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10 **IN THE UNITED STATES DISTRICT COURT**  
11 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

12 R.J. REYNOLDS TOBACCO COMPANY;  
R.J. REYNOLDS VAPOR COMPANY;  
13 AMERICAN SNUFF COMPANY, LLC;  
SANTA FE NATURAL TOBACCO  
14 COMPANY, INC.; PHILIP MORRIS USA  
INC.; JOHN MIDDLETON CO.; U.S.  
15 SMOKELESS TOBACCO COMPANY  
LLC; HELIX INNOVATIONS LLC;  
16 NEIGHBORHOOD MARKET  
ASSOCIATION, INC.; AND MORIJA, LLC  
17 dba VAPIN' THE 619

18 *Plaintiffs,*

19 v.

20 XAVIER BECERRA, in his official capacity  
as Attorney General of California; and  
21 SUMMER STEPHAN, in her official  
capacity as District Attorney for the County  
22 of San Diego,

23 *Defendants.*

No. 20-cv-01990-JLS-WVG

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

Hearing Date: December 10, 2020  
Time: 1:30 PM  
Courtroom: 4D

Judge: Janis L. Sammartino  
Magistrate: William V. Gallo

Action Filed: October 9, 2020  
Trial Date: None Set

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1 providing the Court with the most complete information needed for a fair balancing  
 2 of the hardships in this case and an accurate assessment of the effect of an  
 3 injunction on the public interest.

#### 4 INTRODUCTION

5 The use of tobacco products is the leading cause of preventable death in the  
 6 United States, taking upwards of 480,000 lives every year.<sup>1</sup> The tobacco industry  
 7 has long understood that almost all new tobacco users begin their addiction as kids.  
 8 Ninety percent of adult smokers begin smoking in their teens.<sup>2</sup> The industry has  
 9 also known that to successfully market their products to young people, flavored  
 10 products are essential. No matter what the tobacco product – from cigarettes to  
 11 cigars to e-cigarettes – flavors significantly increase the appeal of tobacco products  
 12 to youth. Data from the U.S. Food and Drug Administration (“FDA”)/NIH  
 13 Population Assessment of Tobacco and Health (“PATH”) study found that almost  
 14 81% of 12-17 year-olds who had ever used a tobacco product initiated use with a  
 15 flavored product.<sup>3</sup> For each tobacco product, at least two-thirds of youth reported  
 16 using these products “because they come in flavors I like.”<sup>4</sup> As the FDA has found,  
 17 “the availability of tobacco products with flavors at these developmental stages  
 18 attracts youth to initiate use of tobacco products and may result in lifelong use.”<sup>5</sup>  
 19 Indeed, flavored e-cigarettes have fueled an explosion of e-cigarette use among  
 20 teens. The 2020 National Youth Tobacco Survey (“NYTS”) showed that almost 1

21 <sup>1</sup> Office of the Surgeon General (OSG), U.S. Department of Health and  
 22 Human Services (HHS), *The Health Consequences of Smoking - 50 Years of*  
 23 *Progress: A Report of the Surgeon General 2* (2014),  
<https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>.

24 <sup>2</sup> Substance Abuse and Mental Health Services Administration (SAMHSA),  
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<http://doi.org/10.3886/ICPSR36361.v1>.

25 <sup>3</sup> Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US*  
 26 *Youth Aged 12-17 Years, 2013-2014*, 314 J. Am. Med. Ass’n 17, 1871-3 (2015),  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6467270/>.

27 <sup>4</sup> *Id.*

28 <sup>5</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”)

1 in 5 (19.6%) of high school students are current users of e-cigarettes, a prevalence  
 2 rate that more than doubled from 2017 to 2019 (from 11.7% to 27.5%).<sup>6,7</sup> An  
 3 alarming 3.6 million high school and middle school students are current e-cigarette  
 4 users – about the same number as when the U.S. Surgeon General first called youth  
 5 e-cigarette use an “epidemic” in 2018.<sup>8</sup> PATH study data shows that 97% of  
 6 *current youth e-cigarette users had used a flavored product in the last month.*<sup>9</sup>

7 By enacting SB 793, California seeks to protect its residents – and  
 8 particularly its young people – from the continuing and increasing scourge of  
 9 flavored tobacco products that lure millions into a lifetime of addiction that  
 10 contributes to significant disease and death. Plaintiffs seek an injunction that would  
 11 deprive Californians of that vital public health protection. Moreover, plaintiffs seek  
 12 an injunction at a time when our nation continues to be ravaged by the horrific  
 13 spread of the novel coronavirus and COVID-19 – a deadly respiratory illness that  
 14 has taken over 230,000 American lives, while affecting daily life in unprecedented  
 15 ways. Dr. Nora Volkow, Director of the U.S. National Institute on Drug Abuse, has  
 16 observed that “[b]ecause it attacks the lungs, the coronavirus that causes COVID-19  
 17 could be an especially serious threat to those who smoke tobacco or marijuana or  
 18 who vape . . . .”<sup>10</sup> Never has it been more important to curb the sale of flavored  
 19

20 <sup>6</sup> CDC, *E-cigarette Use Among Middle and High School Students – United*  
 21 *States, 2020*, 69 Morbidity & Mortality Wkly. Rep. Surveillance Summaries (Sept.  
 22 9, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

22 <sup>7</sup> CDC, *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco*  
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 25 [https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s\\_cid=mm6745a5\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w).

24 <sup>8</sup> OSG, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth*,  
 25 (2018), [https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf)  
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25 <sup>9</sup> FDA, *Modifications to Compliance Policy for Certain Deemed Products:*  
 26 *Guidance for Industry, Draft Guidance*, at 9 (Mar. 13, 2019), [https://beta.](https://beta.regulations.gov/document/FDA-2019-D-0661-0003)  
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27 <sup>10</sup> Nora Volkow, *Potential Implications for Individuals with Substance Use*  
 28 *Disorders*, NIDA: Nora’s Blog (Apr. 6, 2020), [https://www.drugabuse.gov/about-](https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders)  
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[use-disorders](https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders).

1 tobacco products that lure kids to smoking and vaping. Yet the injunction sought  
2 by plaintiffs would not only permit the continued sale of flavored e-cigarettes in  
3 California, but also the sale of mentholated cigarettes, flavored cigars and other  
4 flavored tobacco products.

5 The Food, Drug and Cosmetic Act, as amended by the Family Smoking  
6 Prevention and Tobacco Control Act (“Tobacco Control Act”) confers authority on  
7 the FDA to regulate the manufacture of tobacco products through the issuance of  
8 product standards, while expressly preserving to states and localities their  
9 traditional broad authority to protect the health of their citizens by regulating the  
10 retail sale of finished tobacco products. 21 U.S.C. § 387p(a)(1). Most recently,  
11 federal preemption challenges virtually identical to the one at issue here, one  
12 brought by certain plaintiffs in this action, were rejected by another California  
13 federal district court in *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, No.  
14 CV 20-4880, 2020 WL 4390375, at \*5 (C.D. Cal. July 13, 2020) (order denying  
15 plaintiffs’ motion for preliminary injunction) (“A prohibition on the sale of a  
16 distinct product is simply not a product standard.”), *dismissed*, No. CV 20-4880,  
17 2020 WL 5405668, at \*3 (C.D. Cal. Aug. 7, 2020) (order granting defendants’  
18 motion to dismiss and denying plaintiffs’ motion for summary judgment as moot),  
19 *appeal docketed*, No. 20-55930 (9th Cir. Sept. 8, 2020), and in *CA Smoke & Vape*  
20 *Ass’n v. County of Los Angeles*, No. CV 20-4065, 2020 WL 4390384 (C.D. Cal.  
21 June 9, 2020) (order denying plaintiffs’ motion for preliminary injunction); No. CV  
22 20-4065 (C.D. Cal. Aug. 7, 2020) (order granting defendants’ motion to dismiss).  
23 Indeed, every court that has considered the issue has found that sales restrictions on  
24 flavored tobacco products are not preempted by federal law. *See also R.J. Reynolds*  
25 *Tobacco Co. v. City of Edina*, No. 20-1402, 2020 WL 5106853 (D. Minn. Aug. 31,  
26 2020) (upholding city ordinance restricting flavored tobacco products and finding  
27 that the ordinance was not expressly or impliedly preempted), *appeal docketed*, No.  
28 20-2852 (8th Cir. Sept. 4, 2020); *U.S. Smokeless Tobacco Mfg. Co. v. City of New*

1 *York*, 708 F.3d 428, 433-35 (2d. Cir. 2013) (upholding local sales restrictions on  
2 flavored tobacco products because their application to a particular product “depends  
3 on its characteristics as an end product, and not on whether it was manufactured in  
4 a particular way or with particular ingredients.”); *Nat’l Ass’n of Tobacco Outlets,*  
5 *Inc. v. City of Providence*, 731 F.3d 71, 83, n.11 (1st Cir. 2013) (upholding local  
6 restrictions on sale of flavored tobacco products, given “Congress’ decision to  
7 exempt sales regulations from preemption. . . .”); *Indep. Gas & Serv. Stations*  
8 *Ass’ns, Inc. v. City of Chicago*, 112 F.Supp.3d 749, 754 (N.D. Ill. 2015) (upholding  
9 Chicago’s flavored tobacco sales restrictions as exempt from Tobacco Control Act  
10 preemption provision because Chicago ordinance “regulates flavored tobacco  
11 products without regard for how they are manufactured” and is “not a command to  
12 implement particular manufacturing standards”). SB 793, because it does not  
13 operate as a command to manufacturers limiting how a product is manufactured or  
14 what ingredients it may contain, in no way interferes with FDA authority to set  
15 product standards. Far from interfering with the federal regulatory scheme, SB 793  
16 advances the Tobacco Control Act’s “objective of reducing the use and harmfulness  
17 of tobacco products, especially among young people.” *U.S. Smokeless Tobacco*,  
18 708 F.3d at 436. Thus, plaintiffs are unlikely to succeed on the merits of their  
19 preemption claim.

20 *Amici* focus here on the public interest factors to be weighed by the Court in  
21 determining whether to grant a preliminary injunction: the balance of the equities  
22 and whether an injunction would serve the public interest, two factors that merge  
23 when the government is a party.<sup>11</sup> Plaintiffs’ claims of irreparable harm are either  
24 dependent on the validity of their preemption argument, which has no merit, or the  
25 financial loss of being deprived of the ability to continue to sell tobacco products  
26 that, as the discussion *infra* shows, cause significant harm to public health. As the

27 <sup>11</sup> See *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1271 (9th Cir.  
28 2020) (“When the government is a party, the last two factors (equities and public  
interest) merge.”).

1 *amici* here demonstrate, plaintiffs’ alleged financial harm is far outweighed by the  
 2 health harms long suffered by California residents due to flavored tobacco products.  
 3 Plaintiffs argue that an injunction would simply “preserve the status quo,” Mem. of  
 4 P. & A. in Supp. of Pls.’ Mot. for Prelim. Inj. at 25, ECF No. 6-1 (“Pls.’ Mem.”),  
 5 but that status quo consists of continuing and substantial harm to public health. By  
 6 this brief, *amici* seek to inform the Court of the scope of the harm to public health  
 7 that would be inflicted by an injunction allowing the continued sale of flavored  
 8 tobacco products in California. Because of that harm, a preliminary injunction  
 9 would be profoundly contrary to the public interest.

## 10 ARGUMENT

### 11 **I. The Health Harms of Continued Sale of Flavored E-Cigarettes Weigh** 12 **Significantly Against the Grant of an Injunction.**

#### 13 **A. E-Cigarettes Available in Thousands of Flavors Increase Youth** 14 **Usage and Pose Serious Health Risks to Youth.**

15 The most dramatic surge in youth usage of flavored tobacco products has  
 16 occurred with e-cigarettes,<sup>12</sup> the most commonly used tobacco product among U.S.  
 17 youth since 2014.<sup>13</sup> In December 2018, Surgeon General Jerome Adams issued an  
 18 advisory on e-cigarette use among youth, declaring the growing problem an  
 19 “epidemic.”<sup>14</sup>

20 Young people are not just experimenting with e-cigarettes but are using them  
 21 frequently. Data from the 2020 NYTS show that an increasing proportion of  
 22 current youth e-cigarette users are using these products on a frequent (on at least 20  
 23 of the preceding 30 days) or daily basis. In 2020, 38.9% of high school e-cigarette  
 24

25 <sup>12</sup> By “e-cigarettes,” *amici* refer to the full range of devices within the scope  
 26 of Section 104495(a)(8)(A)(ii) of the California Health and Safety Code, as  
 incorporated by the definition of “tobacco product” in SB 793.

27 <sup>13</sup> CDC, *supra* note 6.

28 <sup>14</sup> OSG, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth*  
 (2018), [https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-  
 advisory-on-e-cigarette-use-among-youth-2018.pdf](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf).

1 users reported frequent use (up from 34.2% in 2019).<sup>15</sup> Even more alarming,  
 2 22.5% of high school e-cigarette users reported *daily* use, a strong indication of  
 3 deep addiction.<sup>16</sup> In total, 1.3 million middle and high school students are frequent  
 4 users of e-cigarettes, including over 700,000 daily users.<sup>17</sup> Trends in e-cigarette use  
 5 in California mirror the trends seen nationwide. According to the California  
 6 Student Youth Tobacco Survey, e-cigarettes are the most commonly used tobacco  
 7 product among youth in California.<sup>18</sup>

8 Tobacco companies have a long history of using flavors to reduce the  
 9 harshness of their products and make them more appealing to new users, almost all  
 10 of whom are under age 18.<sup>19</sup> In recent years, companies have extended this strategy  
 11 to the emerging market for e-cigarettes. As of 2017, researchers had identified  
 12 more than 15,500 unique e-cigarette flavors available online.<sup>20</sup> An earlier study of  
 13 e-cigarette flavors found that among the more than 400 brands available online in  
 14 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.<sup>21</sup> E-  
 15 liquids are being sold in such kid-friendly options as cotton candy, peanut butter  
 16 cup, and gummy bear. The data confirm that flavors play a major role in youth  
 17 initiation and use of e-cigarettes. The 2020 Surgeon General Report on smoking  
 18 cessation notes that “the role of flavors in promoting initiation of tobacco product  
 19 use among youth is well established . . . and appealing flavor is cited by youth as

20 <sup>15</sup> CDC, *supra* note 6.

21 <sup>16</sup> *Id.*

22 <sup>17</sup> *Id.*

23 <sup>18</sup> Shu-Hong Zhu et al., *California Student Tobacco Survey, Results of the*  
*Statewide 2017-18 California Student Tobacco Survey*, 6 (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).

24 <sup>19</sup> OSG, HHS, *Preventing Tobacco Use Among Youth and Young Adults, A*  
*Report of the Surgeon General* 483-628 (2012),  
[https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf\\_NBK99237.pdf](https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf).

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

26 <sup>21</sup> Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-cigarettes and*  
*Counting: Implications for Product Regulation*, 23 *Tobacco Control* iii3 (2014),  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078673/>.



1 one of the main reasons for using e-cigarettes.”<sup>22</sup> As noted above, data from the  
 2 2016–17 wave of the government’s PATH study found that 97% of current youth e-  
 3 cigarette users had used a flavored e-cigarette in the past month.<sup>23</sup>

4 Flavored e-cigarettes and refill liquids typically contain nicotine, a highly  
 5 addictive drug that can have lasting damaging effects on adolescent brain  
 6 development.<sup>24</sup> According to the Surgeon General’s 2018 *Advisory on E-cigarette*  
 7 *Use Among Youth*, “[n]icotine exposure during adolescence can impact learning,  
 8 memory and attention,” and “can also increase risk for future addiction to other  
 9 drugs.”<sup>25</sup> Nicotine also impacts the cardiovascular system.<sup>26</sup> The Surgeon General  
 10 has warned that, “[t]he use of products containing nicotine in any form among  
 11 youth, including in e-cigarettes, is unsafe.”<sup>27</sup> Flavorings in e-cigarettes can pose  
 12 additional health hazards. According to the Surgeon General, some of the  
 13 flavorings found in e-cigarettes have been shown to cause serious lung disease  
 14 when inhaled.<sup>28</sup> An article in the *Journal of the American Medical Association*  
 15 raised concerns that the chemical flavorings found in some e-cigarettes and e-  
 16 liquids could cause respiratory damage when the e-cigarette aerosol is inhaled

19  
 20 <sup>22</sup> OSG, HHS, *Smoking Cessation, A Report of the Surgeon General*, at 611  
 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

21 <sup>23</sup> FDA, *supra* note 9.

22 <sup>24</sup> OSG, *supra* note 1; *see also* Office on Smoking and Health, CDC,  
*Electronic Nicotine Delivery Systems: Key Facts* (2016),  
 23 <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

24 <sup>25</sup> OSG, *supra* note 8, at 1.

25 <sup>26</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* (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53012/>.

26 <sup>27</sup> OSG, HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of*  
*the Surgeon General* (2016), [https://e-cigarettes.surgeongeneral.gov/documents/](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf)  
 27 [2016\\_SGR\\_Full\\_Report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf).

28 <sup>28</sup> OSG, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth*  
 (2018), [https://e-cigarettes.surgeongeneral.gov/](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf)  
[documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf).

1 deeply into the lungs.<sup>29</sup> In *Nicopure Labs, LLC v. FDA*, the U.S. Court of Appeals  
2 for the D.C. Circuit relied on findings that flavors in e-cigarettes are harmful in  
3 upholding the application of FDA’s premarket review process to e-cigarettes. 944  
4 F.3d 267 (D.C. Cir. 2019). Specifically, the court found that:

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

13 *Id.* at 274 (internal citations omitted).

14 Use of e-cigarettes also may function as a gateway to the use of conventional  
15 cigarettes and other combustible tobacco products, thereby undermining decades of  
16 progress in curbing youth smoking. A 2018 report by the National Academies of  
17 Science, Engineering and Medicine (“NASEM”) found “substantial evidence that e-  
18 cigarette use increases risk of ever using combustible tobacco cigarettes among  
19 youth and young adults.”<sup>30</sup> A nationally representative analysis found that from  
20 2013 to 2016, youth e-cigarette use was associated with more than four times the  
21 odds of trying combustible cigarettes and nearly three times the odds of current  
22 combustible cigarette use. The researchers estimated that this translates to over  
23 43,000 current youth combustible cigarette smokers who might not have become  
24 smokers without e-cigarettes,<sup>31</sup> during a period prior to the recent explosion of  
25 youth e-cigarette use. The evidence supporting this gateway effect continues to

26 <sup>29</sup> Jessica L. Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An*  
27 *Unrecognized Respiratory Health Hazard?*, 312 J. Am. Med. Ass’n 2493 (2014),  
28 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361011/>.

29 <sup>30</sup> National Academies of Sciences, Engineering, and Medicine (NASEM),  
30 *Public Health Consequences of E-cigarettes* 10 (2018)  
31 [https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf\\_NBK507171.pdf](https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf).

32 <sup>31</sup> Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with*  
33 *Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, 2 J. Am. Med. Ass’n  
34 Network Open e187794 (2019), [https://jamanetwork.com/journals/](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425)  
35 [jamanetworkopen/fullarticle/2723425](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425).

1 mount. For example, a 2020 Truth Initiative study shows that youth and youth  
2 adults ages 15-27 who had ever used e-cigarettes had seven times higher odds of  
3 starting to smoke combustible cigarettes one year later compared with those who  
4 had never used e-cigarettes.<sup>32</sup>

5 Thus, given the fast-spreading epidemic of youth e-cigarette use, driven by  
6 the appeal of flavored products, the implementation of SB 793 is critical to  
7 California's efforts to protect its young people from the addictive and other harmful  
8 effects of e-cigarettes.

9 **B. The Claimed Risks Posed by California's Prohibition of the Sale of**  
10 **Flavored E-Cigarettes Are Entirely Unsupported and Speculative.**

11 Plaintiffs assert that an injunction against SB 793 would "avoid public health  
12 risks" because a prohibition of the sale of flavored e-cigarettes "could drive adult  
13 users to riskier combustible cigarettes or worse, the black market." Pls.' Mem. at 2.  
14 This claim is made with no support whatsoever. There is no reason to believe that  
15 these risks are substantial or would outweigh the well-established harm to public  
16 health from the continued sale of non-tobacco flavored e-cigarette products.

17 First, plaintiffs do not cite to any data showing that e-cigarette users have  
18 been driven to combustible cigarettes in any of the many jurisdictions that, like SB  
19 793, have banned the sales of flavored e-cigarettes, while allowing tobacco-  
20 flavored products.<sup>33</sup> In fact, tobacco-flavored e-cigarettes were the single most  
21 widely-used flavor on the market through 2017, comprising 30–40% of the retail  
22

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23 <sup>32</sup> Elizabeth C. Hair et al., *Association Between E-Cigarette Use and Future*  
24 *Combustible Cigarette Use: Evidence From a Prospective Cohort of Youth and*  
25 *Young Adults, 2017-2019* 112 *Addictive Behaviors* (2020),  
26 <https://www.sciencedirect.com/science/article/pii/S0306460320307231?via%3Dihub>.

27 <sup>33</sup> The jurisdictions that have taken action against flavored e-cigarettes are set  
28 out in Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted*  
*the Sale of Flavored Tobacco Products* (Aug. 5, 2020), <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

1 market.<sup>34</sup> SB 793 continues to allow the sale of tobacco-flavored e-cigarettes, thus  
2 accommodating smokers who wish to switch to e-cigarettes.

3 Second, the data shows that smokers are not using e-cigarettes to quit  
4 smoking. The recent Surgeon General’s report on smoking cessation summarized  
5 the existing evidence, concluding that “there is presently inadequate evidence to  
6 conclude that e-cigarettes, in general, increase smoking cessation.”<sup>35</sup> Moreover,  
7 according to the CDC, most adult e-cigarette users are dual users, i.e., they continue  
8 to smoke cigarettes.<sup>36</sup> Dual use, even with cutting back the number of cigarettes  
9 smoked, still elevates smokers’ health risks for conditions like cardiovascular  
10 disease.<sup>37</sup> NASEM found that dual use of cigarettes and e-cigarettes “is not a  
11 proven method for combustible tobacco cigarette cessation.”<sup>38</sup> The FDA reached  
12 the same conclusion, finding that “systematic reviews of available evidence indicate  
13 that there is currently insufficient data to draw a conclusion about the efficacy of e-  
14 cigarettes as a cessation device.”<sup>39</sup> The agency cited studies finding that cigarette  
15

16 <sup>34</sup> Alexa R. Romberg et al., *Patterns of Nicotine Concentrations in Electronic*  
17 *Cigarettes Sold in the United States, 2013-2018*, 203 *Drug & Alcohol Dependence*  
18 1 (2019), <https://www.sciencedirect.com/science/article/abs/pii/S0376871619302571?via%3Dihub>.

18 <sup>35</sup> OSG Report 2020, *supra* note 22, at 23.

19 <sup>36</sup> CDC, *QuickStats: Cigarette Smoking Status Among Current Adult E-*  
20 *cigarette Users, by Age Group — National Health Interview Survey, United States,*  
21 *2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1177 (Oct. 28, 2016),  
22 <https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm>; *see also* CDC, *About*  
*Electronic Cigarettes (E-Cigarettes)* (last visited May 18, 2020),  
[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).

23 <sup>37</sup> Kjell Bjartveit & Aage Tverdal, *Health Consequences of Smoking 1-4*  
*Cigarettes per Day*, 14 *Tobacco Control* 315 (2005),  
24 <https://tobaccocontrol.bmj.com/content/14/5/315>; Allen Hackshaw et al., *Low*  
*Cigarette Consumption and Risk of Coronary Heart Disease and Stroke: Meta-*  
25 *Analysis of 141 Cohort Studies in 55 Study Reports*, 360 *BMJ* j5855 (2018),  
<https://www.bmj.com/content/360/bmj.j5855.long>; OSG, HHS, *The Health*  
*Consequences of Smoking: A Report of the Surgeon General* 361-407 (2004)  
26 [https://www.cdc.gov/tobacco/data\\_statistics/sgr/2004/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm).

27 <sup>38</sup> NASEM, *supra* note 30, at 617.

28 <sup>39</sup> Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and  
Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control  
Act; Restrictions on the Sale and Distribution of Tobacco Products and Required

1 smokers who also used e-cigarettes had statistically significantly worse quit rates  
2 than those cigarette smokers who did not use e-cigarettes.<sup>40</sup> The fact is that no e-  
3 cigarette has been approved as a smoking cessation drug or device by the FDA.

4 Moreover, plaintiffs offer no evidence that *flavors* in e-cigarettes play any  
5 role in smoking cessation. There has not been a single randomized controlled trial  
6 to assess the impact of flavored versus non-flavored or tobacco-flavored e-  
7 cigarettes on smoking cessation outcomes.

8 Plaintiffs also speculate that SB 793 “could also drive consumers to the black  
9 market.” Pls.’ Mem. at 25. They cite to no evidence indicating that this has  
10 happened in any of the four states (Massachusetts, New Jersey, New York and  
11 Rhode Island), or in the over 90 localities, that have prohibited the sale of non-  
12 tobacco flavored e-cigarettes and other flavored tobacco products, including  
13 menthol cigarettes.<sup>41</sup> Plainly, sustaining a robust illegal market in flavored e-  
14 cigarettes and other flavored products would be inherently difficult because the  
15 products would be readily identifiable as flavored, and therefore illegal to sell, from  
16 their packaging and from the products themselves. Moreover, the illegal market  
17 could only be sustained by the large-scale *manufacture* of illegal products, an  
18 enterprise that would be especially difficult to conceal. Plaintiffs refer to the  
19 current black market for tobacco products, Pls.’ Mem. at 25, but that largely  
20 involves the illegal interstate movement of legally manufactured cigarettes to avoid  
21 taxation in states with relatively high tobacco taxes.<sup>42</sup> The current illegal market

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22 Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 29,037 (May 20,  
23 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) (“Deeming Rule”).

<sup>40</sup> *Id.* at 29,028, 29,037.

24 <sup>41</sup> For a listing of the jurisdictions that have imposed restrictions on flavored  
e-cigarettes and menthol cigarettes, *see supra* note 33.

25 <sup>42</sup> National Research Council (NRC), *Understanding the U.S. Illicit Tobacco*  
26 *Market: Characteristics, Policy Context, and Lessons from International*  
27 *Experiences, Committee on the Illicit Tobacco Market: Collection and Analysis of*  
28 *the International Experience* 27 (2015), <https://doi.org/10.17226/19016> (NRC  
Report); Dep’t of Treasury, *Report to Congress on Federal Tobacco Receipts Lost*  
*Due To Illicit Trade and Recommendations for Increased Enforcement* 2 (2010)  
(Congress wrote “[i]t should also be noted at the outset, that a significant

1 does not require illegal manufacturing of contraband products; moreover, it is  
 2 possible to disguise the illegality of products trafficked to avoid state taxes through  
 3 the use of counterfeit tax stamps. Even so, studies have shown that, whatever  
 4 illegal market in cigarettes currently exists to avoid high state cigarette taxes is not  
 5 sufficient to nullify the public health benefits of those taxes.<sup>43</sup>

6 Therefore, given the entirely speculative nature of the claimed risks to public  
 7 health from prohibiting non-tobacco flavored e-cigarettes and other flavored  
 8 tobacco products, the concrete and well-documented health risks of flavored e-  
 9 cigarettes, particularly to youth, weigh heavily against the issuance of an injunction  
 10 against SB 793.

11 **II. An Injunction Would be Harmful to the Health of California**  
 12 **Residents by Allowing the Continued Sale of Menthol Cigarettes.**

13 Menthol cigarettes are a substantial threat to public health because they  
 14 increase the risk of youth initiation of smoking, increase addiction, and  
 15 disproportionately affect the African American community, thus exacerbating  
 16 serious health disparities. Because the injunction sought by plaintiffs would expose  
 17 the residents of California to the continued health harms of menthol cigarettes, it is  
 18 decisively contrary to the public interest.

19  
 20 \_\_\_\_\_  
 21 component of illicit tobacco trade in the United States is the illegal shipment of  
 22 tobacco products from low-tax States to high-tax states, in order to evade state  
 23 taxes.”).

24 <sup>43</sup> The strong consensus of economic studies is that every 10% increase in the  
 25 real price of cigarettes reduces overall cigarette consumption by approximately 3-  
 26 5%, reduces the number of young-adult smokers by 3.5%, and reduces the number  
 27 of kids who smoke by 6-7%. See generally, Frank J. Chaloupka et al., *Macro-*  
 28 *Social Influences: The Effects of Prices and Tobacco Control Policies on the*  
*Demand for Tobacco Products*, 1(Supp. 1) *Nicotine and Tobacco Rsch.* S105-09  
 (1999), <https://pubmed.ncbi.nlm.nih.gov/11072413/>; Campaign for Tobacco-Free  
 Kids, *Raising Cigarette Taxes Reduces Smoking, Especially Among Kids (and the*  
*Cigarette Companies Know It)*, [https://www.tobaccofreekids.org/assets/factsheets/](https://www.tobaccofreekids.org/assets/factsheets/0146.pdf)  
 0146.pdf (and sources therein) (last updated June 15, 2020); NRC Report, *supra*  
 note 41 at 27 (“even though tax avoidance and tax evasion might increase in  
 response to higher taxes, the losses from those actions would be less than the gains  
 from higher taxes.”); SG Report 2014, *supra* note 1, at 789.

1                   **A. Menthol Cigarettes Increase Youth Initiation of Smoking.**

2                   Although the tobacco companies know that almost all new tobacco users  
3 begin their addiction as kids, they also know that, to novice smokers, tobacco  
4 smoke can be harsh and unappealing. By masking the harshness and soothing the  
5 irritation caused by tobacco smoke, menthol cigarettes make it easier for beginners  
6 to experiment with cigarettes and ultimately become addicted. Thus, young  
7 smokers are more likely to use menthol cigarettes than any other age group. Over  
8 half of youth smokers ages 12-17 use menthol cigarettes, compared to less than  
9 one-third of smokers aged 35 and older.<sup>44</sup> As the FDA has observed, “[m]ultiple  
10 studies show a greater use of menthol cigarettes by younger smokers and less usage  
11 among older smokers.”<sup>45</sup> The FDA’s Tobacco Products Scientific Advisory  
12 Committee (TPSAC), after an extensive study of the public health impact of  
13 menthol cigarettes, concluded in a 2011 Report that menthol cigarettes increase the  
14 number of children who experiment with cigarettes and the number who become  
15 regular smokers, increasing overall youth smoking, and that young people who  
16 initiate using menthol cigarettes are more likely to become addicted and become  
17 long-term daily smokers.<sup>46</sup> Since 90% of adult smokers begin smoking in their  
18 teens,<sup>47</sup> as a starter product for the young, menthol cigarettes are critical to the  
19 tobacco industry’s need to recruit “replacement smokers” for the half of long-term  
20 smokers who eventually die from tobacco-related disease. In its 2011 TPSAC

21  
22                   <sup>44</sup> Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of*  
23 *Menthol Cigarette Use in the USA, 2004–2014*, 25 *Tobacco Control* ii14 (2016),  
<https://pubmed.ncbi.nlm.nih.gov/27729565/>.

24                   <sup>45</sup> Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,296.

25                   <sup>46</sup> Tobacco Products Scientific Advisory Committee (TPSAC), FDA,  
26 *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and*  
27 *Recommendations* at 136, 199-202 (2011), [https://wayback.archive-](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)  
[it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)  
28 [CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UC](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)  
[M269697.pdf](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf) (TPSAC Menthol Report).

29                   <sup>47</sup> Substance Abuse and Mental Health Services Administration (SAMHSA),  
HHS, *National Survey on Drug Use and Health, 2014*, [https://doi.org/10.3886/](https://doi.org/10.3886/ICPSR36361.v1)  
[ICPSR36361.v1](https://doi.org/10.3886/ICPSR36361.v1).

1 Menthol Report, TPSAC projected that by 2020, about 2.3 million people will have  
 2 started smoking because of menthol cigarettes, leading to 17,000 premature  
 3 deaths.<sup>48</sup> TPSAC concluded that “[r]emoval of menthol cigarettes from the  
 4 marketplace would benefit public health in the United States.”<sup>49</sup>

5 Two years after issuance of the TPSAC Menthol Report, FDA completed its  
 6 own independent, peer-review evaluation of the available science concerning  
 7 menthol cigarettes. FDA evaluated the peer-reviewed literature, industry  
 8 submissions and other materials provided to TPSAC and commissioned additional  
 9 analyses. FDA’s *Preliminary Scientific Evaluation of the Possible Public Health*  
 10 *Effects of Menthol versus Nonmenthol Cigarettes* (FDA Report) reached the overall  
 11 conclusion, consistent with TPSAC’s, that it is “likely that menthol cigarettes pose  
 12 a public health risk above that seen with nonmenthol cigarettes.”<sup>50</sup>

13 Since the reports from TPSAC and FDA, research has continued to  
 14 demonstrate the popularity of menthol cigarettes among youth and menthol’s role  
 15 in smoking initiation. A 2016 study demonstrated that youth smokers are more  
 16 likely to use menthol cigarettes than any other age group and over half (54%) of  
 17 youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third  
 18 of smokers ages 35 and older.<sup>51</sup> Data from Truth Initiative’s Young Adult Cohort  
 19 Study, a national study of 18-34 year olds, showed that 52% of new young adult  
 20 smokers initiated with menthol cigarettes. Initiation with menthol cigarettes was  
 21 higher among black smokers (93.1%) compared to white smokers (43.9%).<sup>52</sup>

22 <sup>48</sup> TPSAC Menthol Report, *supra* note 46, at 221.

23 <sup>49</sup> TPSAC Menthol Report, *supra* note 46, at 225.

24 <sup>50</sup> FDA, *Preliminary Scientific Evaluation of the Possible Public Health*  
*effects of Menthol versus Nonmenthol Cigarettes*, 2013,  
<https://www.fda.gov/media/86497/download> (FDA Report).

25 <sup>51</sup> Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of*  
*Menthol Cigarette Use in the USA, 2004–2014*, 25 *Tobacco Control* ii14, 2016,  
<https://pubmed.ncbi.nlm.nih.gov/27729565/>.

26 <sup>52</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 *Nicotine & Tobacco Rsch.* 9, 1062-1068 (2018)  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6093322/>.



1 The impact of menthol cigarettes in attracting kids, and keeping them  
 2 addicted, has profoundly adverse effects on their health. The FDA has written that  
 3 “smoking cigarettes during adolescence is associated with lasting cognitive and  
 4 behavioral impairments, including effects on working memory in smoking teens  
 5 and alterations in the prefrontal attentional network in young adult smokers.”<sup>53</sup>  
 6 “Use of tobacco products,” according to the FDA, “puts youth and young adults at  
 7 greater risk for future health issues, such as coronary artery disease, cancer, and  
 8 other known tobacco-related diseases. Youth and young adult . . . cigarette smokers  
 9 also are at increased risk for future marijuana and illicit drug use, developmental  
 10 and mental health disorders, reduced lung growth and impaired function, increased  
 11 risk of asthma, and early abdominal aortic atherosclerosis.”<sup>54</sup>

12 Moreover, there is no question that increased smoking prevalence due to  
 13 menthol cigarettes is of heightened concern because of the COVID-19 pandemic.  
 14 According to the Centers for Disease Control and Prevention, “Being a current or  
 15 former cigarette smoker increases your risk of severe illness from COVID-19.”<sup>55</sup>  
 16 The World Health Organization has found that “smokers are more likely to develop  
 17 severe disease with COVID-19 compared to non-smokers.”<sup>56</sup> Thus, as important to  
 18 public health as a prohibition of the sale of menthol cigarettes was before the  
 19 current pandemic, it is even more vital now.

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

21 The TPSAC and FDA Reports found that, in addition to increasing initiation  
 22 of smoking among young people, menthol cigarettes are associated with increased  
 23 nicotine dependence and reduced success in smoking cessation, particularly among  
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25 <sup>53</sup> Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,295.

26 <sup>54</sup> *Id.* at 12,295-96.

27 <sup>55</sup> CDC, *Coronavirus Disease 2019 (COVID-19) – People with Certain*  
 28 *Medical Conditions* (Oct. 16, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

<sup>56</sup> World Health Organization, *Tobacco Use and COVID-19* (May 11, 2020),  
<https://www.who.int/news-room/detail/11-05-2020-who-statement-tobacco-use-and-covid-19>.

1 African American smokers.<sup>57</sup>

2 More recent research bolsters these findings. The 2020 Surgeon General's  
3 Report on smoking cessation cited numerous studies finding an association between  
4 menthol use and lower cessation rates. The report concluded that the evidence is  
5 suggestive that restricting menthol products would lead to increased smoking  
6 cessation.<sup>58</sup> Recent research analyzing four waves of data from the government's  
7 PATH study shows that among daily smokers, menthol cigarette smokers have a  
8 24% lower odds of quitting as compared to non-menthol smokers. Among daily  
9 smokers, African American menthol smokers had a 53% lower odds of quitting  
10 compared to African American non-menthol smokers, while white menthol  
11 smokers had a 22% lower odds of quitting compared to white non-menthol  
12 smokers.<sup>59</sup> This study is one of the most robust longitudinal and nationally  
13 representative assessments of the relationship between menthol and cessation.

14 Data from the 2017 and 2018 NYTS shows that among middle and high  
15 school students, menthol smoking was associated with greater smoking frequency  
16 (smoking on at least 10 of the last 30 days) and intention to continue smoking,  
17 compared to non-menthol smoking.<sup>60</sup> Data from the government PATH study  
18 shows that youth menthol smokers have significantly higher levels of certain  
19 measures of dependence,<sup>61</sup> and that initiation with a menthol-flavored cigarette is

20 <sup>57</sup> TPSAC Menthol Report, *supra* note 46 at 49; FDA Report, *supra* note 50  
21 at 6.

22 <sup>58</sup> Office of the Surgeon General, HHS, *Smoking Cessation, A Report of the  
23 Surgeon General*, 2020, [https://www.hhs.gov/sites/default/files/2020-cessation-sgr-  
24 full-report.pdf](https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf).

25 <sup>59</sup> Sarah D. Mills et al., *The Relationship Between Menthol Cigarette Use,  
26 Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population  
27 Assessment of Tobacco and Health Study*, *Nicotine & Tobacco Rsch.* (Oct. 16,  
28 2020), <https://doi.org/10.1093/ntr/ntaa212>.

<sup>60</sup> Sunday Azagba et al., *Cigarette Smoking Behavior Among Menthol and  
Nonmenthol Adolescent Smokers*, 66 *Journal of Adolescent Health* 545-550 (2020),  
<https://pubmed.ncbi.nlm.nih.gov/31964612/>.

<sup>61</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*, *Drug & Alcohol Dependence* (2019),  
<https://www.sciencedirect.com/science/article/pii/S0376871619304922>.

1 associated with a higher relative risk of daily smoking.<sup>62</sup>

2 The difficulty that menthol smokers have in quitting is reflected in national  
3 smoking prevalence trends. From 2008 to 2014, smoking rates generally declined,  
4 but the proportion of smokers using menthol cigarettes increased significantly.  
5 Menthol smoking rates have increased among young adults and remained constant  
6 among youth and older adults, while non-menthol smoking has decreased in all  
7 three age groups.<sup>63</sup> Overall, about four out of ten (38.8%) smokers used menthol  
8 cigarettes in 2012-2014, an increase from 34.7% in 2008-2010.<sup>64</sup> Sales trends echo  
9 the patterns seen in menthol smoking prevalence. Between 2009 and 2018, sales of  
10 non-menthol cigarettes have declined by 33.1% nationally while sales of menthol  
11 cigarettes have declined by only 8.2% during the same period.<sup>65</sup> Of the decline in  
12 cigarette sales between 2009 and 2018, 91% is attributable to non-menthol  
13 cigarettes.<sup>66</sup>

14 **C. Menthol Cigarettes have led to Significant Health Disparities for**  
15 **African Americans.**

16 In addition to leading millions of youth into tobacco addiction, menthol  
17 cigarettes have played an especially pernicious role in victimizing the African  
18 American community. Dating back to the 1950s, the tobacco industry has targeted  
19 African Americans with marketing for menthol cigarettes through sponsorship of  
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21 <sup>62</sup> Andrea C. Villanti et al., *Association of Flavored Tobacco Use With*  
22 *Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2  
23 *J. Am. Med. Ass'n Network Open* e1913804, 2019,  
[https://jamanetwork.com/journals/  
jamanetworkopen/fullarticle/2753396](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396).

24 <sup>63</sup> Gary A. Giovino et al., *Differential Trends in Cigarette Smoking in the*  
25 *USA: Is Menthol slowing Progress?*, 24 *Tobacco Control* 28-37 (2013),  
<https://tobaccocontrol.bmj.com/content/tobaccocontrol/24/1/28.full.pdf>

25 <sup>64</sup> *Id.*

26 <sup>65</sup> Christine D. Delnevo et al., *Assessment of Menthol and Nonmenthol*  
27 *Cigarette Consumption in the US, 2000 to 2018*, 3 *J. Am. Med. Ass'n Network*  
28 *Open* e2013601, 2020, [https://jamanetwork.com/journals/jamanetworkopen/  
fullarticle/2769132](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132).

<sup>66</sup> *Id.*

1 community and music events, magazine advertising, youthful imagery and  
 2 marketing in the retail environment. The 2018 California Tobacco Retail  
 3 Surveillance Study found significantly more menthol advertisements at stores with  
 4 a higher proportion of African American residents and in neighborhoods with  
 5 higher proportions of school-age youth.<sup>67</sup> Another 2011 California study found  
 6 that, as the proportion of African American high school students in a neighborhood  
 7 rose, the proportion of menthol advertising increased.<sup>68</sup> As TPSAC concluded,  
 8 menthol cigarettes are “disproportionately marketed per capita to African  
 9 Americans. African Americans have been the subjects of specifically tailored  
 10 menthol marketing strategies and messages.”<sup>69</sup>

11 The tobacco industry’s use of menthol cigarettes to target African Americans  
 12 has paid lucrative, but tragic, rewards. The prevalence of menthol use *is highest*  
 13 *among African Americans – 85% of African American smokers smoke menthol*  
 14 *cigarettes*, compared to 29% of Whites.<sup>70</sup> In its 2011 TPSAC Report, the FDA  
 15 concluded that menthol cigarettes are associated with lower levels of smoking  
 16 cessation among African Americans.<sup>71</sup> TPSAC also estimated that by 2020, over  
 17 460,000 African Americans will have started smoking because of menthol  
 18 cigarettes, and 4,700 excess deaths of African Americans will have been  
 19 attributable to menthol cigarettes.<sup>72</sup>

20 Indeed, the public health importance of SB 793 for African Americans is  
 21 made especially clear by the COVID-19 pandemic, which has revealed stark health

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 23 <sup>67</sup> Nina Schleicher et al., Stanford Prevention Research Center, *California*  
 24 *Tobacco Retail Surveillance Study, 2018* 3, 22 (2019), <https://www.cdph.ca.gov/Programs/CCDC/DCDC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf>.

25 <sup>68</sup> Lisa Henriksen et al., *Targeted Advertising, Promotion, and Price for*  
 26 *Menthol Cigarettes in California High School Neighborhoods*, 14 *Nicotine*  
 27 *Tobacco Resch.* 116 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592564/>.

27 <sup>69</sup> TPSAC Menthol Report, *supra* note 46, at 92.

27 <sup>70</sup> OSG Report 2020, *supra* note 35.

28 <sup>71</sup> TPSAC Menthol Report, *supra* note 46, at 147.

28 <sup>72</sup> *Id.* at 206.

1 disparities across our nation. A Harvard University analysis of COVID-19  
 2 mortality rates by race and ethnicity found that Black COVID-19 patients between  
 3 25 and 54 years old were approximately seven to nine times as likely to die from  
 4 COVID-19 as White COVID-19 patients.<sup>73</sup> A CDC report on hospitalization rates  
 5 of patients with confirmed COVID-19 across 14 states found that while only 18%  
 6 of the population captured by the report are African Americans, 33% of all  
 7 hospitalized patients (for which race and ethnicity data were available) were  
 8 African American, suggesting an overrepresentation of African Americans among  
 9 hospitalized patients.<sup>74</sup> Another study currently under review evaluated COVID-19  
 10 diagnoses and deaths across United States counties with disproportionate numbers  
 11 of African American residents. The study found disproportionately higher COVID-  
 12 19 deaths in primarily Black counties in both small metro areas as well as rural  
 13 areas.<sup>75</sup> According to a recent CDC analysis of the effects of COVID-19, “current  
 14 data suggest a disproportionate burden of illness and death among racial and ethnic  
 15 minority groups.”<sup>76</sup>

16 Although multiple and complex factors contribute to racial health disparities  
 17 in the U.S., the disproportionate burden of COVID-19 on the African American  
 18 community surely underscores the urgency of laws like SB 793, given the  
 19 disproportionate impact of menthol cigarettes on that community and the likelihood

20 <sup>73</sup> Mary T. Bassett et al, *The Unequal Toll of COVID-19 Mortality by Age in*  
 21 *the United States: Quantifying Racial/Ethnic Disparities* 1-18 (The Harvard Ctr. for  
 22 Population and Dev. Stud. Working Paper Series No. 3, 2020), [https://cdn1.sph.  
 23 harvard.edu/wp-content/uploads/sites/1266/2020/06/20\\_Bassett-Chen-](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)

24 <sup>74</sup> Shikha Garg et al., *Hospitalization Rates and Characteristics of Patients*  
 25 *Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019—COVID-*  
 26 *NET, 14 States, March 1–30, 2020*, 69 *Morbidity & Mortality Wkly. Report* 458-  
 27 464 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6915e3-H.pdf>.

26 <sup>75</sup> Laura Barrón-Lopez, *A New Study Shows Just How Badly Black People*  
 27 *Have Been Hit by Covid-19*, Politico (May 5, 2020), [https://www.politico.com/  
 28 news/2020/05/05/black-counties-disproportionately-hit-by-coronavirus-237540](https://www.politico.com/news/2020/05/05/black-counties-disproportionately-hit-by-coronavirus-237540).

<sup>76</sup> CDC, *COVID-19 in Racial and Ethnic Minority Groups*,  
[https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-  
 28 minorities.html](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html).

1 that smokers are particularly vulnerable to the worst effects of the novel  
 2 coronavirus. The balance of equities, and the public interest, strongly weigh against  
 3 an injunction against SB 793 in the midst of a pandemic of respiratory disease that  
 4 is having such a deadly and disproportionate effect on the African American  
 5 community.

6 **III. An Injunction Would Be Harmful to the Health of California**  
 7 **Residents by Allowing the Continued Sale of Flavored Cigars.**

8 Like other flavored tobacco products, flavored cigar smoking presents  
 9 substantial health risks – risks that are particularly concerning given the prevalence  
 10 of cigar use among children and the tobacco industry’s efforts to market cigars to  
 11 youth. Historically, cigar manufacturers designed flavored cigars to serve as  
 12 “starter” smokes for youth and young adults because the flavorings helped mask the  
 13 harshness, making the products easier to smoke.<sup>77</sup> According to an industry  
 14 publication, “[w]hile different cigars target a variety of markets, all flavored  
 15 tobacco products tend to appeal primarily to younger consumers.”<sup>78</sup> The vice  
 16 president of one distributor commented, “[f]or a while it felt as if we were operating  
 17 a Baskin-Robbins ice cream store” in reference to the huge variety of cigar flavors  
 18 available – and, no doubt, an allusion to flavors that would appeal to kids.<sup>79</sup>

19 More than 1,400 children under age 18 try cigar smoking for the first time  
 20 every day.<sup>80</sup> The 2013-14 PATH study found that 71.7% of youth cigar smokers  
 21 used a flavored product in the last month.<sup>81</sup> The 2019 NYTS showed that  
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23 <sup>77</sup> Ganna Kostygina et al., *Tobacco Industry Use of Flavours to Recruit New*  
 24 *Users of Little Cigars and Cigarillos*, 25 *Tobacco Control* 66 (2016),  
<https://tobaccocontrol.bmj.com/content/25/1/66>.

25 <sup>78</sup> M. Niksic, *Flavored Smokes: Mmmmm...More Profits?*, *Tobacco Retailer*  
 (Apr. 2007).

26 <sup>79</sup> *Id.*  
 27 <sup>80</sup> SAMHSA, HHS, *2019 National Survey on Drug Use and Health, Table*  
 28 *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*. Cigars are defined as cigars, cigarillos or little cigars.

<sup>81</sup> Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,296.

1 approximately 600,000 middle and high school students had used a flavored cigar  
2 in the last 30 days.<sup>82</sup>

3 As the FDA has found, “[a]ll cigars pose serious negative health risks.”<sup>83</sup> In  
4 2010 alone, regular cigar smoking was responsible for “approximately 9,000  
5 premature deaths or almost 140,000 years of potential life lost among adults 35  
6 years or older.”<sup>84</sup> According to the FDA, “[a]ll cigar smokers have an increased  
7 risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco  
8 users,” as well as “other adverse health effects, such as “increased risk of heart and  
9 pulmonary disease,” “a marked increase in risk for chronic obstructive pulmonary  
10 disease,” a higher risk of death from COPD, and “a higher risk of fatal and nonfatal  
11 stroke compared to non-smokers.”<sup>85</sup>

12 A preliminary injunction that allows the sale of flavored cigars in California  
13 would be plainly contrary to the public interest.

14 **CONCLUSION**

15 For these reasons, the *amici* public health, medical and community  
16 organizations urge the Court to deny plaintiffs a preliminary injunction preventing  
17 enforcement of SB 793.

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27 <sup>82</sup> CDC, *supra* note 6.

<sup>83</sup> Deeming Rule, *supra* note 38, at 29,020.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

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Dated: November 12, 2020

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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. Our mission is  
15 to support and protect the health well-being of infants, children, adolescents, and  
16 young adults in California.

17 The American Cancer Society Cancer Action Network (ACS CAN) is the  
18 nation's leading voice advocating for public policies that are helping to defeat  
19 cancer. As the advocacy affiliate of the American Cancer Society, ACS CAN works  
20 to encourage government officials to make cancer a top priority, including  
21 supporting comprehensive tobacco control.

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

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

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

21 Americans for Nonsmokers’ Rights (ANR) is a national non-profit tobacco  
22 control advocacy organization based in Berkeley, California. Since its formation in  
23 1976, ANR has been dedicated to protecting nonsmokers’ rights to breathe smoke-  
24 free air in enclosed public places and workplaces and to preventing youth addiction  
25 to nicotine, including use of e-cigarettes and other flavored tobacco products. ANR  
26 represents a national constituency of over 12,000 individuals and organizations  
27 concerned about the health risks that tobacco and other nicotine products pose to  
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1 the health and safety of smokers and nonsmokers alike and committed to reducing  
2 and preventing tobacco and e-cigarette use.

3 Breathe California of the Bay Area, Golden Gate, and Central Coast is a  
4 century-old nonprofit that reduces the impact of lung disease through education,  
5 advocacy, patient services and research. Its key roles include: establishing tobacco-  
6 free communities, achieving healthy air quality, and fighting lung diseases like  
7 asthma and tuberculosis. Recent work has focused on the lung health threats of  
8 coronavirus, wildfires, and the vaping epidemic.

9 Breathe Southern California (Breathe SoCal) is an environmental health  
10 nonprofit organization focused on improving lung health and air quality. Breathe  
11 SoCal is a leader in educational programming efforts, including the “Clearing the  
12 Air: The Vaping Trend” community program that discusses the dangers of flavored  
13 tobacco products with students, parents, and teachers.

14 California Academy of Family Physicians (CAFP) is the only organization  
15 solely dedicated to advancing the specialty of family medicine in the state. Since  
16 1948, CAFP has championed the cause of family physicians and their patients.  
17 CAFP is critically important to primary care, with a strong collective voice of more  
18 than 11,000 family physician, family medicine resident, and medical student  
19 members. CAFP is the largest primary care medical society in California and the  
20 largest chapter of the American Academy of Family Physicians.

21 California Dental Association (CDA) is the nonprofit organization  
22 representing organized dentistry in California. Founded in 1870, CDA is committed  
23 to the success of our members in service to their patients and the public. CDA also  
24 contributes to the oral health of Californians through various comprehensive  
25 programs and advocacy. CDA’s membership consists of more than 27,000 dentists,  
26 making it the largest constituent of the American Dental Association. For more  
27 information, visit [cda.org](http://cda.org).

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

9 California Public Interest Research Group (CALPIRG) is a consumer group  
10 that stands up to powerful interests whenever they threaten our health and safety,  
11 our financial security, or our right to fully participate in our democratic society. For  
12 more than forty years, CALPIRG has been an advocate for stronger public health  
13 protections. We have supported efforts at the state and local level to prevent more  
14 children from becoming addicted to nicotine, including but not limited to support  
15 for SB 793. Headquartered in Sacramento, CALPIRG is supported by thousands of  
16 individual contributors across the state of California.

17 California School Nurses Organization (CSNO) is the professional  
18 organization for credentialed school nurses. We are the primary health professional  
19 within California's educational system and as such we strive to assure all children  
20 in school are healthy, ready and able to learn. As the primary health professional in  
21 the schools, we play a vital role in educating, counseling and designing  
22 programs/activities that encourage the development of decision making and  
23 problem solving skills which assist in the student's ability to make healthier  
24 choices.

25 Campaign for Tobacco-Free Kids is a leading force in the fight to reduce  
26 tobacco use and its deadly toll in the United States and around the world. The  
27 Campaign envisions a future free of the death and disease caused by tobacco, and it  
28 works to save lives by advocating for public policies that prevent kids from

1 smoking, help smokers quit and protect everyone from secondhand smoke. The  
2 Campaign for Tobacco-Free Kids has an interest in flavored tobacco restrictions in  
3 California because restrictions impact the use of tobacco products by young people.

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

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

23 Parents Against Vaping e-cigarettes (PAVe) is a national grassroots  
24 organization founded in 2018 by three moms in response to the youth vaping  
25 epidemic. The catalyst for PAVe was their discovery in April, 2018 that a JUUL  
26 representative had entered their sons’ high-school through an outside anti-addiction  
27 group, without the school’s knowledge, and told the 9th-grade students, without  
28 adults present, that JUUL was “totally safe” and would receive FDA approval “any

1 day.” (Their Congressional testimony about this incident was cited by FDA as  
2 evidence that JUUL had marketed directly to kids.) PAVE’s volunteer parent  
3 advocates operate in multiple states across the country, including California. PAVE  
4 believes that regulatory and legislative change at the state level is key to slowing  
5 the explosive growth of teen vaping and protecting teens from the predatory  
6 behavior of Big Tobacco.

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

27 Truth Initiative Foundation, d/b/a Truth Initiative (Truth Initiative) is a  
28 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement

1 agreement that resolved litigation brought by 46 states, five U.S. territories, and the  
2 District of Columbia against the major U.S. cigarette companies. Headquartered in  
3 Washington, D.C., Truth Initiative studies and supports programs in the United  
4 States to reduce youth smoking, vaping and nicotine use and to prevent diseases  
5 associated with tobacco products. Its nationally recognized truth® campaign has  
6 educated hundreds of millions of young people about the health effects and social  
7 costs of tobacco.

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