

Case No. 20

DISCLOSURE STATEMENT

Amici curiae are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

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Cases

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Andrea S. Gentzke, et al., *Tobacco Product Use Among Middle and High School Student – United States, 2020*, 69(50) MORBIDITY & MORTALITY WKLY. REP. 1881 (Dec. 18, 2020).... 20, 26, 27

B.W. Roper, *A Study of People’s Cigarette Smoking Habits and Attitudes Volume I* (1953)..17

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, (2015).....4, 27

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Shu-Hong Zhu et al., <i>California Student Tobacco Survey, Results of the Statewide 2017-18 California Student Tobacco Survey</i> (2019).	20
Shu-Hong Zhu et al., <i>Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation</i> , 23 TOBACCO CONTROL iii3 (2014).	21
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Amici public health, medical, and community organizations submit this brief
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formal programs to urge users to quit, to 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, these *amici* are particularly well suited to inform the Court of the substantial public health benefits to residents of LA County provided by the Flavors Ordinance. 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 local authorities to prohibit and regulate the retail sale of dangerous and addictive tobacco products, as LA County has done with its Flavors Ordinance.

INTRODUCTION AND SUMMARY OF ARGUMENT

Use of tobacco products is the leading cause of preventable death in the United States, resulting in 480,000 deaths per year.² The tobacco industry has long understood that almost all new tobacco users begin their addiction as kids. Ninety percent of adult smokers began smoking in their teens.³ The industry has also

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>.

³ OSG, HHS, *The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General 708* (2014),

known that to successfully market their products to young people, flavored

The Flavors Ordinance does not, as Appellants 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 Ordinance is embedded in the federal scheme. As explained in detail in the County’s Principal Brief and as recognized by the District Court,⁷ 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 and Second Circuit Courts of Appeals reached the same 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. *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433-35 (2d Cir. 2013) (upholding local sales restrictions on flavored tobacco products because their application to a particular product “depends on its characteristics as an end product, and not on whether it was manufactured in a particular way or with particular ingredients”); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 83 & n.11 (1st Cir. 2013) (upholding local restrictions on sale of

⁷ Defendants-Appellees Brief, at 11-12; *R. J. Reynolds Tobacco Co. v. County of Los Angeles*, 471 F.Supp.3d 1010, 1014-17 (C.D. Cal. 2020).

flavored tobacco products, given “Congress’ decision to exempt sales regulations from preemption. . . .”).

By broadly preserving state and local authority over tobacco product sales, the Tobacco Control Act provides localities like LA County the capacity to protect the health of their residents to a greater degree than may be afforded by federal regulation over manufacturer activities alone. Indeed, Section 916 of the TCA (entitled “Preservation of State and Local Authority”) expressly preserves state and local authority “...to enact...any law...in addition to...requirements established under this Chapter, including a law...relating to or prohibiting the sale...of tobacco products...” Far from interfering with the federal regulatory scheme, by providing additional public health protection, the Flavors Ordinance advances the Tobacco Control Act’s “objective of reducing the use and harmfulness of tobacco products, especially among young people.” *U.S. Smokeless Tobacco*, 708 F.3d at 436.

Amici focus here on the significant public health benefits afforded by the Flavors Ordinance – 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. As also explained below, the FDA has never decided “to allow certain flavored tobacco products, including menthol

cigarettes, to stay on the market,” as Appellants erroneously claim.⁸ Indeed, the FDA recently stated its intention to propose product standards within the next year to prevent the continued manufacture of menthol cigarettes and flavored cigars.⁹ Thus, there is no basis for Appellants’ argument that the Flavors Ordinance is impliedly preempted because it stands as an obstacle to current federal policy on menthol cigarettes and flavored cigars; to the contrary, the Flavors Ordinance is entirely consistent with that policy. As for e-cigarettes, Appellants mischaracterize FDA action as “effectively banning” only certain flavored products, when in fact FDA has issued only Guidance describing its current enforcement policies, which do not bind the agency, are subject to change at any time, and therefore can have no preemptive effect on state and local laws.

ARGUMENT

I. The County’s Tobacco Flavors Ordinance Affords County Residents Greater Protection Against the Public Health Harms of Menthol Cigarettes.

Contrary to Appellants’ assertion that “there is no scientific or other justification” for prohibiting the sale of menthol cigarettes, for which Appellants

⁸ Appellants’ Principal Brief, at 5.

⁹ FDA, News release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

menthol cigarettes increase the number of children who experiment with cigarettes and who become regular smokers, increasing overall youth smoking, and that young people who initiate using menthol cigarettes are more likely to become addicted and long-term daily smokers.¹² Since 90% of adult smokers begin smoking in their teens,¹³ as a starter product for the young, menthol cigarettes are critical to the tobacco industry's need to recruit "replacement smokers" for the one-half of long-term smokers who eventually die from tobacco-related disease. In its 2011 Report, TPSAC projected that by 2020, about 2.3 million people will have started smoking because of menthol cigarettes, leading to 17,000 premature deaths.¹⁴ TPSAC concluded that "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States."¹⁵

Two years after issuance of the TPSAC Menthol Report, FDA completed its own independent, peer-reviewed evaluation of the science concerning menthol cigarettes. FDA's *Preliminary Scientific Evaluation of the Possible Public Health Effects of M(e)3.6 (3 (r)3.6 1 (rTw -7.282 -2.291 Td [(Ef)-880.004 Tw e -2.291 vw -7.,(e)3.5 (w*

overall conclusion, consistent with TPSAC’s own findings, that it is “likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”¹⁶

Since the reports from TPSAC and FDA, research has continued to demonstrate the popularity of menthol cigarettes among youth and menthol’s role in smoking initiation. According to the 2019 National Youth Tobacco Survey (“NYTS”), half of current high school smokers use menthol cigarettes.¹⁷ Another government survey, the National Survey of Drug Use and Health, found that preference for menthol among cigarette smokers is inversely correlated with age.¹⁸ 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

¹⁶ FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* 6 (2013), <https://www.fda.gov/media/86497/download>.

¹⁷ Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019*, 68(12) MORBIDITY & MORTALITY WKLY. REP. 1, 15 (2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

¹⁸ Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, NICOTINE & TOBACCO RSCH 1673, 1673 (2021), <https://academic.oup.com/ntr/article/22/10/1673/5906409>.

More recent research bolsters these findings. The 2020 Surgeon General's Report on smoking cessation cited numerous studies finding an association

from the government PATH study shows that youth menthol smokers have significantly higher levels of certain measures of dependence,³¹ and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.³² Thus, there is little doubt that menthol cigarettes have led millions of youth into tobacco addiction.

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

Menthol cigarettes have played an especially pernicious role in causing disease and death in the African American community.

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.³³ For example, the industry has strategically placed

³¹ 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>.

³² Andrea C. Villanti et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2(10) J. AM. MED. ASS'N NETWORK OPEN 1, 12 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

³³ 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.

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.³⁴ The industry marketed menthol brands with popular community events, particularly focused around music. Industry-sponsored events included appellant 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.³⁵ R.J. Reynolds estimated that they reached at least half of African Americans in five cities through their street festivals.³⁶

The industry also targeted African Americans through targeted branding and culturally appropriated images. For example, in 2004, Brown & Williamson launched an ad campaign for Kool featuring images of young Black rappers, DJs and dancers on cigarette packs and in advertising. The campaign also included

³⁴ Hope Landrine et al., *Cigarette Advertising in Black, Latino and White*
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radio giveaways with cigarette purchases and a hip hop DJ competition in major cities.³⁷

Hispanic White neighborhoods.⁴¹ 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.⁴²

The tobacco industry's use of menthol cigarettes to target African Americans has paid lucrative, but tragic, rewards. In the early 1950s, 5% of Black American smokers preferred menthol brands.⁴³ In 2018, 85% of African American smokers smoke menthol cigarettes, compared to 29% of Whites.⁴⁴ In its 2011 TPSAC Report, the FDA concluded that menthol cigarettes are associated with lower levels of smoking cessation among African Americans.⁴⁵ TPSAC also estimated that by 2020, over 460,000 African Americans will have started smoking because of menthol cigarettes, and 4,700 excess deaths of African Americans will have been attributable to menthol cigarettes.⁴⁶

⁴¹ 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.

⁴² *Id.*

⁴³ See Phillip S. Gardiner, *The African Americanization of Menthol Cigarette use in the United States*, 6(Suppl 1) NICOTINE & TOBACCO RSCH S55, S59 (2004); B.W. Roper, *A Study of People's Cigarette Smoking Habits and Attitudes Volume I*, in TRUTH TOBACCO INDUSTRY DOCUMENTS (1953), <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fhcv0035>.

⁴⁴ Delnevo et al., *supra* note 18, at 1674.

⁴⁵ TPSAC Menthol Report, *supra* note 12, at 147.

⁴⁶ *Id.* at 206.

II. The Flavors Ordinance Provides the Residents of LA County Greater Protection against the Health Harms of Continued Sale of Flavored E-Cigarettes.

The Flavors Ordinance also provides residents of LA County with protection against the public health harm from the continued sale of flavored e-cigarettes, particularly among the County’s young people.

The most dramatic surge in youth usage of flavored tobacco products has occurred with e-cigarettes,⁴⁹ the most commonly used tobacco product among U.S. youth since 2014.⁵⁰ In December 2018, Surgeon General Jerome Adams issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.”⁵¹ The 2020 NYTS showed that almost 1 in 5 (19.6%) of high school students are current users of e-cigarettes,⁵²

school and middle school students are current e-cigarette users⁵⁴ – about the same number as when the Surgeon General first called youth e-cigarette use an “epidemic” in 2018.⁵⁵ Trends in e-cigarette use in California mirror the trends seen nationwide. According to the California Student Youth Tobacco Survey, e-cigarettes are the most commonly used tobacco product among youth in California.⁵⁶

Young people are not just experimenting with e-cigarettes, but are using them frequently. Data from the 2020 NYTS show that 38.9% of high school e-cigarette users reported frequent use (up from 34.2% in 2019).⁵⁷ Even more alarming, 22.5% of high school e-cigarette users reported *daily* use, a strong indication of deep addiction.⁵⁸ In total, 1.3 million middle and high school students are frequent users of e-cigarettes, including over 700,000 daily users.⁵⁹

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In recent years, tobacco companies have extended to e-cigarettes their highly successful strategy of using flavored products to appeal to youth. As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available online.⁶⁰ An earlier study of e-cigarette flavors found that among the more than 400 brands available online in 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.⁶¹ E-liquids are being sold in such kid-friendly options as cotton candy, peanut butter cup and gummy bear. The d sc180.964aeu (gu)-8.3 (m)4.8 (7 d (or)3.72.1

development.⁶⁴ According to the Surgeon General’s *Advisory on E-cigarette Use Among Youth*, “[n]icotine exposure during adolescence can impact learning, memory and attention,” and “can also increase risk for future addiction to other drugs.”⁶⁵ Nicotine also impacts the cardiovascular system.⁶⁶ The Surgeon General has warned that, “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”⁶⁷

Flavorings in e-cigarettes can pose additional health hazards. In *Nicopure Labs LLC v. FDA*, the U.S. Court of Appeals for the D.C. Circuit relied on findings

had ever used e-cigarettes had seven times higher odds of starting to smoke combustible cigarettes one year later compared with those who had never used e-cigarettes.⁷⁰

Thus, given the fast-spreading epidemic of youth e-cigarette use, driven by the appeal of flavored products, the Flavors Ordinance is providing LA County residents, and particularly its young people, with substantial protection from the addictive and other harmful effects of flavored e-cigarettes.

III. The Flavors Ordinance Provides LA County 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.⁷¹ According to an industry publication, “[w]hile different cigars target a variety of markets, all flavored

⁷⁰ Elizabeth C. Hair et al., *Association Between E-Cigarette Use and Future Combustible Cigarette Use: Evidence From a Prospective Cohort of Youth and Young Adults, 2017-2019*, 112 ADDICTIVE BEHAVIORS 1, 4 (2020), <https://www.sciencedirect.com/science/article/pii/S0306460320307231?via%3Dihub>.

⁷¹ Ganna Kostygina et al., *Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos*, 25 T

tobacco products tend to appeal primarily to younger consumers.”⁷² The vice president of one distributor commented, “[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.⁷³ In proposing the Deeming Rule extending its regulatory jurisdiction to cigars, the FDA observed that young people are far more likely than older smokers to prefer flavored cigars.⁷⁴

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,⁷⁵ with sugary flavors from candy to chocolate to lemonade and names like “Sweet Dreams” and “Da Bomb

⁷² Melissa Niksic, *Flavored Smokes: Mmmmm...More Profits?*, TOBACCO RETAILER (Apr. 2007), https://web.archive.org/web/20081121103907/http://www.tobaccoretailer.com/uploads/Features/2007/0407_flavored_smokes.asp.

⁷³ *Id.*

⁷⁴ 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. R[(n)8.320]LE.1 rd.

Blueberry.”⁷⁶ From 2008 to 2015, the number of unique cigar flavor names more than doubled.⁷⁷ Dollar sales of flavored cigar products increased by nearly 50% between 2008 and 2015, increasing flavored cigars’ share of the overall cigar market to 52.1% in 2015.⁷⁸

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.”⁷⁹ Cigar use among high school students now exceeds cigarette usage.⁸⁰ More than 1,400 children under age 18 try cigar smoking for the first time every day.⁸¹ The 2013-14 PATH study found that 73.8% of youth cigar smokers smoked cigars “because they come in flavors I

like.”⁸² The 2019 NYTS showed that approximately 600,000 middle and high

this reasoning fallacious on its face, but the fact is that the FDA has never decided against a ban on menthol in cigarettes. Indeed, as recently as November 2020, in a pending case in the Northern District of California alleging the FDA has engaged in “unreasonable delay” in failing to address the menthol cigarette issue, the district court noted, in denying in part a motion to dismiss, that the FDA has “disclaimed any decision not to ban menthol”⁹²

Moreover, recent events have now thoroughly undermined Appellants’ argument. On April 29 of this year, the

Not only does LA County’s ban on the retail sale of menthol cigarettes not stand as an obstacle to federal policy, it is entirely supportive of that policy, which is now to prohibit the manufacture of menthol cigarettes through notice-and-comment rulemaking. The Flavors Ordinance is equally consonant with the FDA’s proposal to issue a product standard to prohibit the manufacture of all flavored cigars.

As for flavored e-cigarettes, Appellants’ argument is based entirely on a mischaracterization of FDA action. Because the e-cigarettes on the market lack the statutorily-mandated marketing orders, they are subject to FDA enforcement actions. Appellants rely on an FDA Guidance issued originally in January 2020 for its claim that FDA “recently prohibited most flavored cartridge-based ENDS products – *except* menthol- or tobacco-flavored products – unless and until FDA specifically authorizes such products to be on the market.”⁹⁵ But the Guidance itself makes clear that it represents only the “current thinking” of FDA on the agency’s exercise of enforcement discretion as to e-cigarettes and “does not establish any rights for any person and is not binding on FDA or the public.”⁹⁶ Indeed, FDA already has modified the enforcement policy announced in that

⁹⁵ Appellants’ Principal Brief, at 51.

⁹⁶ Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised), 85 Fed. Reg. 23,973, 23,974 (April 30, 2020).

CONCLUSION

For these reasons, the *amici* public health, medical, and community organizations urge the Court to affirm the district court's judgment upholding the LA County Flavors Ordinance.

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ADDENDUM

Description of *Amici Curiae*

1. African American Tobacco Control Leadership Council

The African American Tobacco Control Leadership Council (AATCLC), formed in 2008, is composed of a cadre of dedicated community activists, academics, and researchers. Our work has shaped the national discussion and direction of tobacco control policy, practices, and priorities, especially as they affect the lives of Black Americans, African immigrant populations and ultimately, all smokers. AATCLC has an interest in flavored tobacco restrictions because such restrictions reduce death and disease especially among Black Americans and others who are disproportionately burdened by tobacco.

2. American Academy of Pediatrics, California

The American Academy of Pediatrics, California (AAP-CA) is a nonprofit organization incorporated in the state of California. It is comprised of the four AAP California regional chapters statewide, representing more than 5,000 California primary care and subspecialty pediatricians and pediatric residents. Our mission is to support and protect the health well-being of infants, children, adolescents, and young adults in California.

3. American Academy of Pediatrics, California Chapter 2

The most important element of the mission of the American Academy of Pediatrics, California Chapter 2 (AAP-CA2) is to champion optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. The AAP-CA2 has been advocating American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN), the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, makes cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, including supporting the Los Angeles County ordinance throughout the legislative process.

5.

AMA and CMA join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

9. Americans for Nonsmokers' Rights

Americans for Nonsmokers' Rights (ANR) is a national non-profit tobacco control advocacy organization based in Berkeley, California. Since its formation in 1976, ANR has been dedicated to protecting nonsmokers' rights to breathe smoke-free air in enclosed public spaces and workplaces and to preventing youth addiction to nicotine, including use of e-cigarettes and other flavored tobacco products. ANR represents a national constituency of over 12,000 individuals and organizations concerned about the health risk

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and implementation of strong tobacco laws and regulations that will lead to a

16. California

prevent the implementation of flavored tobacco sales restrictions is the industry placing their profits over the lives of LGBTQ+ people.

23. Parents Against Vaping e-cigarettes

Parents Against Vaping e-cigarettes (PAVe) is a national grassroots organization founded in 2018 by three moms in response to the youth vaping epidemic. The catalyst for PAVe was their discovery in April, 2018 that a JUUL representative had entered their sons' high-school through an outside anti-addiction group, without the school's knowledge, and told the 9th-grade students, without adults present, that JUUL was "totally safe" and would receive FDA approval "any day." (Their Congressional testimony about this incident was cited by FDA as evidence that JUUL had marketed directly to kids.) PAVe's volunteer parent advocates operate in multiple states across the country, including California. PaVe believes

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community organizations, faith-based organizations, and schools in the Los Angeles area.

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2021, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Ninth Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

/s/ Jordan Raphael