

**Case No. 20-55930**

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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

Appellants,

v.

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

Appellees.

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On Appeal from the United States District Court for the Central  
District of California No. 2:20-cv-4880 (Hon. Dale S. Fischer)

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**BRIEF OF PUBLIC HEALTH AND MEDICAL  
ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF  
APPELLEES**

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## **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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*Amici* public health, medical, and community organizations submit this brief urging the Court to uphold the District Court orders granting Defendants’ Motion to Dismiss and Denying Plaintiffs’ Motion for Summary Judgment, thus upholding LA County’s ordinance prohibiting the retail sale of flavored tobacco products (the “Flavors Ordinance”).<sup>1</sup> This brief is filed with the consent of the parties.

**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 California
- American Academy of Pediatrics, California Chapter 2
- American Cancer Society Cancer Action Network
- American College of Physicians, California Services Chapter
- American Heart Association
- American Lung Association
- American Medical Association
- Americans for Nonsmokers’ Rights

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

- American Public Health Association
- American Thoracic Society
- Breathe Southern California
- California Academy of Family Physicians
- California Medical Association
- California Public Interest Research Group
- California Society of Addiction Medicine
- California Thoracic Society
- Campaign for Tobacco-Free Kids
- Equality California
- Kaiser Permanente
- Los Angeles County Medical Association
- OUT Against Big Tobacco Los Angeles
- Parents Against Vaping E-cigarettes
- Truth Initiative
- St. John's Well Child and Family Center

As is evident from the description of the *amici* included in the Addendum to this brief, each of these groups works, on a daily basis, to reduce the devastating health harms of tobacco products. From pediatricians who counsel their young patients and their parents about the hazards of tobacco use, to organizations with

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.<sup>2</sup> 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.<sup>3</sup> The industry has also

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<sup>2</sup> 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>.

<sup>3</sup> 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 products are essential. No matter what the tobacco product – from cigarettes to e-cigarettes to 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 (“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.<sup>4</sup> Indeed, at least two-thirds of youth tobacco users reported using these products “because they come in flavors I like.”<sup>5</sup> 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.”<sup>6</sup> By enacting the Flavors Ordinance, LA County has sought to protect its residents – and particularly its young people – from the continuing and increasing scourge of flavored tobacco products that lure millions into a lifetime of addiction and contribute so significantly to disease and death.

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[https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\\_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf)

<sup>4</sup> 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>.

<sup>5</sup> *Id.* at 1873.

<sup>6</sup> 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) (“Advance Notice of Proposed Rulemaking”).

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,<sup>7</sup> 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

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<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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

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<sup>8</sup> Appellants’ Principal Brief, at 5.

<sup>9</sup> 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>.

cite only their own comments to FDA,<sup>10</sup> menthol cigarettes are a substantial threat to public health because they increase the risk of youth initiation of smoking, increase addiction, and disproportionately affect the African American community, thus exacerbating serious health disparities. By preserving broad local authority to adopt laws relating to or prohibiting the sale of tobacco products, the Tobacco Control Act makes possible the additional public health benefits provided by the Flavors Ordinance to the residents of LA County.

**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. By masking the harshness and soothing the irritation caused by tobacco smoke, menthol cigarettes make it easier for beginners to experiment with cigarettes and ultimately become addicted. Thus, young smokers are more likely to use menthol cigarettes than any other age group. As the FDA has stated, “[m]ultiple studies show a greater use of menthol cigarettes by younger smokers and less usage among older smokers.”<sup>11</sup> 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

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<sup>10</sup> See Appellants’ Principal Brief, at 11.

<sup>11</sup> Advance Notice of Proposed Rulemaking, *supra* note 6, at 12,296.

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.<sup>12</sup> Since 90% of adult smokers begin smoking in their teens,<sup>13</sup> 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.<sup>14</sup> TPSAC concluded that "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States."<sup>15</sup>

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 Menthol versus Nonmenthol Cigarettes* ("FDA Report") reached the

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<sup>12</sup> Tobacco Products Scientific Advisory Committee (TPSAC), FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* at 136, 199-202 (2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> ("TPSAC Menthol Report").

<sup>13</sup> OSG, *supra* note 3.

<sup>14</sup> TPSAC Menthol Report, *supra* note 12, at 221.

<sup>15</sup> *Id.* at 225.

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.”<sup>16</sup>

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.<sup>17</sup> Another government survey, the National Survey of Drug Use and Health, found that preference for menthol among cigarette smokers is inversely correlated with age.<sup>18</sup> 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

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

<sup>17</sup> 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>.

<sup>18</sup> 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>.

menthol cigarettes.<sup>19</sup> Initiation with menthol cigarettes was higher among black smokers (93.1%) compared to white smokers (43.9%).<sup>20</sup>

The devastating health impact of menthol cigarettes is perhaps most dramatically shown by a recent study by researchers from the University of Michigan. With the same methodology used by TPSAC, the new study estimates that, by slowing down the decline in smoking prevalence, 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.<sup>21</sup> 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.<sup>22</sup>

The impact of menthol cigarettes in attracting kids, and keeping them addicted, has profoundly adverse effects on their health. The FDA has found that “smoking cigarettes during adolescence is associated with lasting cognitive and behavioral impairments, including effects on working memory in smoking teens

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<sup>19</sup> 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(9) NICOTINE & TOBACCO RSCH 1062, 1064 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6093322/>.

<sup>20</sup> *Id.*

<sup>21</sup> Thuy Le & David Mendez, *An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018*, TOBACCO CONTROL, 3 (Feb. 25, 2021) <https://tobaccocontrol.bmj.com/content/early/2021/02/09/tobaccocontrol-2020-056256.info>.

<sup>22</sup> *Id.*

and alterations in the prefrontal attentional network in young adult smokers.”<sup>23</sup>

“Use of tobacco products,” according to the FDA, “puts youth and young adults at greater risk for future health issues, such as coronary artery disease, cancer, and other known tobacco-related diseases.”<sup>24</sup>

Moreover, the increased smoking prevalence due to menthol cigarettes is of heightened concern because of the COVID-19 pandemic. According to the Centers for Disease Control and Prevention (“CDC”), “[b]eing a current or former cigarette smoker *can make you more likely* to get severely ill from COVID-19.”<sup>25</sup> Thus, just as prohibiting of the sale of menthol cigarettes was important to public health in LA County before the current pandemic, it is even more vital now.

### **B. Menthol Cigarettes Increase Addiction and Reduce Cessation.**

The TPSAC and FDA reports found that, in addition to increasing initiation of smoking among young people, menthol cigarettes are associated with increased nicotine dependence and reduced success in smoking cessation, particularly among African American smokers.<sup>26</sup>

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<sup>23</sup> Advance Notice of Proposed Rulemaking, *supra* note 6.

<sup>24</sup> *Id.* at 12,295-96.

<sup>25</sup> CDC, *Coronavirus Disease 2019 (COVID-19) – People with Certain Medical Conditions* (Mar. 29, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

<sup>26</sup> TPSAC Menthol Report, *supra* note 12, at 49; FDA Report, *supra* note 16, at 6.

More recent research bolsters these findings. The 2020 Surgeon General's Report on smoking cessation cited numerous studies finding an association between menthol use and lower cessation rates. The report concluded that the evidence is suggestive that restricting menthol products would lead to increased smoking cessation.<sup>27</sup> Recent 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 smokers.<sup>28</sup> 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.<sup>29</sup>

Data from the 2017 and 2018 NYTS 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.<sup>30</sup> Data

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<sup>27</sup> OSG, HHS, *Smoking Cessation: A Report of the Surgeon General*, 12 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>28</sup> 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*, NICOTINE & TOBACCO RSCH, 4 (Oct. 16, 2020), <https://doi.org/10.1093/ntr/ntaa212>.

<sup>29</sup> *Id.*

<sup>30</sup> Sunday Azagba et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent Smokers*, 66(5) J. OF ADOLESCENT HEALTH 545, 548-549 (2020), <https://pubmed.ncbi.nlm.nih.gov/31964612/>.

from the government PATH study shows that youth menthol smokers have significantly higher levels of certain measures of dependence,<sup>31</sup> and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.<sup>32</sup> 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.<sup>33</sup> For example, the industry has strategically placed

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<sup>31</sup> 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>.

<sup>32</sup> 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>.

<sup>33</sup> 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](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.<sup>34</sup> 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.<sup>35</sup> R.J. Reynolds estimated that they reached at least half of African Americans in five cities through their street festivals.<sup>36</sup>

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

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<sup>34</sup> Hope Landrine et al., *Cigarette Advertising in Black, Latino and White Magazines, 1998-2002: An Exploratory Investigation*, 15(1) ETHNIC DISPARITIES 63, 65 (2005), <https://www.ethndis.org/priorarchives/Ethn-15-01-63.pdf>.

<sup>35</sup> 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. Yerger et al., *Racialized Geography, Corporate Activity, and Health Disparities: Tobacco Industry Targeting of Inner Cities*, 18(4 Suppl) 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>.

<sup>36</sup> Yerger et al., *supra* note 35.

radio giveaways with cigarette purchases and a hip hop DJ competition in major cities.<sup>37</sup> 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.”<sup>38</sup>

To this day, Black 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.<sup>39</sup> Another 2011 California study found that, as the proportion of African American high school students in a neighborhood rose, the proportion of menthol advertising increased.<sup>40</sup> A 2021 study found that in LA County, stores located in predominantly African American neighborhoods had significantly higher odds of selling Newport cigarettes (the most popular menthol brand) than stores in Hispanic or non-

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<sup>37</sup> Hafez & Ling, *supra* note 35, at 362-63.

<sup>38</sup> TPSAC Menthol Report, *supra* note 12, at 92.

<sup>39</sup> Nina Schleicher et al., *California Tobacco Retail Surveillance Study 2018*, 3, 22 (2019), <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf>.

<sup>40</sup> Lisa Henriksen et al., *Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods*, 14 NICOTINE TOBACCO RSCH 116, 118 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592564/>.

Hispanic White neighborhoods.<sup>41</sup> 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.<sup>42</sup>

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.<sup>43</sup> In 2018, 85% of African American smokers smoke menthol cigarettes, compared to 29% of Whites.<sup>44</sup> In its 2011 TPSAC Report, the FDA concluded that menthol cigarettes are associated with lower levels of smoking cessation among African Americans.<sup>45</sup> 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.<sup>46</sup>

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<sup>41</sup> 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](https://www.cdc.gov/PCD/issues/2021/20_0144.htm).

<sup>42</sup> *Id.*

<sup>43</sup> 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>.

<sup>44</sup> Delnevo et al., *supra* note 18, at 1674.

<sup>45</sup> TPSAC Menthol Report, *supra* note 12, at 147.

<sup>46</sup> *Id.* at 206.

Indeed, the public health impact of menthol cigarettes on African Americans is made especially clear by the COVID-19 pandemic, which has revealed stark health disparities across our nation. A Harvard University analysis of COVID-19 mortality rates by race and ethnicity found that Black COVID-19 patients between 25 and 54 years old were approximately seven to nine times as likely to die from COVID-19 as White COVID-19 patients.<sup>47</sup> According to CDC, “COVID-19 has unequally affected many racial and ethnic minority groups, putting them more at risk of getting sick and dying from COVID-19.”<sup>48</sup> The disproportionate burden of COVID-19 on the African American community underscores the importance of the Flavors Ordinance to that community in LA County, given the disproportionate impact of menthol cigarettes on its Black residents, which, in turn, increases the vulnerability of Black smokers to the worst effects of the novel coronavirus.

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<sup>47</sup> Mary T. Bassett et al., *The Unequal Toll of COVID-19 Mortality by Age in the United States: Quantifying Racial/Ethnic Disparities*, 9 (2020), [https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20\\_Bassett-Chen-Krieger\\_COVID-19\\_plus\\_age\\_working-paper\\_0612\\_Vol-19\\_No-3\\_with-cover-1.pdf](https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20_Bassett-Chen-Krieger_COVID-19_plus_age_working-paper_0612_Vol-19_No-3_with-cover-1.pdf).

<sup>48</sup> CDC, *Health Equity Considerations and Racial and Ethnic Minority Groups* (Apr. 19, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>.

## 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,<sup>49</sup> the most commonly used tobacco product among U.S. youth since 2014.<sup>50</sup> In December 2018, Surgeon General Jerome Adams issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.”<sup>51</sup> The 2020 NYTS showed that almost 1 in 5 (19.6%) of high school students are current users of e-cigarettes,<sup>52</sup> a prevalence rate that more than doubled from 2017 to 2019 (from 11.7% to 27.5%).<sup>53</sup> An alarming 3.6 million high

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<sup>49</sup> By “e-cigarettes,” *amici* refer to the full range of devices within the scope of the definition of “electronic smoking devices” in the Flavors Ordinance. *See* L.A. COUNTY, CAL., CODE § 11.35.020(I) (2021).

<sup>50</sup> Karen A. Cullen et al., *e-Cigarette use among Youth in the United States, 2019* 322(21) J. AM. MED. ASS’N 2095, 2096 (2019), <https://jamanetwork.com/journals/jama/fullarticle/2755265>.

<sup>51</sup> 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>.

<sup>52</sup> Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69(37) MORBIDITY & MORTALITY WKLY. REP. 1310, 1310 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

<sup>53</sup> Cullen et al., *supra* note 50, at 2097.

school and middle school students are current e-cigarette users<sup>54</sup> – about the same number as when the Surgeon General first called youth e-cigarette use an “epidemic” in 2018.<sup>55</sup> 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.<sup>56</sup>

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).<sup>57</sup> Even more alarming, 22.5% of high school e-cigarette users reported *daily* use, a strong indication of deep addiction.<sup>58</sup> In total, 1.3 million middle and high school students are frequent users of e-cigarettes, including over 700,000 daily users.<sup>59</sup>

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<sup>54</sup> Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Student – United States, 2020*, 69(50) MORBIDITY & MORTALITY WKLY. REP. 1881, 1884 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf>.

<sup>55</sup> OSG, *supra* note 51.

<sup>56</sup> Shu-Hong Zhu et al., *Tobacco Use among High School Students in Los Angeles County: Findings from the 2017-18 California Student Tobacco Survey*, 9 (2019), [http://publichealth.lacounty.gov/tob/pdf/Tobacco\\_Use\\_among\\_High\\_School\\_Students\\_in\\_Los\\_Angeles\\_County\\_Findings\\_from\\_the\\_2017-18\\_CSTS.pdf](http://publichealth.lacounty.gov/tob/pdf/Tobacco_Use_among_High_School_Students_in_Los_Angeles_County_Findings_from_the_2017-18_CSTS.pdf).

<sup>57</sup> Wang et al., *supra* note 52.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

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.<sup>60</sup> 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.<sup>61</sup> E-liquids are being sold in such kid-friendly options as cotton candy, peanut butter cup and gummy bear. The data confirm that flavors play a major role in youth initiation and use of e-cigarettes. 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.”<sup>62</sup> NYTS 2020 data show that 83% of current middle and high school e-cigarette users had used a flavored product in the past month.<sup>63</sup>

Flavored e-cigarettes and refill liquids typically contain nicotine, a highly addictive drug that can have lasting damaging effects on adolescent brain

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<sup>60</sup> Greta Zhu et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites*, 20(3) J. MED. INTERNET RSCH. e80 (2018), <https://www.jmir.org/2018/3/e80/>.

<sup>61</sup> Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3, iii5 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078673/>.

<sup>62</sup> OSG, *supra* note 27, at 611.

<sup>63</sup> Wang et al., *supra* note 52.

development.<sup>64</sup> 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.”<sup>65</sup> Nicotine also impacts the cardiovascular system.<sup>66</sup> The Surgeon General has warned that, “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”<sup>67</sup>

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 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

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<sup>64</sup> HHS, *Know the Risks: E-Cigarettes & Young People* (2021), <https://e-cigarettes.surgeongeneral.gov/>; see also CDC, *Electronic Nicotine Delivery Systems: Key Facts* (2016), <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

<sup>65</sup> OSG, *supra* note 51, at 1.

<sup>66</sup> OSG, HHS, *Cardiovascular System, in How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, 407 (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53012/>.

<sup>67</sup> 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](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf).



conventional cigarettes, exhaled aerosol from e-cigarettes may include nicotine and other toxicants that can pose risks for non-users.

*Nicopure*, 944 F.3d 267, 274 (D.C. Cir. 2019) (internal citations omitted).

Use of e-cigarettes also may 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.”<sup>68</sup> 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. The researchers estimated that this translates to over 43,000 current youth combustible cigarette smokers who might not have become smokers without e-cigarettes during a period prior to the recent explosion of youth e-cigarette use.<sup>69</sup> The evidence supporting this gateway effect continues to mount. A 2020 Truth Initiative study found that youth and youth adults ages 15-27 who

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<sup>68</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-cigarettes* 10 (2018), [https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf\\_NBK507171.pdf](https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf)

<sup>69</sup> Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, 2(2) J. AM. MED. ASS’N NETWORK OPEN 1, 6 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.

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.<sup>70</sup>

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.<sup>71</sup> According to an industry publication, “[w]hile different cigars target a variety of markets, all flavored

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<sup>70</sup> 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>.

<sup>71</sup> 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>.

tobacco products tend to appeal primarily to younger consumers.”<sup>72</sup> 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.<sup>73</sup> 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.<sup>74</sup>

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

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<sup>72</sup> 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](https://web.archive.org/web/20081121103907/http://www.tobaccoretailer.com/uploads/Features/2007/0407_flavored_smokes.asp).

<sup>73</sup> *Id.*

<sup>74</sup> 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.”).

<sup>75</sup> 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”).

Blueberry.”<sup>76</sup> From 2008 to 2015, the number of unique cigar flavor names more than doubled.<sup>77</sup> 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.<sup>78</sup>

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

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<sup>76</sup> 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](https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf).

<sup>77</sup> Cristine D. Delnevo et al., *Changes in the Mass-merchandise Cigar Market Since the Tobacco Control Act*, 3(2 Suppl 1) TOBACCO REG. SCIENCE S8, S12 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351883/pdf/nihms852155.pdf>.

<sup>78</sup> *Id.* at S10.

<sup>79</sup> 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, 29,023 (May 10, 2016) (“Final Deeming Rule”).

<sup>80</sup> Gentzke et al., *supra* note 54.

<sup>81</sup> SAMHSA, 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>.

like.”<sup>82</sup> The 2019 NYTS showed that approximately 600,000 middle and high school students had used a flavored cigar in the last 30 days.<sup>83</sup>

Moreover, as with menthol cigarettes, years of research have documented greater cigar availability and more cigar marketing, including flavored cigars and price promotion, in Black neighborhoods.<sup>84</sup> It is not surprising, therefore, that in 2020, 9.2% of Black high school students reported smoking cigars, compared to 5% of all high school students,<sup>85</sup> and Black high school students smoked cigars at more than three times the rate of cigarettes.<sup>86</sup>

As the FDA has found, “[a]ll cigars pose serious negative health risks.”<sup>87</sup> 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.”<sup>88</sup> 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

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<sup>82</sup> Ambrose et al., *supra* note 4, at 1873.

<sup>83</sup> Wang et al., *supra* note 17.

<sup>84</sup> Campaign for Tobacco-Free Kids et al., *Stopping Menthol, Saving Lives*, *supra* note 33, at 10.

<sup>85</sup> Gentzke et al., *supra* note 54.

<sup>86</sup> *Id.*

<sup>87</sup> Final Deeming Rule, *supra* note 79, at 29,020.

<sup>88</sup> *Id.*

disease (COPD),” a higher risk of death from COPD, and “a higher risk of fatal and nonfatal stroke” compared to non-smokers.<sup>89</sup>

Thus, there is no question that the Flavors Ordinance affords LA County residents with greater protection from the adverse public impact of flavored cigars, particularly on young people.

#### **IV. Appellants’ Account of FDA Activity on Flavored Tobacco Products is Misleading and Should Have No Impact on the Preemption Issue.**

In the face of express language in the Tobacco Control Act preserving broad state and local authority to enact laws “relating to or prohibiting the sale . . . of tobacco products,” Appellants argue that federal law impliedly preempts the Flavors Ordinance, ostensibly both through the FDA’s inaction (on menthol cigarettes and certain flavored e-cigarettes)<sup>90</sup> and its active consideration of a ban on flavored cigars.<sup>91</sup>

As to menthol cigarettes, Appellants’ reasoning is as follows: because FDA has considered banning menthol in cigarettes and has received comments (from the industry) opposing such a product standard, it necessarily follows that FDA’s inaction on menthol constitutes a regulatory decision against banning menthol in cigarettes which, in turn, impliedly preempts the Flavors Ordinance. Not only is

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<sup>89</sup> *Id.*

<sup>90</sup> Appellants’ Principal Brief, at 51-55.

<sup>91</sup> *Id.* at 51.

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 . . . .”<sup>92</sup>

Moreover, recent events have now thoroughly undermined Appellants’ argument. On April 29 of this year, the FDA announced that it intended to issue “proposed product standards within the next year to ban menthol as a characterizing flavor in cigarettes and ban all characterizing flavors (including menthol) in cigars.”<sup>93</sup> The FDA’s Acting Commissioner, Dr. Janet Woodcock, stated that such product standards “will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products. All together these actions represent powerful, science-based approaches that will have an extraordinary public health impact.”<sup>94</sup>

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<sup>92</sup> Order Granting in Part and Denying in Part Motion to Dismiss at 9, *AATCLC v. FDA*, No. 4:20-cv-04012-KAW (N.D. Cal. Nov. 12, 2020), ECF No. 34.

<sup>93</sup> FDA, *supra* note 9.

<sup>94</sup> *Id.*

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.”<sup>95</sup> 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.”<sup>96</sup> Indeed, FDA already has modified the enforcement policy announced in that

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<sup>95</sup> Appellants’ Principal Brief, at 51.

<sup>96</sup> 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).



Guidance by now prioritizing enforcement against flavored disposable e-cigarettes,<sup>97</sup> and it may further revise its enforcement priorities in the future.

Appellants cite to no case holding that the transient enforcement policies of an agency preempt state and local laws. Statutes are impliedly preempted only when it is “the clear and manifest purpose of Congress” to do so. *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Santa Fe Elevator Corp.* 331 U.S. 218, 230). It is the express preservation of state and local authority in the Tobacco Control Act that establishes the “manifest purpose” of Congress, not FDA’s transient enforcement policies.<sup>98</sup> That the FDA is not currently prioritizing enforcement against certain menthol and tobacco-flavored e-cigarettes has no preemptive impact on the Flavors Ordinance.

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<sup>97</sup> Press Release, Commissioner of Food and Drugs – Food and Drug Administration (December 2019 – January 2021), Stephen M. Hahn, M.D., National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products (Sept. 9, 2020), <https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use>.

<sup>98</sup> This is especially true in the case of FDA’s enforcement policy toward tobacco products on the market without the required marketing orders, given that FDA’s enforcement policy itself was previously held contrary to the Tobacco Control Act, in a lawsuit brought by some of the *amici* here. *See Am. Acad. Of Pediatric v. FDA*, 379 F.Supp. 3d 461, 494 (D.Md. 2019), *appeal dismissed as moot, In re Cigar Ass’n of Am.*, 812 F. App’x 128 (4th Cir. 2020) (“The decision here, not to enforce the premarket review requirements against any manufacturers, . . . is inconsistent with the Tobacco Control Act and . . . cannot stand.”).

## 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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Respectfully submitted,

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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 to ban the sale of flavored tobacco in our seven-county region since 2018. As an organization representing 1,600 pediatricians and pediatric subspecialists, our goal is to eliminate flavored tobacco, a highly addictive product that lures our youth into lifetime addiction.

#### 4. 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. American College of Physicians, California Services Chapter

The American College of Physicians (ACP) California Services Chapter is the advocacy arm of the California ACP which is one of the largest medical specialty organization in the State of California and nationally. The ACP members include internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment and compassionate care of adults across the spectrum from health to complex illness. California ACP Services supports national ACP policy that recommends flavors, including menthol, be eliminated from all tobacco products.

6. American Heart Association

The American Heart Association (AHA) is a voluntary health organization that, since 1924, has been devoted to saving people from heart disease and stroke—the two leading causes of death in the world. AHA teams with millions of volunteers to fund innovative research, fight for stronger public health policies, and provide lifesaving tools and information to prevent and treat these diseases. The Dallas-based association with local offices in all 50 states, as well as in Washington, D.C. and Puerto Rico, is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke.

7. American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including supporting eliminating the sale of all flavored tobacco products.

8. American Medical Association

The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including California. The

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 that tobacco and other nicotine products pose to the health and safety of smokers and nonsmokers alike and committed to reducing and preventing tobacco and e-cigarette use.

10. American Public Health Association

The American Public Health Association (APHA) champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices, and advocates for public health policies grounded in research. APHA represents over 23,000 individual members and is the only organization that combines a nearly 150-year perspective and a broad-based member community with an interest in improving the public's health. APHA advocates for tobacco control measures to protect the public's health from the adverse effects of tobacco products.

11. American Thoracic Society

The American Thoracic Society is a 16,000-member medical professional society dedicated to the prevention, detection, treatment and cure of respiratory disease, critical care illness and sleep disordered breathing. As lung doctors, ATS members know first-hand the needless death and disease caused by tobacco use and support policies to reduce nicotine use.

12. Breathe Southern California

Breathe Southern California is a 501(c)(3) nonprofit organization with a mission to improve lung health and air quality. The organization advocates for the adoption

and implementation of strong tobacco laws and regulations that will lead to a meaningful reduction in tobacco use and related illnesses. Additionally, Breathe Southern California provides an education program called FiRST!, which aims to provide students with the skills and knowledge to resist tobacco and nicotine use and empower them to lead the first smoke-free generation.

13. California Academy of Family Physicians

The California Academy of Family Physicians (CAFP) is the only organization solely dedicated to advancing the specialty of family medicine in the state. Since 1948, CAFP has championed the cause of family physicians and their patients. CAFP is critically important to primary care, with a strong collective voice of more than 11,000 family physician, family medicine resident, and medical student members. CAFP is the largest primary care medical society in California and the largest chapter of the American Academy of Family Physicians.

14. California Medical Association

The California Medical Association (CMA) is a non-profit, incorporated professional physician association of approximately 50,000 members throughout the State of California. For more than 160 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's membership includes California physicians engaged in the private practice of medicine in all specialties and settings. CMA and its physician members advocate for laws and policies that promote the health of their patients and communities.

15. California Public Interest Research Group

The California Public Interest Research Group (CALPIRG) is a consumer group that stands up to powerful interests whenever they threaten our health and safety, our financial security, or our right to fully participate in our democratic society. For more than forty years, CALPIRG has been an advocate for stronger public health protections. We have supported efforts at the state and local level to prevent more children from becoming addicted to nicotine. Headquartered in Sacramento, CALPIRG is supported by thousands of individual contributors across the state of California.

16. California Society of Addiction Medicine

California Society of Addiction Medicine (CSAM), founded in 1973, is the largest and most active state chapter of the American Society of Addiction Medicine (ASAM). The specific purpose of the Society is to advance the treatment of addictions through the education of physicians, other health professionals, and policy makers. CSAM members engage in a wide spectrum of public policy activities in California, advocating for patients and producing large scale and local education programs.

17. California Thoracic Society

The California Thoracic Society (CTS) is a professional society committed in its mission to improve California lung health and to advance the science and practice of pulmonary and critical care medicine through advocacy and education. Members of the CTS are fully aware of the preventable morbidity and mortality borne by the citizens of California caused by tobacco products and CTS supports state action to reduce its toll.

18. Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke. The Campaign for Tobacco-Free Kids has an interest in flavored tobacco restrictions in Los Angeles County because restrictions impact the use of tobacco products by young people.

19. Equality California

Founded in 1999, Equality California is the nation's largest statewide lesbian, gay, bisexual, transgender and queer (LGBTQ+) civil rights organization. Equality California brings the voices of LGBTQ+ people and allies to institutions of power in California and across the United States, striving to create a world that is healthy, just, and fully equal for all LGBTQ+ people. We advance civil rights and social justice by inspiring, advocating, and mobilizing through an inclusive movement that works tirelessly on behalf of those we serve. Equality California frequently participates in litigation in support of the rights of LGBTQ+ persons. The tobacco industry has preyed on LGBTQ+ people and the diverse communities to which

LGBTQ+ people belong for decades, as affirmed by the Centers for Disease Control and Prevention.

20. Kaiser Permanente

Kaiser Permanente (KP) is the largest private integrated health care delivery system in the United States, serving more than 12.4 million members in eight states and the District of Columbia, including 9.2 million members in California. KP's mission is not just to provide health care to our members, but also to create healthier communities. Reducing youth tobacco use has been a key goal at KP for many years. We are looked to as having expertise in clinical care, including tobacco prevention and cessation programs, and for our efforts in the broader community to help children and young adults value and maintain a tobacco-free lifestyle. KP supports removing all flavored tobacco products from the market and advocated strongly in favor of SB 793 (Hill – 2020). In addition, KP's national leadership in a broad portfolio of pioneering tobacco control efforts demonstrates a strong psychological stake and demonstrated interest in this case because upholding the legislation in question will have a positive impact on KP's steadfast mission to improve the health of our members and communities we serve.

21. Los Angeles County Medical Association

Los Angeles County Medical Association (LACMA) is the nation's largest county medical organization with over 7,000 members and has been an emphatic voice on protecting the health and well-being of the most vulnerable populations across the Los Angeles region; specifically fighting the egregious marketing tactics deployed by the flavored tobacco industry from device companies to retailers.

22. OUT Against Big Tobacco Los Angeles

The OUT Against Big Tobacco Los Angeles Coalition ("the Coalition") is an alliance of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, allies and community organizations collectively working to address tobacco control and health inequity issues within Los Angeles County's LGBTQ+ community. The Coalition advocates for common sense policies that protect LGBTQ+ people — especially the most vulnerable members of the LGBTQ+ community, including LGBTQ+ people of color, transgender and gender-nonconforming people, and LGBTQ+ young people — from the tobacco industry's documented predatory marketing tactics. Attempts by Big Tobacco to delay or



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 that regulatory and legislative change at the state level is key to slowing the explosive growth of teen vaping and protecting teens from the predatory behavior of Big Tobacco.

### 24. Truth Initiative

Truth Initiative Foundation d/b/a Truth Initiative (Truth Initiative) is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth smoking, vaping, and nicotine use and to prevent diseases associated with tobacco products. Its national recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.

### 25. St. John's Well Child and Family Center

St. John's Well Child and Family Center is a Federally Qualified Health Center in Los Angeles County that operates 19 clinics, including nine school-based health centers, and two mobile clinics that provide services for over 400,000 patient visits annually. We conduct tobacco use screenings and are an active member of the Asthma Coalition of Los Angeles County. St. John's provides one-on-one education in addition to educational presentations on various health conditions impacting the community along with information on our services to individuals,

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

**CERTIFICATE OF COMPLIANCE**

I certify:

- (i) That this brief complies with the type-volume limits of Fed. R. App. P. 29(a)(5) because it contains 6,820 words, excluding the parts exempted by Fed. R. App. P. 32(f).
- (ii) That this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared using Microsoft Office Word 16 and is set in 14-point Time New Roman font.

May 14, 2021

/s/ Jordan Raphael

**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