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UNITED STATES DISTRICT COURT

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CENTRAL DISTRICT OF CALIFORNIA

11

WESTERN DIVISION

12

CA SMOKE & VAPE ASSOCIATION
INC., D/B/A CARR and ACE SMOKE
SHOP,

Case No. 2:20-cv-4065-DSF(KSx)

13

Plaintiffs,

**[PROPOSED] BRIEF OF AMICI
CURIAE IN OPPOSITION TO
PLAINTIFFS' MOTION FOR
PRELIMINARY INJUNCTION**

14

v.

Hearing

15

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

Date: June 8, 2020
Time: 1:30 p.m.
Ctvm: 7D, the Hon. Dale S. Fischer

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Defendants.

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1 Deeming Tobacco Product To Be Subject to the Federal Food, Drug,
2 and Cosmetic Act, as Amended by the Family Smoking Prevention
3 Tobacco Control Act; Restrictions on the Sale and Distribution of
4 Tobacco Products and Required Warning Statements for Tobacco
5 Products (Final Rule), 81 Fed. Reg. 28,974 (May 20, 2016)..... 14
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1 struggling to free young people from nicotine addiction, each of these organizations
2 has a direct and immediate interest in curbing the sale of flavored tobacco products,
3 as well as demonstrable expertise in the role those products play in enticing young
4 people to tobacco use. An injunction preventing enforcement of the Flavors
5 Ordinance in Los Angeles County would undercut the efforts of these organizations
6 to curb tobacco use, particularly among the young. The *amici* are particularly well
7 suited to inform the Court of the full range of community health harms that an
8 injunction would cause, thus providing the Court with the most complete
9 information needed for a fair balancing of the hardships in this case and an accurate
10 assessment of the effect of an injunction on the public interest.

11 INTRODUCTION

12 The use of tobacco products is the leading cause of preventable death in the
13 United States, taking upwards of 480,000 lives every year.¹ The tobacco industry
14 has long understood that almost all new tobacco users begin their addiction as kids.
15 Ninety percent of adult smokers begin smoking before leaving their teens.² The
16 industry has also known that to successfully market their products to young people,
17 flavored products are essential. No matter what the tobacco product – from
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19 ¹ U.S. Department of Health and Human Services (HHS), *The Health*
20 *Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*
21 2 (2014), <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>.

² HHS, SAMHSA, *National Survey on Drug Use and Health*, (2014),
<http://doi.org/10.3886/ICPSR36361.v1>.

1 cigarettes to cigars to smokeless tobacco to e-cigarettes to hookah -- flavors
2 substantially increase the appeal of tobacco products to youth. Data from the U.S.
3 Food and Drug Administration (FDA)/NIH Population Assessment of Tobacco and
4 Health (PATH) study found that almost 81% of 12-17 year-olds who had ever used
5 a tobacco product initiated use with a flavored product.³ For each tobacco product,
6 at least two-thirds of youth reported using these products “because they come in
7 flavors I like.”⁴ As the FDA has found, “the availability of tobacco products with
8 flavors at these developmental stages attracts youth to initiate use of tobacco
9 products and may result in lifelong use.”⁵

10 Indeed, flavored e-cigarettes – the products plaintiffs seek to continue to sell
11 in Los Angeles County – have fueled an explosion of e-cigarette use among teens.
12 Among high school students, e-cigarette use more than doubled from 2017 to 2019,
13 increasing from 11.7% to 27.5%. Over 5.3 million youth were current e-cigarette
14 users in 2019 – a remarkable increase of over 3 million students since 2017.⁶

17 ³ Bridget K. Ambrose, et al., *Flavored Tobacco Product Use Among US Youth*
18 *Aged 12-17 Years, 2013-2014*, 314(7) JAMA 1871-3 (2015),

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6467270/>

19 ⁴ *Id.*

⁵ FDA, Regulation of Flavored in Tobacco Products, Advance notice of proposed
20 rulemaking, 83 Fed. Reg. 12,294, 12,295 (March 21, 2018),

<https://www.govinfo.gov/content/pkg/FR-2018-03-21/pdf/2018-05655.pdf>.

⁶ CDC, *Tobacco Product Use and Associated Factors Among Middle and High*
21 *School Students—United States, 2019*, 68(12) MMWR 18 (Dec. 6, 2019),

<https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

1 PATH study data shows that 97% of current youth e-cigarette users had used a
2 flavored product in the last month.⁷

3 By enacting the Flavors Ordinance, Los Angeles County has sought to
4 protect its residents – and particularly its young people – from the continuing and
5 increasing scourge of flavored tobacco products that lure millions into a lifetime of
6 addiction, disease and death. Plaintiffs seek an injunction that would deprive the
7 public of that vital public health protection. Moreover, plaintiffs seek an injunction
8 at a time when our nation is ravaged by the horrific spread of the novel coronavirus
9 and COVID-19 -- a deadly respiratory illness that has taken tens of thousands of
10 lives, while paralyzing daily life. Dr. Nora Volkow, Director of the U.S. National
11 Institute on Drug Abuse, has observed that “[b]ecause it attacks the lungs, the
12 coronavirus that causes COVID-19 could be an especially serious threat to those
13 who smoke tobacco or marijuana or who vape”⁸ Never has it been more
14 important to curb the sale of flavored tobacco products that lure kids to smoking
15 and vaping. Yet the injunction sought by plaintiffs would not only permit the
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18 ⁷ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance* 9 (Mar. 13, 2019),
19 <https://www.fda.gov/media/121384/download>.

20 ⁸ NIDA, *COVID-19: Potential Implications for Individuals with Substance Use Disorders*, Nora’s Blog (Mar. 24, 2020), <https://www.drugabuse.gov/about-nida/noras-blog/2020/03/covid-19-potential-implications-individuals-substance-use-disorders>.

1 continued sale of flavored e-cigarettes, but also the sale of mentholated cigarettes,
2 flavored cigars and other flavored tobacco products.

3 The County’s brief persuasively demonstrates that plaintiffs have little
4 likelihood of succeeding on the merits of their claims against the Flavors
5 Ordinance. As to federal preemption of local law, the County has shown that the
6 Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and
7 Tobacco Control Act (Tobacco Control Act) confers authority on the FDA to
8 regulate the manufacture of tobacco products through the issuance of product
9 standards, while expressly preserving to states and localities their traditional broad
10 authority to protect the health of their citizens by regulating the retail sale of
11 finished tobacco products. Indeed, every court that has considered the issue has
12 found that sales restrictions on flavored tobacco products are not preempted by
13 federal law. *See U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708
14 F.3d 428, 433-5 (2d. Cir. 2013) (upholding local sales restrictions on flavored
15 tobacco products because their application to a particular product “depends on its
16 characteristics as an end product, and not on whether it was manufactured in a
17 particular way or with particular ingredients.”); *Nat’l Ass’n of Tobacco Outlets, Inc.*
18 *v. City of Providence, R.I.*, 731 F.3d 71, 83, n.11 (1st Cir. 2013) (upholding local
19 restrictions on sale of flavored tobacco products, given “Congress’ decision to
20 exempt sales regulations from preemption. . . .”; *Indep. Gas & Serv. Stations*
21 *Ass’ns., Inc. v. City of Chicago*, 112 F.Supp.3d 749, 754 (N.D. Ill. 2015) (upholding

1 Chicago’s flavored tobacco sales restrictions as exempt from Tobacco Control Act
2 preemption provision because Chicago ordinance “regulates flavored tobacco
3 products without regard for how they are manufactured” and is “not a command to
4 implement particular manufacturing standards”). The Flavors Ordinance, because it
5 does not operate as a command to manufacturers limiting how a product is
6 manufactured or what ingredients it may contain, in no way interferes with FDA
7 authority to set product standards. Far from interfering with the federal regulatory
8 scheme, the Flavors Ordinance advances the Tobacco Control Act’s “objective of
9 reducing the use and harmfulness of tobacco products, especially among young
10 people.” *U.S. Smokeless Tobacco*, 708 F.3d at 436.

11 The County also has persuasively demonstrated that the Flavors Ordinance is
12 not unconstitutionally vague and does not promote arbitrary enforcement. Plaintiffs
13 here rely on an artificially constructed uncertainty as to what constitutes a
14 “characterizing flavor” under the Ordinance, while at the same time their own
15 declarant is sufficiently confident of its meaning as to assert that “[t]obacco
16 retailers, particularly smoke shops, maintain an inventory comprised of
17 approximately 90 to 95 percent in flavored tobacco products.” Pls.’ Mem. of P. &
18 A. 19; Decl. of Nader Faragi, ¶¶ 9-10, ECF No. 25. The “vagueness” of the
19 County’s Flavors Ordinance is imagined, not real.

20 Given the County’s thorough demonstration that plaintiffs are unlikely to
21 prevail on the merits of their legal claims, *amici* focus here on other factors to be

1 weighed by the Court in determining whether to grant a preliminary injunction: the
2 balance of the equities and whether an injunction would serve the public interest.
3 Plaintiffs' only claim of irreparable harm is the financial loss of being deprived of
4 the ability to continue to sell flavored e-cigarettes that are causing an epidemic of
5 youth nicotine addiction. As the *amici* here demonstrate, that financial harm is far
6 outweighed by the health harms long suffered by the residents of Los Angeles
7 County due to flavored tobacco products. By this brief, *amici* seek to inform the
8 Court of the scope of harm to public health that would be inflicted by an injunction
9 that would allow the continued sale in this County of flavored tobacco products.⁹
10 Because of that harm, the balance of equities tips decisively against a preliminary
11 injunction and such an injunction would be profoundly contrary to the public
12 interest.

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20 ⁹ The *amici's* discussion will focus on the harm from the continued sale of e-
21 cigarettes, menthol cigarettes and flavored cigars, although the public interest is
served by the Flavors Ordinance prohibition of other harmful and addictive flavored
tobacco products as well, including hookah and smokeless tobacco.

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ARGUMENT

I. The Health Harms of Continued Sale Of Flavored E-Cigarettes Weigh Significantly Against The Grant Of An Injunction.

A. E-Cigarettes Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth.

The most dramatic surge in youth usage of flavored tobacco products has occurred with e-cigarettes,¹⁰ as they have become by far the most commonly used tobacco product among U.S. youth. Whereas the 2019 National Youth Tobacco Survey (NYTS) showed that 5.8% of high school students smoked regular cigarettes, 27.5% used e-cigarettes.¹¹ In December 2018, Surgeon General Jerome Adams issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.”¹²

Kids are not just experimenting with e-cigarettes but are using them frequently. Alarming, 1 in 9 of all high school seniors (11.7%) report that they vaped nicotine nearly daily, a strong indication of deep addiction.¹³ Trends in e-

¹⁰ By “e-cigarettes,” *amici* refer to the full range of “electronic smoking devices” included in the definition of “tobacco product” in the Flavors Ordinance.

¹¹ *Supra* note 6.

¹² HHS, Office of the Surgeon General, *Surgeon General’s Advisory on E-Cigarette Use Among Youth* (Dec. 18, 2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

¹³ Richard Miech et al., *Trends in Adolescent Vaping, 2017-2019*, 381 *New Eng. J. Med.* 1490, 1491 (Oct. 10, 2019), <https://www.nejm.org/doi/full/10.1056/NEJMc1910739>.

1 cigarette use in Los Angeles County mirror the trends that are seen nationwide.
2 According to the California Student Tobacco Survey, e-cigarettes are the most
3 commonly used tobacco product among youth in Los Angeles County, surpassing
4 cigarettes, cigars, smokeless tobacco, and hookah.¹⁴

5 Tobacco companies have a long history of using flavors to reduce the
6 harshness of their products and make them more appealing to new users, almost all
7 of whom are under age 18.¹⁵ In recent years, companies have extended this strategy
8 to the emerging market for e-cigarettes. As of 2017, researchers had identified
9 more than 15,500 unique e-cigarette flavors available online.¹⁶ An earlier study of
10 e-cigarette flavors found that among the more than 400 brands available online in
11 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.¹⁷ E-
12 liquids are being sold in such kid-friendly options as cotton candy, peanut butter
13 cup, and gummy bear.

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15 ¹⁴ Shy-Hong Zhu, et al. *California Student Tobacco Survey, Los Angeles County*
16 *Findings* 7 (2017-18),
17 http://publichealth.lacounty.gov/tob/pdf/Tobacco_Use_among_High_School_Students_in_Los_Angeles_County_Findings_from_the_2017-18_CSTS.pdf.

18 ¹⁵ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the*
19 *Surgeon General* 483-628 (2012),
20 https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

21 ¹⁶ Greta Zhu et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to*
2016-2017: Analysis of Brand Websites, 20(3):e80 *J. Med. Internet Res.* (2018),
<https://www.jmir.org/2018/3/e80/>.

¹⁷ Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-cigarettes and*
Counting: Implications for Product Regulation, 23(3) *Tobacco Control* (2014),
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078673/>.

1 The data confirms that flavors play a major role in youth initiation and use of
2 e-cigarettes. The 2020 Surgeon General Report on smoking cessation notes that
3 “the role of flavors in promoting initiation of tobacco product use among youth is
4 well established . . . and appealing flavor is cited by youth as one of the main
5 reasons for using e-cigarettes.”¹⁸ As noted above, data from the 2016–17 wave of
6 the government’s PATH study found that 97% of current youth e-cigarette users
7 had used a flavored e-cigarette in the past month.¹⁹

8 Flavored e-cigarettes and refill liquids typically contain nicotine, a highly
9 addictive drug that can have lasting damaging effects on adolescent brain
10 development.²⁰ Nicotine also impacts the cardiovascular system.²¹ The Surgeon
11 General has warned that, “[t]he use of products containing nicotine in any form
12 among youth, including in e-cigarettes, is unsafe.”²²

15 ¹⁸ HHS, *Smoking Cessation, A Report of the Surgeon General* 611 (2020),
<https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

16 ¹⁹ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance* 9 (Mar. 13, 2019),
17 <https://www.fda.gov/media/121384/download>.

18 ²⁰ *Supra* note 1; see also CDC Office of Smoking and Health, *Electronic Nicotine Delivery Systems: Key Facts* (2016),
<https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

19 ²¹ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General* Chapter 6
20 (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53012/>.

21 ²² HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of the Surgeon General* 5 (2016), https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.

1 Flavorings in e-cigarettes can pose additional health hazards. According to
2 the Surgeon General, some of the flavorings found in e-cigarettes have been shown
3 to cause serious lung disease when inhaled.²³ An article in the Journal of the
4 American Medical Association raised concerns that the chemical flavorings found
5 in some e-cigarettes and e-liquids could cause respiratory damage when the e-
6 cigarette aerosol is inhaled deeply into the lungs.²⁴ *See also, Nicopure Labs, LLC v.*
7 *FDA*, 944 F.3d 267, 274 (D.C. Cir. 2019) (relying on findings that flavors in e-
8 cigarettes are harmful in upholding the application of FDA’s premarket review
9 process to e-cigarettes).

10 Use of e-cigarettes also may function as a gateway to the use of conventional
11 cigarettes and other combustible tobacco products, thereby undermining decades of
12 progress in curbing youth smoking. A 2018 report by the National Academies of
13 Science, Engineering and Medicine (NASEM) found “substantial evidence that e-
14 cigarette use increases risk of ever using combustible tobacco cigarettes among
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18 ²³ HHS, *Office of the Surgeon General, Surgeon General’s Advisory on E-Cigarette*
19 *Use Among Youth* (Dec. 18, 2018), [https://e-](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf)
20 [cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf)
21 [use-among-youth-2018.pdf](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf).

22 ²⁴ Jessica L. Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An*
Unrecognized Respiratory Health Hazard?, 312(23) *The Journal of the American*
23 *Medical Association* 2493-4 (2014),
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361011/>.

1 youth and young adults.”²⁵ A nationally representative analysis found that from
2 2013 to 2016, youth e-cigarette use was associated with more than four times the
3 odds of trying cigarettes and nearly three times the odds of current cigarette use.
4 The researchers estimated that this translates to over 43,000 current youth cigarette
5 smokers who might not have become smokers without e-cigarettes,²⁶ during a period
6 prior to the explosion of youth e-cigarette use from 2017-2019.

7 Thus, given the fast-spreading epidemic of youth e-cigarette use, caused in
8 large part by the appeal of flavored products, the immediate implementation of the
9 LA County Ordinance is critical to the County’s efforts to protect its young people
10 from the addictive and other harmful effects of e-cigarettes.

11 **B. Plaintiffs Exaggerate the Claimed Health Benefits of E-cigarettes.**

12 In seeking a preliminary injunction, plaintiffs speculate that former smokers
13 would return to more harmful combustible cigarettes if non-tobacco flavored
14 products were no longer available. Pls.’ Mem. of P. & A. 2, ECF No. 25. Plaintiffs
15 cite to no data showing that smokers have returned to combustible cigarettes in any
16 of the many jurisdictions that have banned the sales of flavored e-cigarettes, while
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18 _____
19 ²⁵ National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-cigarettes* 10 (2018)

20 https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

21 ²⁶ Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, 2(2):e187794 JAMA Network Open (2019),

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.

1 allowing tobacco-flavored products.²⁷ In fact, until the popular e-cigarette Juul was
2 introduced into the market and pushed the market to its flavored products, tobacco-
3 flavored e-cigarettes were the single most widely-used flavor, comprising 30–40%
4 of the retail market.²⁸ Moreover, the argument that e-cigarette users, deprived of
5 flavored products, would return to combustible cigarettes presumes that these users
6 had previously switched to e-cigarettes. According to the CDC, however, most
7 adult e-cigarette users are dual users, i.e., they continue to smoke cigarettes.²⁹ Dual
8 use, even with cutting back the number of cigarettes smoked, still elevates smokers'
9 health risks for conditions like cardiovascular disease.³⁰ Moreover, NASEM found

11 ²⁷ The jurisdictions that have taken action against flavored e-cigarettes are set out in
12 Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted the*
Sale of Flavored Tobacco Products (May 8, 2020),
13 <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

14 ²⁸ Alexa R. Romberg et al., *Patterns of Nicotine Concentrations in Electronic*
Cigarettes Sold in the United States, 2013-2018, 203 *Drug and Alcohol*
15 *Dependence* 1-7 (2019),
<https://www.sciencedirect.com/science/article/abs/pii/S0376871619302571?via%3Dihub>.

16 ²⁹ CDC, *QuickStats: Cigarette Smoking Status Among Current Adult E-cigarette*
Users, by Age Group — National Health Interview Survey, United States, 2015,
17 65(42) *Morbidity and Mortality Weekly Report* 1177 (Oct. 28, 2016),
<https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm>; see also CDC, *About*
Electronic Cigarettes (E-Cigarettes) (last visited May 18, 2020),
18 [https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#who-is-using-e-cigarettes)
[cigarettes.html#who-is-using-e-cigarettes](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#who-is-using-e-cigarettes).

19 ³⁰ Kjell Bjartveit & Aage Tverdal, *Health Consequences of Smoking 1-4 Cigarettes*
per Day, 14 *Tobacco Control* 315 (2005),
20 <https://tobaccocontrol.bmj.com/content/14/5/315>; Allen Hackshaw et al., *Low*
cigarette consumption and risk of coronary heart disease and stroke: meta-analysis
21 *of 141 cohort studies in 55 study reports*, 360:j5855 *BMJ* (2018),
<https://www.bmj.com/content/360/bmj.j5855.long>; HHS, *The Health Consequences*

1 that dual use of cigarettes and e-cigarettes “is not a proven method for combustible
2 tobacco cigarette cessation.”³¹ FDA reached the same conclusion and stated that,
3 “systematic reviews of available evidence indicate that there is currently
4 insufficient data to draw a conclusion about the efficacy of e-cigarettes as a
5 cessation device.”³² The fact is that no e-cigarette has been approved as a smoking
6 cessation drug or device by the FDA.

7 Moreover, plaintiffs offer no evidence that *flavors* in e-cigarettes play any
8 role in smoking cessation. While there may be anecdotal reports of smokers who
9 say flavored e-cigarettes helped them quit, there is no evidence that smokers could
10 not have quit without non-tobacco flavors. There has not been a single randomized
11 controlled trial to assess the impact of flavored versus non-flavored or tobacco-
12 flavored e-cigarettes on smoking cessation outcomes.

13 As the recent Surgeon General’s Report on Smoking Cessation put it, “the
14 potential benefit of e-cigarettes for cessation among adult smokers cannot come at
15 the expense of escalating rates of use of these products by youth.”³³ Because the
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17 *of Smoking: A Report of the Surgeon General* 361-407 (2004)
18 https://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

18 ³¹ *Supra* note 25, at 617.

19 ³² Deeming Tobacco Product To Be Subject to the Federal Food, Drug, and
20 Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control
21 Act; Restrictions on the Sale and Distribution of Tobacco Products and Required
Warning Statements for Tobacco Products (Final Rule), 81 Fed. Reg. 28,974,
29,037 (May 20, 2016) (the “Deeming Rule”).

21 ³³ *Supra* note 18, at 25.

1 benefits of flavored e-cigarettes are largely anecdotal and speculative—and the
2 risks of flavored e-cigarettes, particularly to youth, are well-documented and real—
3 the public interest weighs heavily against the grant of an injunction.

4 **II. An Injunction Would be Harmful to the Health of County Residents**
5 **by Allowing the Continued Sale of Menthol Cigarettes.**

6 Menthol cigarettes are a substantial threat to public health because they
7 increase the risk of youth initiation of smoking, increase addiction, and
8 disproportionately affect the African American community, thus exacerbating
9 serious health disparities. Because the injunction sought by plaintiffs would expose
10 the residents of Los Angeles County to the continued health harms of menthol
11 cigarettes, it is decisively contrary to the public interest.

12 **A. Menthol Cigarettes Increase Youth Initiation of Smoking and**
13 **Make it Harder for Smokers to Quit.**

14 Although the tobacco companies know that almost all new tobacco users
15 begin their addiction as kids, they also know that to novice smokers, tobacco smoke
16 can be harsh and unappealing. By masking the harshness and soothing the irritation
17 caused by tobacco smoke, menthol cigarettes make it easier for beginners to
18 experiment with cigarettes and ultimately become addicted. Thus, young smokers
19 are more likely to use menthol cigarettes than any other age group. Over half of
20 youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third
21

1 of smokers aged 35 and older.³⁴ As the FDA has observed, “[m]ultiple studies
2 show a greater use of menthol cigarettes by younger smokers and less usage among
3 older smokers.³⁵ The FDA’s Tobacco Products Scientific Advisory Committee
4 (TPSAC), after an extensive study of the public health impact of menthol cigarettes,
5 concluded in a 2011 Report that they increase the number of children who
6 experiment with cigarettes and the number who become regular smokers, increasing
7 overall youth smoking, and that young people who initiate using menthol cigarettes
8 are more likely to become addicted and become long-term daily smokers.³⁶

9 The impact of menthol cigarettes in attracting kids, and keeping them
10 addicted, has profoundly adverse effects on their health. The FDA has written that
11 “smoking cigarettes during adolescence is associated with lasting cognitive and

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13 ³⁴ Andrea Villanti, A., et al., *Changes in the Prevalence and Correlates of Menthol*
14 *Cigarette Use in the USA, 2004–2014*, 25(2) *Tobacco Control* ii14-ii20 (Oct. 20,
2016), <https://pubmed.ncbi.nlm.nih.gov/27729565/>.

14 ³⁵ *Supra* note 5, 83 Fed. Reg. at 12,296.

15 ³⁶ FDA, Tobacco Products Scientific Advisory Committee, *Menthol Cigarettes and*
16 *Public Health: Review of the Scientific Evidence and Recommendations*, 2011, at
17 136, 199-202, [https://wayback.archive-
it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/
18 CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UC
19 M269697.pdf](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf) (TPSAC Menthol Report). Plaintiffs’ Memorandum takes out of
20 context an expression of concern, in a Congressional Report on the Tobacco
21 Control Act, that immediately prohibiting a widely-used tobacco product may lead
to addicted smokers suffering “sudden withdrawal” and other “unknown
consequences.” Pls.’ Mem. P. & A. 7. Plaintiffs fail to mention that the Act
mandated TPSAC to study the menthol issue in all its dimensions, TPSAC did a
thorough study and concluded that “[r]emoval of menthol cigarettes from the
marketplace would benefit public health in the United States.” TPSAC Menthol
Report at 225.

1 behavioral impairments, including effects on working memory in smoking teens
2 and alterations in the prefrontal attentional network in young adult smokers.”³⁷
3 “Use of tobacco products,” according to the FDA, “puts youth and young adults at
4 greater risk for future health issues, such as coronary artery disease, cancer, and
5 other known tobacco-related diseases. Youth and young adult . . . cigarette smokers
6 also are at increased risk for future marijuana and illicit drug use, developmental
7 and mental health disorders, reduced lung growth and impaired function, increased
8 risk of asthma, and early abdominal aortic atherosclerosis.”³⁸

9 In its 2011 Report, TPSAC projected that by 2020, about 2.3 million people
10 will have started smoking because of menthol cigarettes, leading to 17,000
11 premature deaths.³⁹ Moreover, there is no question that increased smoking
12 prevalence due to menthol cigarettes is of heightened concern because of the
13 COVID-19 pandemic. As Dr. Brian King of the CDC recently warned, “Cigarette
14 smoking can suppress the immune system and cause heart and lung diseases. A
15 person who smokes may be at greater risk for, and may have a harder time
16 recovering from, COVID-19.”⁴⁰ Thus, as important to public health as a
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³⁷ *Supra* note 5, 83 Fed. Reg. at 12,295.

20 ³⁸ *Id.* at 12,295-96.

21 ³⁹ *Supra* note 36, at 221.

⁴⁰ Brian King, Webinar, *Update with CDC for Chronic Disease Partners on COVID-19*, American Lung Association, April 17, 2020.

1 prohibition of the sale of menthol cigarettes was before the current pandemic, it is
2 even more vital now.

3 **B. Menthol cigarettes have led to significant health disparities for**
4 **African Americans.**

5 In addition to leading millions of youth into tobacco addiction, menthol
6 cigarettes have played an especially pernicious role in victimizing the African
7 American community. Dating back to the 1950s, the tobacco industry has targeted
8 African Americans with marketing for menthol cigarettes through sponsorship of
9 community and music events, targeted magazine advertising, youthful imagery and
10 marketing in the retail environment. The 2018 California Tobacco Retail
11 Surveillance Study found significantly more menthol advertisements at stores with
12 a higher proportion of African American residents and in neighborhoods with
13 higher proportions of school-age youth.⁴¹ Another 2011 California study found
14 that, as the proportion of African American high school students in a neighborhood
15 rose, the proportion of menthol advertising increased.⁴² As TPSAC concluded,
16 menthol cigarettes are “disproportionately marketed per capita to African
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18 ⁴¹ Nina Schleicher, et al., *California Tobacco Retail Surveillance Study, 2018*,
Stanford Prevention Research Center 3, 22 (2019),
19 [https://www.cdph.ca.gov/Programs/CCDCPHP/DCDIC/CTCB/CDPH%20Document](https://www.cdph.ca.gov/Programs/CCDCPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf)
20 [%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceS](https://www.cdph.ca.gov/Programs/CCDCPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf)
tudyReport-2018.pdf.

21 ⁴² Lisa Henriksen et al., *Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods*, 14(1) *Nicotine Tob. Res.* 116-21 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592564/>.

1 Americans. African Americans have been the subjects of specifically tailored
2 menthol marketing strategies and messages.”⁴³

3 The tobacco industry’s use of menthol cigarettes to target African Americans
4 has paid handsome, but tragic, rewards. The prevalence of menthol use *is highest*
5 *among African Americans – 85% of African American smokers smoke menthol*
6 *cigarettes, compared to 29% of Whites.*⁴⁴ In its 2011 TPSAC report, FDA
7 concluded that menthol cigarettes are associated with lower levels of smoking
8 cessation among African Americans.⁴⁵ TPSAC also estimated that by 2020, over
9 460,000 African Americans will have started smoking because of menthol
10 cigarettes, and 4,700 excess deaths of African Americans will have been
11 attributable to menthol cigarettes.⁴⁶

12 Indeed, the public health importance of the Flavors Ordinance for African
13 Americans is made especially clear by the COVID-19 pandemic, which has
14 revealed stark health disparities across our nation. A Washington Post analysis
15 showed that counties that are majority-black have three times the rates of COVID-
16 19 infections and almost six times the rate of deaths as counties where white
17 residents are in the majority.⁴⁷ According to a recent CDC analysis of the effects of

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19 ⁴³ *Supra* note 36, at 92.

20 ⁴⁴ *Supra* note 34.

⁴⁵ *Supra* note 36, at 147.

⁴⁶ *Id.* at 206.

21 ⁴⁷ Reis Thebault et al., *The coronavirus is infecting and killing black Americans at an alarmingly high rate*, The Washington Post, April 7, 2020,

1 COVID-19, “current data suggest a disproportionate burden of illness and death
2 among racial and ethnic minority groups.”⁴⁸ Race and ethnicity data from 580
3 patients hospitalized with lab-confirmed COVID-19 across 14 states, including
4 California, found that 33% of hospitalized patients were black compared to 18% of
5 individuals in the surrounding community.⁴⁹

6 Although multiple and complex factors contribute to racial health disparities
7 in the U.S., the disproportionate burden of COVID-19 on the African American
8 community surely underscores the urgency of laws like the Flavors Ordinance,
9 given the disproportionate impact of menthol cigarettes on that community and the
10 likelihood that smokers are particularly vulnerable to the worst effects of the novel
11 coronavirus. The balance of equities, and the public interest, strongly weigh against
12 an injunction against the Flavors Ordinance in the midst of a pandemic of
13 respiratory disease that is having such a deadly and disproportionate effect on the
14 African American community.

19 <https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true>

20 ⁴⁸CDC, *COVID-19 in Racial and Ethnic Minority Groups*,
<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>

21 ⁴⁹ *Id.*

1 **III. An Injunction Would Be Harmful to the Health of County Residents**
2 **by Allowing the Continued Sale of Flavored Cigars.**

3 Like other flavored tobacco products, flavored cigar smoking presents
4 substantial health risks – risks that are particularly concerning given the prevalence
5 of cigar use among children and the tobacco industry’s efforts to market cigars to
6 youth. Historically, cigar manufacturers designed flavored cigars to serve as
7 “starter” smokes for youth and young adults because the flavorings helped mask the
8 harshness, making the products easier to smoke.⁵⁰ According to an industry
9 publication, “While different cigars target a variety of markets, all flavored tobacco
10 products tend to appeal primarily to younger consumers.”⁵¹ The vice president of
11 one distributor commented, “For a while it felt as if we were operating a Baskin-
12 Robbins ice cream store” in reference to the huge variety of cigar flavors available
13 – and, no doubt, an allusion to flavors that would appeal to kids.⁵²

14 The FDA has concluded that the availability of flavored cigars has
15 contributed to a sharp increase in youth usage of cigars.⁵³ More than 1,600 children
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19 ⁵⁰ Ganna Kostygina et al., *Tobacco Industry use of Flavours to Recruit New Users*
20 *of Little Cigars and Cigarillos*, 25(1) *Tobacco Control* 66-74 (Jan. 2016),
<https://tobaccocontrol.bmj.com/content/25/1/66>.

21 ⁵¹ M. Niksic, *Flavored Smokes: Mmmmm...More Profits?*, *Tobacco Retailer* (April 2007).

⁵² *Id.*

⁵³ 81 Fed. Reg. at 28,985.
2:20-cv-4065-DSF(KSx)

1 under age 18 try cigar smoking for the first time every day.⁵⁴ The 2013-14 PATH
2 study found that 71.7% of youth cigar smokers used a flavored product in the last
3 month.⁵⁵ The 2014 NYTS showed that approximately 900,000 middle and high
4 school students had used a flavored cigar in the last 30 days.⁵⁶

5 As the FDA has found, “[a]ll cigars pose serious negative health risks.”⁵⁷ In
6 2010 alone, regular cigar smoking was responsible for “approximately 9,000
7 premature deaths or almost 140,000 years of potential life lost among adults 35
8 years or older.”⁵⁸ According to the FDA, “[a]ll cigar smokers have an increased
9 risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco
10 users,” as well as “other adverse health effects, such as “increased risk of heart and
11 pulmonary disease,” “a marked increase in risk for chronic obstructive pulmonary
12 disease,” a higher risk of death from COPD, and “a higher risk of fatal and nonfatal
13 stroke compared to non-smokers.”⁵⁹

14 A preliminary injunction that allows the sale of flavored cigars would be
15 plainly contrary to the public interest.

17 ⁵⁴ HHS, Substance Abuse and Mental Health Services Administration (SAMHSA),
18 *2018 National Survey on Drug Use and Health*, Table 4.10A, Past Year Initiation
19 of Substance Use Among Persons Aged 12 or Older Who Initiated Use Prior to Age
18. Cigars are defined as cigars, cigarillos or little cigars.

⁵⁵ 83 Fed. Reg. at 12,296.

⁵⁶ *Id.*

⁵⁷ 81 Fed. Reg. at 29,020.

⁵⁸ *Id.*

⁵⁹ *Id.*

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CONCLUSION

For these reasons, the amicus public health, medical and community organizations urge the Court to deny plaintiffs a preliminary injunction preventing enforcement of the Flavors Ordinance.

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Attorneys for Proposed *Amici Curiae*

1 **APPENDIX**

2 **DESCRIPTION OF AMICI CURIAE**

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

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

17 The American Academy of Pediatrics (AAP-CA2) Southern California
18 Chapter covers seven counties: Kern, Los Angeles, San Bernardino, San Luis
19 Obispo, Santa Barbara, Riverside, and Ventura. We have 1,500 members, including
20 800 pediatricians in Los Angeles County. Our mission is to champion optimal
21 physical, mental and social health and well-being for all infants, children,

1 adolescents and young adults, and to advocate for and support our members in these
2 endeavors.

3 The American Cancer Society Cancer Action Network (ACS CAN) is the
4 nation's leading voice advocating for public policies that are helping to defeat
5 cancer. As the advocacy affiliate of the American Cancer Society, ACS CAN
6 works to encourage government officials to make cancer a top priority, including
7 supporting comprehensive tobacco control. ACS CAN supported Los Angeles
8 County's countywide ban on the sale of all flavored tobacco products, without
9 exception, as the best option to protect our youth.

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

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

3 The American Medical Association (AMA) is the largest professional
4 association of physicians, residents, and medical students in the United States.
5 Additionally, through state and specialty medical societies and other physician
6 groups seated in its House of Delegates, substantially all physicians, residents, and
7 medical students in the United States are represented in the AMA's policy-making
8 process. The AMA was founded in 1847 to promote the art and science of medicine
9 and the betterment of public health, and these remain its core purposes. AMA
10 members practice in every medical specialty and in every state, including
11 California. The AMA and CMA join this brief on their own behalves and as
12 representatives of the Litigation Center of the American Medical Association and
13 the State Medical Societies. The Litigation Center is a coalition among the AMA
14 and the medical societies of each state and the District of Columbia. Its purpose is
15 to represent the viewpoint of organized medicine in the courts.

16 Americans for Nonsmokers' Rights (ANR) is a national non-profit tobacco
17 control advocacy organization based in Berkeley, California. Since its formation in
18 1976, ANR has been dedicated to protecting nonsmokers' rights to breathe smoke-
19 free air in enclosed public places and workplaces and to preventing youth addiction
20 to nicotine, including use of e-cigarettes and other flavored tobacco products. ANR
21 represents a national constituency of over 12,000 individuals and organizations

1 concerned about the health risks that tobacco and other nicotine products pose to
2 the health and safety of smokers and nonsmokers alike and committed to reducing
3 and preventing tobacco and e-cigarette use.

4 BREATHE California of Los Angeles County is a nonprofit, non-partisan
5 organization that promotes clean air and healthy lungs through education, research,
6 technology, and advocacy. Since 1903, BREATHE LA has and remains committed
7 to improving environmental health for all Southern California residents.

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

16 California School Nurses Organization (CSNO) is the leading force for
17 excellence in school health services CSNO's mission is to ensure that school
18 nurses optimize student health and enhance learning through a network
19 distinguished by: facilitating grassroots efforts within regional sections; developing
20 and providing professional learning opportunity; fostering the development of
21

1 leaders; conducting research and using evidence based practice; providing standards
2 of care; and advocating for school health services.

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

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

18 The Los Angeles County Medical Association (LACMA) is the nation's
19 largest county medical organization with over 7,000 members and has been an
20 emphatic voice on protecting the health and well-being of the most vulnerable
21 populations across the Los Angeles region; specifically fighting the egregious

1 marketing tactics deployed by the flavored tobacco industry from device companies
2 to retailers.

3 OUT Against Big Tobacco (OABT) is a coalition of over 20 LGBTQ+
4 community organizations and allies throughout LA County and is staffed by
5 Equality California. OABT has been active in the fight against the tobacco-related
6 health disparities that impact LGBTQ+ people and all of the diverse communities
7 that we are a part of. Big tobacco purposefully infiltrated LGBT spaces with their
8 ad buys and marketing campaigns that included Prides and HIV/AIDS networks;
9 now, we are fighting back. Our coalition has an interest in flavored tobacco
10 restrictions, including menthol, in LA County due to the higher rate of tobacco and
11 flavored tobacco product use among the LGBTQ+ community when compared to
12 their non-LGBTQ+ peers. Flavored tobacco restrictions will save lives within our
13 communities and should not be delayed.

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

1 advocates operate in multiple states across the country, including California. PAVe
2 believes that regulatory and legislative change at the state level is key to slowing
3 the explosive growth of teen vaping and protecting teens from the predatory
4 behavior of Big Tobacco.

5 The Public Health Law Center is a public interest legal resource center
6 dedicated to improving health through the power of law and policy, grounded in the
7 belief that everyone deserves to be healthy. Located at the Mitchell Hamline School
8 of Law in Saint Paul, Minnesota, the Center helps local, state, national, tribal, and
9 global leaders promote health by strengthening public policies. For almost twenty
10 years, the Center has worked with public officials and community leaders across the
11 nation to develop, implement, and defend effective public health laws and policies,
12 including those designed to reduce commercial tobacco use, improve the nation's
13 diet, encourage physical activity, protect the nation's public health infrastructure,
14 and promote health equity. The Public Health Law Center's commercial tobacco
15 control program operates as part of a national network of nonprofit legal centers
16 working to protect public health from the devastating consequences of tobacco use.
17 The Center's affiliated legal organizations include: Public Health Advocacy
18 Institute and the Center for Public Health and Tobacco Policy, both at Northeastern
19 University School of Law, Boston, Massachusetts; ChangeLab Solutions, Oakland,
20 California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy,
21 at University of Maryland Francis King Carey School of Law, Baltimore,

1 Maryland; Smoke-Free Environments Law Project, at the University of Michigan,
2 Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at
3 New Jersey GASP, Summit, New Jersey.

4 Truth Initiative Foundation, d/b/a Truth Initiative (Truth Initiative) is a
5 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement
6 agreement that resolved litigation brought by 46 states, five U.S. territories, and the
7 District of Columbia against the major U.S. cigarette companies. Headquartered in
8 Washington, D.C., Truth Initiative studies and supports programs in the United
9 States to reduce youth tobacco use and to prevent diseases associated with tobacco
10 use. Its nationally recognized truth® campaign has educated hundreds of millions
11 of young people about the health effects and social costs of tobacco.

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CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2020, the foregoing document was filed electronically with the Clerk of Court through the Court’s CM/ECF system, which will automatically serve all counsel of record.

Dated: May 20, 2020

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