sciencedirect.com/science/article/pii/S0376871619304922>.

²⁵ Andrea C. Villanti et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2 *JAMA NETWORK OPEN* 1, 12 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

characterizing flavor in cigarettes, FDA found both that “[y]outh and young adults are particularly susceptible to becoming addicted to nicotine” and that “[m]enthol enhances the effects of nicotine in the brain by affecting mechanisms involved in nicotine addiction.”²⁶ Thus, the data demonstrate that menthol cigarettes have led millions of youth into tobacco addiction.

C. Menthol Cigarettes Have Led to Significant Health Disparities for African Americans.

Remarkably, Applicants assert that the Flavors Statute “could cause significant negative consequences for communities of color, including African Americans.” Appl. 39 n.8. In fact, menthol cigarettes have played an especially pernicious role in causing disease and death in the African American community.

Applicants note that “African American smokers . . . disproportionately prefer menthol cigarettes,” *id.*, but this “preference” is no accident. Since at least the 1950s, the tobacco industry has targeted African Americans with marketing for menthol cigarettes through magazine advertising, sponsorship of community and music events, and youthful imagery and marketing in the retail environment.²⁷ For example, the industry has

²⁶ Menthol proposed rule, 87 Fed. Reg. at 26,464.

²⁷ See generally Campaign for Tobacco-Free Kids et al., *Stopping Menthol, Saving Lives: Ending Big Tobacco’s Predatory Marketing to Black Communities* 7-9 (2021), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf.

strategically placed menthol cigarettes in magazines with high Black readership, featuring Black models. One study found that from 1998-2002, *Ebony* was 9.8 times more likely than *People* magazine to carry ads for menthol cigarettes.²⁸ The industry marketed menthol brands with popular community events, particularly focused around music. Industry-sponsored events included R.J. Reynolds' Salem Summer Street Scenes festivals, Brown & Williamson's Kool Jazz Festival, and Philip Morris' Club Benson & Hedges promotional bar nights, which targeted clubs frequented by Black Americans.²⁹ Applicant R.J. Reynolds estimated that it reached at least half of African Americans in five cities through its street festivals.³⁰ As TPSAC concluded, menthol cigarettes are "disproportionately marketed per capita to African Americans. African Americans have been the subjects of specifically tailored menthol marketing strategies and messages."³¹

²⁸ Hope Landrine et al., *Cigarette Advertising in Black, Latino and White Magazines, 1998-2002: An Exploratory Investigation*, 15 *ETHNICITY & DISEASE* 63, 65 (2005), <https://www.ethndis.org/priorarchives/Ethn-15-01-63.pdf>.

²⁹ Navid Hafez & Pamela M. Ling, *Finding the Kool Mixx: How Brown & Williamson used Music Marketing to Sell Cigarettes*, 15 *TOBACCO CONTROL* 359, 360 (2006), <https://tobaccocontrol.bmj.com/content/15/5/359>; Valerie B. Yeger et al., *Racialized Geography, Corporate Activity, and Health Disparities: Tobacco Industry Targeting of Inner Cities*, 18 (Supp. 4) *J. HEALTH CARE POOR & UNDERSERVED* 10, 25 (2007), <https://pubmed.ncbi.nlm.nih.gov/18065850/>; see also R.J. Reynolds, *Black Street Scenes 1993 Review and Recommendations*, in *TRUTH TOBACCO INDUSTRY DOCUMENTS*, <http://legacy.library.ucsf.edu/tid/onb19d00>.

³⁰ Yeger et al., *supra* note 29, at 25.

³¹ TPSAC Menthol Report, *supra* note 11, at 92.

To this day, African American neighborhoods have a disproportionate concentration of menthol cigarette advertising and cheaper pricing of menthol cigarettes. The 2018 California Tobacco Retail Surveillance Study found significantly more menthol advertisements at stores with a higher proportion of African American residents and in neighborhoods with higher proportions of school-age youth.³² A 2021 study found that in Los Angeles County, stores located in predominantly African American neighborhoods had significantly higher odds of selling Newport cigarettes (the most popular menthol brand, marketed by R.J. Reynolds) than stores in Hispanic or non-Hispanic White neighborhoods.³³ Additionally, the study found that the estimated price of a Newport single pack was \$0.38 higher in non-Hispanic White neighborhoods than African American neighborhoods.³⁴

The tobacco industry's use of menthol cigarettes to target African Americans has paid lucrative, but tragic, dividends. In the early 1950s, 5% of African American smokers preferred menthol brands.³⁵ In

³² Nina Schleicher et al., *California Tobacco Retail Surveillance Study 2018* 3, 22 (2019), <https://www.cdph.ca.gov/Programs/CCDC/DCDC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf>.

³³ Sabrina L. Smiley et al., *Retail Marketing of Menthol Cigarettes in Los Angeles, California: a Challenge to Health Equity*, 18 PREVENTING CHRONIC DISEASE (2021), https://www.cdc.gov/PCD/issues/2021/20_0144.htm.

³⁴ *Id.*

³⁵ See Phillip S. Gardiner, *The African Americanization of Menthol Cigarette use in the United States*, 6 (Supp. 1) NICOTINE & TOBACCO RES. S55, S59 (2004); Burns W. Roper, *A Study of People's Cigarette Smoking Habits and Attitudes Volume I, in*

2018, 85% of African American smokers smoked menthol cigarettes, compared to 29% of White smokers.³⁶ A recent study found that among the African American community, menthol cigarettes were responsible for 1.5 million extra smokers, 157,000 smoking-related premature deaths, and 1.5 million excess life-years lost between 1980 and 2018.³⁷ Applicants' assertion that the Flavors Statute, by addressing this plague caused by R.J. Reynolds and other cigarette companies, will have "negative consequences for communities of color," Appl. 39 n.8, is astonishing and contrary to the available data.

D. Applicants' Arguments that an Injunction Would Be in the Public Interest Are Unavailing.

Against this devastating impact on the health of African Americans, Applicants posit that the Flavors Statute will expose that population to "negative encounters with law enforcement." Appl. 39, n.8. The issue of police abuse of African American people and other communities of color is, of course, a matter of urgent national concern, but Applicants offer no valid support for their argument that a statute which prohibits only the retail sale of flavored tobacco

TRUTH TOBACCO INDUSTRY DOCUMENTS (1953), <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fhcv0035>.

³⁶ Delnevo et al., *supra* note 15, at 1674.

³⁷ David Mendez & Thuy T.T. Le, *Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018*, *Tobacco Control* 1, 2 (2021), <https://pubmed.ncbi.nlm.nih.gov/34535507/>.

products, but not their possession or use, will increase the risk of negative encounters with law enforcement.

Applicants speculate that the Flavors Statute will lead to illicit trade in the affected products, but rely almost entirely on Reynolds' own comments opposing a proposed FDA regulation, Appl. 39, and overlook FDA's conclusion that the regulation at issue (the "Deeming Rule" extending FDA jurisdiction to e-cigarettes and other products) will yield public health benefits greater than any negative effects from an increase in illicit markets.³⁸

Applicants ignore the fact that prohibiting all retail sales of youth-appealing flavored products will reduce youth demand for tobacco products and thereby curb a significant component of the current illicit market for tobacco products – sales of products to underaged buyers. Moreover, an extensive study commissioned by FDA and conducted by the National Research Council and the Institute of Medicine found that "the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest."³⁹ It is reasonable to reach a similar conclusion as to the sales restrictions in the Flavors Statute.

³⁸ Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974, 29,007 (May 10, 2016) ("Final Deeming Rule").

³⁹ National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences* 9 (2015), <https://nap.nationalacademies.org/catalog/19016/understanding-the-us-illicit-tobacco-market-characteristics-policy-context-and>.

Indeed, after surveying the impact of local sales restrictions, FDA concluded that “[o]verall, the evidence supports that sales and use of tobacco products decrease as a result of flavored tobacco product sales restrictions.”⁴⁰

As to Applicants’ speculation that the Flavors Statute will lead to more use of non-flavored products, again relying on Reynolds’ own regulatory comments, Appl. 40, tobacco retail sales data in both San Francisco and Massachusetts, which enacted comprehensive flavored product sales bans, show statistically significant declines in both flavored and overall tobacco sales, demonstrating that there was not a complete substitution with unflavored products.⁴¹ In summary, the data firmly rebut Applicants’ assertion that the public health benefits of the Flavors Statute will be overcome by illicit markets or the substitution of unflavored products.

II. The Flavors Statute Provides California Residents with Greater Protection Against the Health Harms of Flavored E-Cigarettes.

The most dramatic surge in youth usage of flavored tobacco products has occurred with e-

⁴⁰ C, 87 Fed. Reg. at 26,472.

⁴¹ See Doris G. Gammon, et al., *Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales*, TOBACCO CONTROL (published online June 4, 2021), <https://pubmed.ncbi.nlm.nih.gov/34088881/>; Samuel Asare, et al., *Association of Cigarette Sales with Comprehensive Menthol Flavor Ban in Massachusetts*, 182 JAMA INTERNAL MED. 231 (2022), <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2787781>.

cigarettes, the most commonly used tobacco product among U.S. youth since 2014.⁴² In December 2018, the Surgeon General issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.”⁴³ Youth e-cigarette use remains a serious public health concern today, with over 2.5 million youth, including 14.1% of high schoolers, reporting current e-cigarette use in 2022.⁴⁴ Trends in e-cigarette use in California mirror the national trends. According to the California Student Tobacco Survey, e-cigarettes are the most commonly used tobacco product among California high school students.⁴⁵

Young people are not just experimenting with e-cigarettes—they are using them frequently. In 2022, 46% of high school e-cigarette users reported using e-cigarettes on at least 20 of the preceding 30 days.⁴⁶ Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine

⁴² Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1283 (2022), <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

⁴³ OSG, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth* 2 (2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf> (“OSG Advisory”).

⁴⁴ Cooper et al., *supra* note 42, at 1283, 1285.

⁴⁵ Shu-Hong Zhu et al., *Results of the Statewide 2019-20 California Student Tobacco Survey* 1 (2021), https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/FactsandFigures/2019-20CSTSBiennialReport_7-27-2021.pdf.

⁴⁶ Cooper et al., *supra* note 42, at 1284 tbl.

addiction.⁴⁷ Roughly 700,000 middle and high school students are vaping on a daily basis.⁴⁸

As several federal circuit courts have recognized, “*flavored* e-cigarettes disproportionately appeal to children,” *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021) (emphasis in original), and are largely driving the alarming rates of youth e-cigarette use. *See also, e.g., Prohibition Juice Co.*, 45 F.4th at 11 (“Flavored tobacco products lie at the heart of the problem” of youth e-cigarette use.). The 2020 Surgeon General Report on smoking cessation notes that “the role of flavors in promoting initiation of tobacco product use among youth is well established . . . and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes.”⁴⁹ According to the 2022 NYTS, 84.9% of current middle and high school e-cigarette users had used a flavored product in the past month.⁵⁰

Flavored e-cigarettes and refill liquids typically contain nicotine, which is “among the most addictive substances used by humans,” *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019), and which can have lasting damaging effects on adolescent brain development.⁵¹ According to the Surgeon General, “[n]icotine exposure during adolescence can impact

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ OSG Smoking Cessation, *supra* note 20, at 611.

⁵⁰ Cooper et al., *supra* note 42, at 1283.

⁵¹ OSG, HHS, *Know the Risks: E-Cigarettes & Young People* (2021), <https://e-cigarettes.surgeongeneral.gov/>; *see also* Centers for Disease Control and Prevention (“CDC”), *Electronic Nicotine Delivery Systems: Key Facts* (2016), <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

learning, memory and attention,” and “can also increase risk for future addiction to other drugs.”⁵² The Surgeon General has warned that “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”⁵³

Flavorings in e-cigarettes can pose additional health hazards. In *Nicopure*, the U.S. Court of Appeals for the D.C. Circuit relied on findings that flavors in e-cigarettes are harmful in upholding the application of FDA’s premarket review process to e-cigarettes. The Court found that:

Aldehydes, “a class of chemicals that can cause respiratory irritation” and “airway constriction,” appear in many flavored e-cigarettes, including cotton candy and bubble gum. One study found that the flavors “dark chocolate” and “wild cherry” exposed e-cigarette users to more than twice the recommended workplace safety limit for two different aldehydes. Like secondary smoke inhalation from conventional cigarettes, exhaled aerosol from e-cigarettes may include nicotine and other toxicants that can pose risks for non-users.

Nicopure, 944 F.3d at 274 (internal citations omitted).

⁵² OSG Advisory, *supra* note 43, at 1.

⁵³ OSG, HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of the Surgeon General*, 5 (2016) https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

Use of e-cigarettes may also function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Science, Engineering, and Medicine (“NASEM”) found “substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”⁵⁴ Additionally, a nationally representative analysis found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying combustible cigarettes and nearly three times the odds of current combustible cigarette use.⁵⁵

Finally, although Applicants imply that those who smoke cigarettes may be using menthol-flavored e-cigarettes to stop smoking (and may turn back to combustible cigarettes if the Flavors Statute is implemented), Appl. 40, the leading public health authorities in the U.S., including the Surgeon General, the U.S. Preventive Services Task Force (“USPSTF”), the CDC, and NASEM, have all concluded that there is insufficient evidence to recommend any e-cigarettes for smoking cessation.⁵⁶ In a 2020 report, the Surgeon

⁵⁴ NASEM, *Public Health Consequences of E-cigarettes* 10 (2018), https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

⁵⁵ Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1, 7 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.

⁵⁶ OSG Smoking Cessation, *supra* note 20, at 7; USPSTF, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J.

General stated that “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”⁵⁷ As FDA has repeatedly found, there also is little evidence that flavors in e-cigarettes aid in helping smokers to stop smoking. For example, FDA recently denied marketing authorization for a menthol e-cigarette product, finding the evidence insufficient to show that “menthol-flavored e-cigarettes are more effective in promoting complete switching or significant cigarette use reduction relative to tobacco-flavored e-cigarettes among adult smokers.”⁵⁸

Thus, given the ongoing public health crisis of youth e-cigarette use, driven by the appeal of flavored products, the Flavors Statute will provide California residents, and particularly its young people,

AM. MED. ASS'N 265 (2021), <https://jamanetwork.com/journals/jama/fullarticle/2775287>; CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html (Jan. 23, 2020); NASEM, *supra* note 54, at 10.

⁵⁷ OSG Smoking Cessation, *supra* note 20, at 7.

⁵⁸ FDA News Release, *FDA Denies Marketing of Logic’s Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (Oct. 26, 2022), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-logics-menthol-e-cigarette-products-following-determination-they-do-not-meet>; *see also Prohibition Juice Co.*, 45 F.4th at 11 (FDA found that manufacturers applying for marketing authorization “had presented insufficient evidence that their flavored products are more effective than unflavored products in helping adult cigarette smokers decrease or quit harmful tobacco uses . . .”).

substantial protection from the addictive and other harmful effects of flavored e-cigarettes.

III. The Flavors Statute Provides California Residents Greater Protection Against the Health Harms of Flavored Cigars.

Like other flavored tobacco products, flavored cigar smoking presents substantial health risks – risks that are particularly concerning given the prevalence of cigar use among children and the tobacco industry’s efforts to market cigars to youth. Historically, cigar manufacturers designed flavored cigars to serve as “starter” smokes for youth and young adults because the flavorings helped mask the harshness, making the products easier to smoke.⁵⁹ According to an industry publication, “[w]hile different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers.”⁶⁰ The vice president of one distributor commented that “[f]or a while it felt as if we were operating a Baskin-Robbins ice cream store” in reference to the huge variety of cigar flavors available – and an apparent allusion to flavors that would appeal to kids.⁶¹ In proposing the regulation to extend its regulatory jurisdiction to cigars, the FDA

⁵⁹ Ganna Kostygina et al., *Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos*, 25 *TOBACCO CONTROL* 66, 67, 69 (2016), <https://tobaccocontrol.bmj.com/content/25/1/66>.

⁶⁰ Melissa Niksic, *Flavored Smokes: Mmmm...More Profits?*, *TOBACCO RETAILER* (Apr. 2007), https://web.archive.org/web/20081121103907/http://www.tobaccoretailer.com/uploads/Features/2007/0407_flavored_smokes.asp.

⁶¹ *Id.*

found that young people are far more likely than older smokers to prefer flavored cigars.⁶²

After Congress enacted the Tobacco Control Act and its prohibition of flavored cigarettes (with the exception of menthol), the cigar industry flooded the market with a dizzying array of new, small, cheap, mass-produced cigars, many virtually indistinguishable from cigarettes,⁶³ with sugary flavors from candy to chocolate to lemonade and names like “Sweet Dreams” and “Da Bomb Blueberry.”⁶⁴ From 2008 to 2015, the number of unique cigar flavor names more than doubled.⁶⁵ Dollar sales of flavored cigar products increased by nearly 50% between 2008 and

⁶² Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 79 Fed. Reg. 23,141, 23,146 (proposed Apr. 25, 2014) (“[S]ugar preference is strongest among youth and young adults and declines with age.”).

⁶³ Under the Tobacco Control Act, the essential difference between a cigarette and a cigar is that a cigar contains tobacco in the wrapper, while a cigarette does not. *Compare* 15 U.S.C. § 1332(1)(a) (defining “cigarette”) *with* 21 C.F.R. § 1143.1 (defining “cigar”).

⁶⁴ See generally Campaign for Tobacco-Free Kids, *Not Your Grandfather’s Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids*, 9, 14 (2013), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf.

⁶⁵ Cristine D. Delnevo et al., *Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act*, 3 (2 Supp. 1) TOBACCO REG. SCIENCE 1, 4 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351883/pdf/nihms852155.pdf>.

2015, increasing flavored cigars' share of the overall cigar market to 52.1% in 2015.⁶⁶

The result of this reorientation of cigars toward the youth market has been predictable and disturbing. As FDA has found, "youth cigar use has not declined when compared to use of other tobacco products."⁶⁷ Cigar usage among high school students now exceeds cigarette usage.⁶⁸ More than 1,400 children under age 18 try cigar smoking for the first time every day.⁶⁹ The 2013-14 PATH study found that 73.8% of youth cigar smokers smoked cigars "because they come in flavors I like."⁷⁰ The 2020 NYTS showed that approximately 550,000 middle and high school students had used a flavored cigar in the last 30 days.⁷¹

Moreover, as with menthol cigarettes, years of research have documented greater cigar availability

⁶⁶ *Id.* at 10 tbl.2.

⁶⁷ Final Deeming Rule, 81 Fed. Reg. at 29,023.

⁶⁸ Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY REP. 1881, 1884 tbl. (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf>.

⁶⁹ Substance Abuse and Mental Health Services Administration, HHS, *2019 National Survey on Drug Use and Health, Table 4.9A, Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, Prior to Age 21, and at Age 21 or Older: Numbers in Thousands, 2018 and 2019* (Sept. 11, 2020), <https://www.samhsa.gov/data/report/2019-nsduh-detailed-tables>.

⁷⁰ Ambrose et al., *supra* note 4, at 1873.

⁷¹ Tiffany A. Parms et al., *Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020*, 62 AM. J. PREVENTIVE MED. E39, E40 (2021), [https://www.ajpmonline.org/article/S0749-3797\(21\)00405-0/fulltext](https://www.ajpmonline.org/article/S0749-3797(21)00405-0/fulltext).

and more cigar marketing, including flavored cigars and price promotion, in African American neighborhoods.⁷² It is not surprising, therefore, that in 2020, 9.2% of African American high school students reported smoking cigars, compared to 5% of all high school students, and African American high school students smoked cigars at more than three times the rate of cigarettes.⁷³

As the FDA has found, “[a]ll cigars pose serious negative health risks.”⁷⁴ In 2010 alone, regular cigar smoking was responsible for “approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older.”⁷⁵ According to the FDA, “[a]ll cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users,” as well as “other adverse health effects, such as increased risk of heart and pulmonary disease,” “a marked increase in risk for chronic obstructive pulmonary disease (COPD),” a higher risk of death from COPD, and “a higher risk of fatal and nonfatal stroke” compared to non-smokers.⁷⁶

In summary, the Flavors Statute affords California residents with greater protection from the adverse public health impact of flavored cigars, particularly on young people.

⁷² Campaign for Tobacco-Free Kids et al., *Stopping Menthol, Saving Lives*, *supra* note 27, at 10.

⁷³ Gentzke et al., *supra* note 68, at 1884 tbl.

⁷⁴ Final Deeming Rule, 81 Fed. Reg. at 29,020.

⁷⁵ *Id.*

⁷⁶ *Id.*

CONCLUSION

Amici public health, medical, and community organizations urge the Court to deny the Emergency Application for Writ of Injunction.

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