

**STATE OF MICHIGAN**  
**IN THE COURT OF APPEALS**

MARC SLIS and 906 VAPOR,

Plaintiff-Appellees,

Court of Appeals Case No. 351211

Court of Claims Case No. 2019-000152-MZ

v.

STATE OF MICHIGAN and MICHIGAN  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Defendant-Appellants.

*Consolidated with*

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A CLEAN CIGARETTE CORPORATION, a  
Michigan Corporation,

Plaintiff-Appellee,

Court of Appeals Case No. 351212

Court of Claims Case No. 2019-000154-MZ

v.

GOVERNOR GRETCHEN WHITMER, in her  
Official capacity and the STATE OF  
MICHIGAN, Acting through the Governor's  
Office, MICHIGAN DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

Defendant-Appellants.

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**FIRST AMENDED BRIEF OF AMICI CURIAE**  
**PUBLIC HEALTH AND MEDICAL ORGANIZATIONS**

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**STATEMENT OF QUESTIONS PRESENTED**

This first amended brief of amicus curiae will address the question of 1) whether the Court of Claims erred in finding that there was no genuine emergency sufficient to meet the conditions for emergency rules under MCL 24.248(1) and 2) whether a preliminary injunction issued to prevent enforcement of the Michigan Protection of Youth from Nicotine Product Addiction Emergency Rules harms the public interest.

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## **INTRODUCTION AND STATEMENT OF INTEREST OF AMICI CURIAE**

Amici curiae are filing this first amended brief in support of the Defendant-Appellant's appeal of the grant of a preliminary injunction against the Michigan Protection of Youth from Nicotine Product Addiction Emergency Rules (Emergency Rules). The amici are the following local, state and national public health and medical organizations: American Heart Association, American Indian Veterans of Michigan, American Lung Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Genesee County Prevention Coalition, Genesee Health Plan, Hurley Medical Center, Karmanos Cancer Center, Mercy Health & St. Joseph Mercy Health System, Michigan Academy of Family Physicians, Michigan Association for Local Public Health, Michigan Chapter – American Academy of Pediatrics, Michigan Chapter – March of Dimes, Michigan Council for Maternal & Child Health, Michigan Council of Nurse Practitioners, Michigan Health & Hospital Association, Michigan League for Public Policy, Michigan Osteopathic Association, Michigan Society of Hematology & Oncology, Michigan Society for Respiratory Care, Michigan State Medical Society, Michigan Thoracic Society, South Eastern Michigan Indians, Inc., Tobacco Free Michigan, and Truth Initiative.<sup>1</sup>

A description of these organizations is provided in Attachment A.

By this filing, amici seek to demonstrate that the Court of Claims erred in 1) finding that there was no genuine emergency and thus no basis for the issuance of emergency rules under MCL 24.248(1); and 2) failing to find that a preliminary injunction against Michigan's Emergency Rules is contrary to the public interest because it deprives residents of the state, and particularly its young

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<sup>1</sup> Pursuant to MCR 7.212(H)(3), Amici Curiae state that neither party's counsel authored this brief in whole or in part, nor contributed money that was intended to fund the preparation or submission of the brief. Further, no person other than the amici curiae has contributed money intended to fund the preparation and submission of this brief.

people, of the demonstrable public health benefits of prohibiting the sale of flavored vapor products.<sup>2</sup>

The amici have a strong interest in the implementation of tobacco control policies that will prevent the initiation of tobacco use by young people and thereby reduce the death and disease from tobacco products. Reducing the availability of flavored vaping products that are especially appealing to young people is one such policy. Flavored e-cigarettes are addicting a new generation of kids to nicotine and threaten to reverse decades of progress in reducing youth tobacco use. The amici have an interest in enhancing this Court’s understanding of the public health benefits of the Emergency Rules under attack and in assuring their timely implementation.

### **SUMMARY OF ARGUMENT**

Youth e-cigarette use in the United States has skyrocketed to what the U.S. Surgeon General and the U.S. Food and Drug Administration (FDA) have called “epidemic” levels. It is a public health crisis and *it is getting worse*. Newly released data from the 2019 National Youth Tobacco Survey (NYTS) shows that e-cigarette use among high school students more than doubled from 2017 to 2019, to 27.5 percent of students, or more than 1 in 4 high schoolers.<sup>3</sup> Altogether, 5 *million* middle and high school students used e-cigarettes in 2019 – an increase of nearly 3 million users in two years.<sup>4</sup> The Emergency Rules constitute a proper and appropriate use of the State’s

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<sup>2</sup> The Emergency Rules state that e-cigarettes are also known as vapor products. We use the terms e-cigarettes and vapor products interchangeably in this brief.

<sup>3</sup> FDA, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, September 11, 2019, [https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non?utm\\_source=CTPEblast&utm\\_medium=email&utm\\_term=stratout&utm\\_content=pressrelease&utm\\_campaign=ctp-vaping](https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non?utm_source=CTPEblast&utm_medium=email&utm_term=stratout&utm_content=pressrelease&utm_campaign=ctp-vaping).

<sup>4</sup> Edney, A., et al., *Vaping Furor Intensifies as Trump Vows Tough U.S. Scrutiny*, Bloomberg, September 11, 2019, <https://www.bloomberg.com/news/articles/2019-09-11/trump-to-hold-meeting-on-vaping-after-reports-of-u-s-illness>.

emergency authority to address the youth vaping epidemic and protect the health of Michigan’s children.

In granting a preliminary injunction against the Emergency Rules, the Court of Claims erred in two fundamental respects. First, it determined that, despite the clear evidence that youth vaping was increasing at an alarming rate, with severe public health consequences, “there was no genuine emergency” because the State could have acted sooner than it did. Second, it failed to find that an injunction against the Emergency Rules is contrary to the public interest because the rules represent a science-based policy that is critical to curbing the youth e-cigarette epidemic that is currently facing the State of Michigan.<sup>5</sup> See *M & S, Inc v Attorney General*, 165 Mich App 301 (1987) (finding issue of an injunction would harm public interest).

## ARGUMENT

### **I. The Emergency Rules Are Necessary to Address the Vaping Crisis Among Youth.**

#### **A. The Vaping Crisis among Michigan Youth is a Public Health Emergency.**

The Emergency Rules respond to an epidemic of youth usage of flavored e-cigarettes by ending the sale of flavored vaping products in Michigan (except tobacco flavored products). The severity of this epidemic cannot be overstated. E-cigarettes have become by far the most commonly used tobacco products among U.S. youth. Whereas the 2019 NYTS showed that 5.8% of high school students smoked regular cigarettes, use of e-cigarettes by high school students soared to 27.5% in 2019, up from 20.8% in 2018 and 11.7% in 2017.<sup>6</sup> Adolescents are not just

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<sup>5</sup> Remarkably, Plaintiff-Appellees argue that protecting the health of Michigan’s youth is incongruent with protecting the “public health, safety, or welfare.” MCL 24.248; see also MCL 333.2226(d). According to Plaintiff-Appellees, the Governor and Department of Health and Human Services could never declare an emergency to protect Michigan’s youth because they constitute merely a subset of the population. This interpretation of the law runs contrary to the most basic social values that long have placed the highest priority on protecting the health and welfare of our children.

<sup>6</sup> FDA, *supra* note 3.



experimenting with e-cigarettes; they are using them frequently. More than a quarter (27.7%) of high school e-cigarette users are frequent users, using e-cigarettes on at least 20 of the preceding 30 days.<sup>7</sup> Alarming, 1 in 9 of all high school seniors (11.7%) report that they vaped nicotine nearly daily, a strong indication of addiction.<sup>8</sup>

Trends in e-cigarette use in Michigan mirror the epidemic levels that are seen nationwide. According to the 2017 Youth Risk Behavior Study, 14.8% of Michigan high school students use e-cigarettes, compared to 4.9% of adults.<sup>9</sup> Between the years 2015-16 and 2017-18, counties across Michigan witnessed between a 30% and 118% increase in high school students who used an e-cigarette during the past month. In several Michigan counties, more than a third of high school students use e-cigarettes.<sup>10</sup>

Both the Commissioner of the FDA and the Surgeon General of the United States have recognized that youth usage of e-cigarettes has reached epidemic proportions. According to Norman E. “Ned” Sharpless, when he was Acting Commissioner of the FDA, “Years of progress

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<sup>7</sup> CDC, *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018*, Morbidity and Mortality Weekly Report (MMWR), 67(45): 1276-1277; CDC, *Behavioral Risk Factor Surveillance System, Prevalence and Trends, E-Cigarette Use, Michigan (2017)*, <https://nccd.cdc.gov/BRFSSPrevalence/>.

<sup>8</sup> Miech, R, et al., “Trends in Adolescent Vaping, 2017-2019,” *New England Journal of Medicine*, published online September 18, 2019.

<sup>9</sup> CDC, *Youth Risk Behavior Surveillance – United States, 2017*, Morbidity and Mortality Weekly Report (MMWR), 67(8), Table 67, <https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf>.

<sup>10</sup> MDE and MDHHS, *Michigan Profile for Healthy Youth Survey, 39 County Data from 2015-2016 and 2017-2018 for e-cigarette usage among high school students*, [https://www.michigan.gov/documents/mdhhs/ENDS\\_MI\\_County-Level\\_Data\\_659995\\_7.pdf](https://www.michigan.gov/documents/mdhhs/ENDS_MI_County-Level_Data_659995_7.pdf); Testimony of Dr. Joneigh S. Khaldun, MD, MPH, FACEP, Chief Medical Executive, State of Michigan, Chief Deputy Director for Health, Michigan Department of Health and Human Services, Hearing, *Sounding the Alarm: The Public Health Threats of E-Cigarettes*, Department of Health and Human Services, State of Michigan, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, September 25, 2019, <https://docs.house.gov/meetings/IF/IF02/20190925/110008/HHRG-116-IF02-Bio-KhaldunMDMPHJ-20190925.pdf>.

to combat youth use of tobacco – to prevent lifetimes of addiction to nicotine – is now threatened by an epidemic of e-cigarette use by kids.”<sup>11</sup> In December 2018, the Surgeon General issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.” The Surgeon General called for “aggressive steps to protect our children from these highly potent products that risk exposing a new generation of young people to nicotine.”<sup>12</sup> A U.S. District Court recently declared e-cigarettes to constitute a “clear public health emergency.” See *Am Acad of Peds v FDA*, 399 FSupp3d 479, 486 (D Md, 2019), *appeal docketed*, No. 19-2130 (4th Cir, Oct. 18, 2019) (citing “the uncertainty in the efficacy of e-cigarettes as smoking cessation devices,” the “recalcitrance” of the e-cigarette industry, “the continued availability of e-cigarettes,” and “their acknowledged appeal to youth.”).

The increasing number of vaping related pulmonary illnesses around the country only heightens the concern about initiation of vaping by youth.<sup>13</sup> Doctors report that the lung damage in some people who have become ill after vaping resembles a chemical burn. Speaking about the pattern of injuries observed in the lungs, a surgical pathologist noted, “To be honest, they look like the kind of change you would expect to see in an unfortunate worker in an industrial accident

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<sup>11</sup> FDA, *Statement on the agency’s actions to tackle the epidemic of youth vaping and court ruling on application submission deadlines for certain tobacco products, including e-cigarettes*, Statement from Acting Commissioner of Food and Drug Administration, July 15, 2019, <https://www.fda.gov/news-events/press-announcements/statement-agencys-actions-tackle-epidemic-youth-vaping-and-court-ruling-application-submission>.

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

<sup>13</sup> CDC, *Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping*, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html) (last updated January 28, 2020).

where a big barrel of toxic chemicals spills, and that person is exposed to toxic fumes and there is a chemical burn in the airways.”<sup>14</sup>

Indeed, as of January 21, 2020, 2,711 confirmed or probable cases of acute lung illness associated with the use of e-cigarette or vaping products have been reported to the Centers for Disease Control and Prevention (CDC) from all 50 states, and 2 U.S. territories, and 60 deaths have been confirmed in 27 states.<sup>15</sup> As of January 23, 2020, the Michigan Department of Health and Human Services (MDHHS) has reported 2 deaths and 69 vaping-associated lung injury cases in Michigan.<sup>16</sup> The known vaping associated illnesses in Michigan have afflicted teens and other young people, with the youngest victim being 15 years old.<sup>17</sup> MDHHS notes on its website that “while it appears that vitamin E is associated with [the lung illnesses], there are many different substances and product sources that are being investigated, and there may be more than once cause.”<sup>18</sup>

There is little doubt therefore that the youth vaping crisis in Michigan, as in other states across the nation, is a true public health emergency. As explained more fully below, any injunction delaying implementation of the Emergency Rules deprives this State of a vital tool to bring this epidemic under control.

**B. Vaping Products Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth.**

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<sup>14</sup> Grady, D., *Lung Damage From Vaping Resembles Chemical Burns, Report Says*, The New York Times, Oct. 2, 2019.

<sup>15</sup> CDC, *supra* note 13.

<sup>16</sup> Michigan Department of Health and Human Services (MDHHS), Health Advisory: Severe Lung Injury Associated with Electronic Cigarette Product Use or Vaping, [https://www.michigan.gov/mdhhs/0,5885,7-339-71550\\_2955\\_2973\\_94238\\_95655---,00.html](https://www.michigan.gov/mdhhs/0,5885,7-339-71550_2955_2973_94238_95655---,00.html).

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

<sup>18</sup> *Id.*

In recent years, tobacco companies have significantly increased the introduction and marketing of flavored non-cigarette tobacco products, especially e-cigarettes. Flavored e-cigarettes are undermining the nation’s overall efforts to reduce youth tobacco use and putting a new generation of kids at risk of addiction and the serious health harms that result from it.

Internal tobacco industry documents show that tobacco companies have a long history of using flavors to reduce the harshness of their products and to make them more appealing to new users, almost all of whom are under age 18.<sup>19</sup> In recent years, companies have extended this strategy of using flavored products to attract kids to the emerging market for e-cigarettes. As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available online.<sup>20</sup> An earlier study of e-cigarette flavors found that among the more than 400 brands available online in 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.<sup>21</sup> In addition to the more conventional candy and fruit flavors like mint and mango, e-liquids are also being sold in such kid-friendly options as cotton candy and gummy bear. These products are widely available through convenience stores, other retail outlets and online retailers.

News stories across the country have documented the popularity of flavored e-cigarettes like JUUL. According to one high school student, “It [JUUL] spread like wildfire for two reasons...the first reason is the flashy flavors like crème brulee. The flavors are responsible for bringing the kids in, the nicotine keeps them.”<sup>22</sup>

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<sup>19</sup> HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.

<sup>20</sup> Zhu, S-H, et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites*, *Journal of Medical Internet Research*, 20(3), J Med Internet Res 2018;20(3):e80, <https://www.jmir.org/2018/3/e80/>.

<sup>21</sup> Zhu, S-H, et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

<sup>22</sup> Ramanathan, L, *We killed the cigarette. What we got in return is mango-flavored nicotine in ‘party mode,’* Washington Post, August 8, 2018,

The data confirms that flavors play a major role in youth initiation and continued use of e-cigarettes. The 2020 Surgeon General Report on smoking cessation notes that “the role of flavors in promoting initiation of tobacco product use among youth is well established...and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes.”<sup>23</sup> The 2016 Surgeon General Report on e-cigarettes also had concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.<sup>24</sup> Data from the 2016-2017 wave of the government’s Population Assessment of Tobacco and Health (PATH) study found that 70.3% of current youth e-cigarette users say they use e-cigarettes “because they come in flavors I like.”<sup>25</sup> The PATH study also found that 97% of current youth e-cigarette users had used a flavored e-cigarette in the past month.<sup>26</sup> The 2019 NYTS found that 63.9% of high school e-cigarette users use mint or menthol flavors, an increase from 51.2% in 2018.<sup>27</sup>

Flavored tobacco products play a key role in enticing new users, particularly kids, to a lifetime of addiction. There is growing concern that use of e-cigarettes may function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Science, Engineering and Medicine (NASEM) concluded that, “There is substantial evidence that

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[https://www.washingtonpost.com/lifestyle/style/we-killed-the-cigarette-what-we-got-in-return-is-mango-flavored-nicotine-in-party-mode/2018/08/08/bf4db3a8-8b8a-11e8-8aea-86e88ae760d8\\_story.html?noredirect=on&utm\\_term=.2a6418f461f3](https://www.washingtonpost.com/lifestyle/style/we-killed-the-cigarette-what-we-got-in-return-is-mango-flavored-nicotine-in-party-mode/2018/08/08/bf4db3a8-8b8a-11e8-8aea-86e88ae760d8_story.html?noredirect=on&utm_term=.2a6418f461f3)

<sup>23</sup> HHS, *Smoking Cessation, A Report of the Surgeon General*, 2020, at 611 (2020 SG Report), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>24</sup> HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

<sup>25</sup> FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, at 9, March 13, 2019, <https://www.fda.gov/media/121384/download>.

<sup>26</sup> *Id.*

<sup>27</sup> FDA, *supra* note 3.

e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”<sup>28</sup> A nationally representative analysis found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying cigarettes and nearly three times the odds of current cigarette use (when compared to non-users of e-cigarettes). The researchers estimate that this translates to over 43,000 current youth cigarette smokers who might not have become smokers without e-cigarettes.<sup>29</sup>

Moreover, use of e-cigarettes is not limited to youth who are likely to become cigarette smokers. E-cigarette use is associated with trying cigarettes even among youth who are unlikely to smoke. Several studies have found that the link between e-cigarette use and starting to smoke cigarettes is stronger for youth who had lower risk factors for smoking.<sup>30</sup>

E-cigarettes and refill liquids contain widely varying levels of nicotine, and the nicotine delivered through the aerosol can also vary depending on the device characteristics and user practices.<sup>31</sup> Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development.<sup>32</sup> Nicotine also impacts the cardiovascular system.<sup>33</sup> The Surgeon

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<sup>28</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Public health consequences of e-cigarettes*, 2018, Washington, DC: The National Academies Press, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

<sup>29</sup> Berry, KM, et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, JAMA Network Open, 2(2), published online February 1, 2019.

<sup>30</sup> *Id.* See also, Barrington-Trimis, JL, et al., *E-Cigarettes and Future Cigarette Use, Pediatrics*, 138(1), July 2016; Wills, TA, et al., *E-cigarette use is differentially related to smoking onset among lower risk adolescents*, Tobacco Control, published online August 19, 2016.

<sup>31</sup> NASEM, *supra* note 28.

<sup>32</sup> HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>. See also, CDC Office on Smoking and Health, *Electronic Nicotine Delivery Systems: Key Facts*, July 2015.

<sup>33</sup> HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, Centers for Disease Control and

General concluded that, “[T]he use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”<sup>34</sup> The FDA recently submitted a brief to a U.S. District Court in which it described the highly addictive and dangerous characteristics of nicotine at length.<sup>35</sup> According to the 2020 Surgeon General’s Report, “[O]nce erroneously considered a habit that could be broken by simply deciding to stop, nicotine addiction is now recognized as a chronic, relapsing condition.”<sup>36</sup>

Flavorings in e-cigarettes can pose additional health hazards. According to the Surgeon General, “while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.<sup>37</sup> An article in the *Journal of the American Medical Association* raised concerns that the chemical flavorings found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs.<sup>38</sup> In *Nicopure Labs LLC v FDA*, the U.S.

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Prevention, Office on Smoking and Health, 2010  
<http://www.ncbi.nlm.nih.gov/books/NBK53017/>.

<sup>34</sup> HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

<sup>35</sup> See Mot to Dismiss and Opp to Mot for Pre Inj at 11, *VTA v FDA* (D Ky, Oct. 11, 2019), (Docket No. 19-cv-00330), ECF No. 23 (noting that nicotine is “one of the most addictive substances used by humans.”; Ingesting or touching e-liquids can cause nicotine poisoning, which can be fatal; noting that there were 1,700 e-liquid exposures reported to U.S. poison control centers from 2010-2013, mostly involving young children including a toddler who died after ingesting liquid nicotine) (internal citations omitted), dismissed, ECF No. 52 (Jan. 16, 2020).

<sup>36</sup> 2020 SG Report, *supra* note 23.

<sup>37</sup> *Id.*

<sup>38</sup> Barrington-Trimis, JL, Samet, JM, & McConnell, R, *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, *The Journal of the American Medical Association*, doi:10.1001/jama.2014.14830, published online November 10, 2014.

Court of Appeals for the D.C. Circuit relied on findings that flavors in e-cigarettes are harmful in upholding the application of FDA’s premarket review process to e-cigarettes. See 944 F3d 266 (DC Cir, 2019). Specifically, the court found that:

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

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

Thus, given the fast-spreading epidemic of youth e-cigarette use, caused in large part by the appeal of flavored products, the Emergency Rules are critical to this State’s efforts to protect its young people from the addictive and other harmful effects of e-cigarettes.

**C. The Court of Claims Incorrectly Concluded There Was No Genuine Emergency.**

Despite the overwhelming evidence of a youth vaping crisis, fueled by flavored products, the Court of Claims concluded that there was no genuine emergency and that MDHHS *created* an emergency by its own failure to act. This was clear error.

The Court’s conclusion that there was no genuine emergency is based on its assessment that MDHHS had data indicating a crisis of vaping among youth months before it acted and thus could have acted sooner. It bears noting that, as indicated by the Plaintiff-Appellees themselves,<sup>39</sup> Michigan was the first state in the nation to issue emergency rules to address the youth e-cigarette epidemic; Michigan’s rules took effect two days before New York’s. Other states followed.<sup>40</sup>

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<sup>39</sup> Appeal Br for Pls-Appellees Marc Slis and 906 Vapor, at 1.

<sup>40</sup> In addition to Michigan and New York, the states of Montana, Rhode Island, Washington, Massachusetts, Utah, and Oregon have issued emergency rules to address the youth vaping crisis.



Nothing in Michigan law remotely suggests that the MDHHS loses its authority to adopt emergency rules if it does not act within an unspecified time period. In *Michigan State AFL-CIO v Sec’y of State*, the Court noted that under MCL 24.248(1), “an emergency rule is justified if three conditions are satisfied”:

- (1) “the agency ‘finds that preservation of the public health, safety, or welfare requires promulgation of an emergency rule without following the notice and participation procedures required by section 41 and 42;’”
- (2) “the agency ‘states in the rule the agency’s reasons for that finding’”; and
- (3) “‘the governor concurs in the finding of emergency.’”

230 Mich App 1, 21 (1998) (quoting MCL 24.248(1)).

The issue under this statutory provision is whether the preservation of the public health, safety or welfare required issuance of an emergency rule *at the time the rule was issued*, not whether such circumstances may have existed at some point before the rule was issued. Here the lower court itself found “there is no serious dispute that a vaping-use crisis exists among youth.” Order at 10. As noted previously, far from abating, the crisis is getting worse. Yet the Court of Claims enjoined the State from taking emergency action, not because there is no public health crisis demanding emergency action, but because it may have been possible for the State to have acted sooner. The lower court’s injunction directly contradicts decades-old precedent established by the Michigan Supreme Court that “the courts have no jurisdiction to interfere with acts of health authorities except in cases of palpable abuse of the discretion conferred.” See *Rock v Carney*, 216 Mich 280, 289 (1921). The MDHHS’s first-in-the-nation emergency action to protect Michigan’s young people from e-cigarette addiction can hardly be judged an abuse of its discretion.

The lower court further invoked the doctrine that “an agency cannot create an emergency by way of its own failure to act,” and relied on federal case law that “an agency’s inaction or delay undercuts the notion that an emergency exists.” Order at 12. But this is not a case like *Council of*

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*S Mountains, Inc v Donovan*, 653 F2d 573, 581 (DC Cir, 1981), in which the Court expressed concern that federal agencies could avoid notice and comment rulemaking by waiting “until the eve of a statutory, judicial, or administrative deadline” before issuing a regulation and then assert that there was “good cause” for not complying with required notice and comment procedures. In the present case, the MDHHS did not create the youth vaping epidemic by its own failure to act; rather, the epidemic confronted the State of Michigan with the same public health crisis faced by other states and Michigan acted more expeditiously than any other state in protecting its citizens, particularly its young people. Nor is this case like *Washington Alliance of Tech Workers v United States Dept of Homeland Sec*, in which the court considered whether an economic crisis could sustain a good-cause determination for emergency rulemaking. See 202 FSupp3d 20 (DDC, 2016) (citing *Washington Alliance of Tech Workers*, 156 FSupp3d 123, 145-147 (DDC, 2015), judgment vacated by *Washington Alliance of Tech Workers*, 650 Fed Appx 13 (DC Cir, 2016)), aff’d 857 F3d 907 (DC Cir, 2017).<sup>41</sup> The Department of Homeland Security failed to provide sufficient economic data to demonstrate that the emergency rule was necessary to forestall a fiscal emergency, and waited *four years* before using an emergency rulemaking to address an ongoing and “entirely predictable” labor shortage. 156 FSupp3d at 145-7. Here, the emergency is not an economic one, there is no dispute that a vaping crisis exists and the State did not wait four years to promulgate a rule.

MDHHS’s failure to issue an emergency ban sooner than September 2019 *did not create* the vaping crisis. Nor is it relevant to whether the agency satisfied the statutory requirements for

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<sup>41</sup> The case cited by the Court of Claims and Plaintiff-Appellees, 202 FSupp3d 20 is an action for attorney fees. The relevant court opinion from the *Washington Alliance of Tech. Workers* litigation addressing emergency rulemaking is 156 FSupp3d 123 (DC Cir, 2015), judgment vacated by 650 Fed Appx 13 (DC Cir, 2016).

emergency rulemaking. When it acted in September, 2019, the MDHHS properly concluded that youth vaping was a public health emergency and that the preservation of public health required emergency rulemaking. The lower court had no basis to nullify the legitimate exercise of the agency's emergency authority.

## **II. The Harm to Public Interest Factor Weighs Significantly Against the Grant of an Injunction.**

The Court of Claims also erred in finding that the real health risks posed by e-cigarettes do not weigh significantly against the issuance of the preliminary injunction. In reaching this conclusion, the court erroneously gave equal weight to the real health risks they pose as detailed *supra* and the entirely speculative benefits of e-cigarettes for smoking cessation. See *Michigan AFSCME Council 25 v Woodhaven-Brownstown School Dist*, 293 Mich App 143, 157 (2011) (speculation is insufficient to justify an injunction). Because the harms posed by e-cigarettes are real and extensively well-documented, while the benefits of e-cigarettes to current smokers are entirely unproved, the Court should have found that the grant of an injunction harms the public interest.

### **A. Plaintiff-Appellees Exaggerate the Scientific Evidence of Claimed Health Benefits of E-Cigarettes Relative to Conventional Cigarettes and Ignore the Real Health Risks E-Cigarettes Pose.**

General statements that e-cigarettes are “safer” than conventional cigarettes do not sufficiently convey the health risks of e-cigarettes, particularly to young people. Plaintiff-Appellees greatly exaggerate what is known about the safety of e-cigarettes relative to cigarettes and oversimplify the relative health effects of using e-cigarettes by relying heavily on conclusions widely debunked as arbitrary, unscientific, and misleading.

Plaintiff-Appellees' evidence in support of the conclusion that vaping is significantly less harmful relies upon a statement by Public Health England (PHE), England's public health agency,

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that cites one group’s unscientific assertion that e-cigarettes are 95% safer than traditional cigarettes. See Pls. Proposed Findings of Fact and Conclusions of Law (Oct. 11, 2019), (Pls. App. Vol. 1, p. 79, ¶¶ 22-23). Significantly, not a single U.S. health authority or government resource has supported this claim.

The FDA examined and rejected the “95% safer” claim. FDA noted that the panelists conducting the underlying harm analysis “were selected without any formal criterion,” that there was a “lack of hard evidence” supporting most of the harm analysis, and that the methodology for arriving at the relative harm assessments underlying the “95% safer” conclusion was “unclear.” 81 Fed Reg at 29,029-30 (internal quotations omitted). Notably, several peer reviewed journals have also sharply criticized the scientific reliability of the “95% safer” claim. The Lancet’s critique noted that “the opinions of a small group of individuals with no pre-specified expertise in tobacco control were based on an almost total absence of evidence of harm. It is on this extraordinarily flimsy foundation that PHE based the major conclusion and message of its report.”<sup>42</sup> Another recent analysis concluded, “The “95% safer” estimate is a “factoid”: unreliable information repeated so often that it becomes accepted as fact.”<sup>43</sup> The article suggests that the 95% figure lacked rigorous scientific analysis and represented the conclusions made by a small group of people who based the estimate on limited evidence about e-cigarettes.<sup>44</sup> Significantly, the article raises concern about relying on the 95% statistic today, given that the range of e-cigarette products available on the market are drastically different from those available in 2013 when this estimate

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<sup>42</sup> Editorial, *E-cigarettes: Public Health England’s evidence-based confusion*, *The Lancet*, vol. 386, at 829 (Aug. 29, 2017)

<sup>43</sup> Eissenberg, T., et al., *Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes*, *AJPH*, published online January 8, 2020, <https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305424>

<sup>44</sup> *Id.*

was made.<sup>45</sup> For example, in addition to using different materials and various heating devices, many e-cigarettes today can attain power output that exceeds that of most 2013 models by 10 to 20 times.<sup>46</sup> Since 2013, thousands of new flavors of e-liquid have also entered the market.<sup>47</sup> These flavored e-liquids use chemicals that may be recognized as safe for ingestion but have unknown pulmonary toxicity.<sup>48</sup> More research also has emerged about the toxicants in e-cigarettes, and their potential respiratory and cardiovascular effects.<sup>49</sup> Thus, the 95% figure was based on little evidence when it was made and is even less valid today.

Contrary to the assertions of amicus Dr. Michael Siegel that switching from combustible cigarettes to e-cigarettes improves respiratory and cardiovascular health,<sup>50</sup> the extent of such salutary effects remains uncertain. A recent review article published in *The BMJ* concluded, “current knowledge of these [e cigarette] effects is insufficient to determine whether the respiratory health effects of e-cigarette are less than those of combustible tobacco products.”<sup>51</sup> The article concluded “that, to date, no long term vaping toxicological/safety studies have been done in humans; without these data, saying with certainty that e-cigarettes are safer than combustible cigarettes is impossible.”<sup>52</sup> The Surgeon General’s 2020 Report on tobacco cessation notes that “[a]lthough e-cigarette aerosol generally contains fewer toxic chemicals than conventional cigarette smoke, all tobacco products, including e-cigarettes carry risks.”<sup>53</sup> In *Nicopure Labs*,

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<sup>45</sup> *Id.*

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

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> Siegel Amicus Br, at 1-4.

<sup>51</sup> Jeffrey Gotts, et. al, *What are the respiratory effects of e-cigarettes?*, *The BMJ*, 2019; 366. <https://www.bmj.com/content/366/bmj.l5275>.

<sup>52</sup> *Id.*

<sup>53</sup> 2020 SG Report, *supra* note 24, at 23.

*supra*, a federal appellate court relied on findings regarding the known harms of e-cigarettes versus its speculative benefits. The court specifically noted, “[e]-cigarettes are indisputably highly addictive and pose health risks, especially to youth, that are not well understood.” 944 F.3d at 271. Moreover, the court noted that “[e]-cigarette liquids and vapor contain chemicals in addition to nicotine that pose known risks. The aerosol emitted from e-cigarettes is not simply water vapor; rather e-cigarette aerosols have been found to contain at least carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds. *Id.* at 274. The court noted that “e-cigarettes provide a trendy on-ramp to tobacco use for people who otherwise might have never used it. Accordingly, while e-cigarettes have been touted as less risky than combustible cigarettes, those claims remain unproved.<sup>54</sup> Meanwhile, e-cigarettes clearly have the potential to increase tobacco use and net health costs for the public as a whole.” *Id.* at 275.

**B. E-Cigarettes Have Not Been Approved as a Smoking Cessation Drug or Device in the U.S.**

Although Plaintiff-Appellees and Dr. Siegel assert that flavored e-cigarettes facilitate smoking cessation,<sup>55 56</sup> no e-cigarette has been approved, or even reviewed, as a smoking cessation drug or device by the FDA. The U.S. Preventive Services Task Force concluded that “the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation...”<sup>57</sup> The same NASEM report cited by Plaintiff-Appellees also concluded, “Overall,

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<sup>54</sup> In upholding emergency rules restricting the sale of flavored vapor products in Montana, a court in that state recently noted that Dr. Siegel lacked credibility in arguing that vaping is a safer delivery mechanism for nicotine given that there are no peer reviewed studies establishing that fact. See *Montana Smokefree Association, Inc v Montana Department of Public Health and Human Services*, unpublished opinion of the Montana 21st District Court, issued Dec. 17, 2019 (Docket No. DV-19-388), p 14.

<sup>55</sup> See e.g., Pl-Appellees Marc Slis and 906 Vapor’s Br In Supp of Mot for Pre Inj, Sep. 27, 2019, at 5-6, (Pls App Vol 1, p 17).

<sup>56</sup> Siegel Amicus Br at 5.

<sup>57</sup> U.S. Preventive Services Task Force, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women*: U.S. Preventive Services

there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”<sup>58</sup> According to CDC researchers, “There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.”<sup>59</sup> A 2018 systematic review of 66 articles published on consumer preference for e-cigarettes has supported these conclusions and also found inconclusive evidence as to whether e-cigarettes assist smoking cessation.<sup>60</sup>

Furthermore, according to CDC data, most adult smokers do not switch completely to e-cigarettes; rather, they use both e-cigarettes and cigarettes (dual use).<sup>61</sup> NASEM found that dual use of cigarettes and e-cigarettes “is not a proven method for combustible tobacco cigarette cessation.”<sup>62</sup> FDA reached the same conclusion and stated, “[T]here is not sufficient evidence to conclude that youth and young adults are using [e-cigarettes] as a means to quit smoking.” See 81 Fed Reg 29,028. According to the FDA, “systematic reviews found insufficient evidence to conclude that e-cigarettes aid smoking cessation.” *Id* at 29,037. In reaching this conclusion, the

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Task Force Recommendation Statement, *Annals of Internal Medicine*, Vol. 163, No. 8, October 2015, <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1>.

<sup>58</sup> NASEM, *supra* note 28.

<sup>59</sup> King, BA, et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., *Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013*, *Nicotine & Tobacco Research*, first published online September 19, 2014.

<sup>60</sup> Zare, S, et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, *PLoS One*. 2018 Mar 15;13(3):e0194145. doi: 10.1371/journal.pone.0194145

<sup>61</sup> CDC, “QuickStats: Cigarette Smoking Status Among Current Adult E-cigarette Users, by Age Group — National Health Interview Survey, United States, 2015,” *MMWR* 65(42):1177, October 28, 2016, <https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm>. See also CDC, “About Electronic Cigarettes (E-Cigarettes),” Last reviewed November 15, 2018, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-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)

<sup>62</sup> NASEM, *supra* note 28, at 18-24.

FDA recognized that several studies have found that cigarette smokers who also used e-cigarettes had statistically significantly worse quit rates than those cigarette smokers who did not use e-cigarettes. See *id.* at 29, 028, 29,037. In a recent brief filed in federal court, the FDA stated that, “the claim that vaping helps smokers quit in meaningful numbers remains unproven.” *Am Acad of Peds, supra*, ECF No 46. at 14. The recent Surgeon General’s report on smoking cessation confirms this finding and notes that whether e-cigarettes “produce[s] an effective method of cessation is presently inconclusive from the emerging base of empirical evidence.”<sup>63</sup> The report explains that “when considering e-cigarettes as a potential cessation aid for adult smokers, it is also important to take into account factors related to both safety and efficacy. [FDA-approved] NRT [nicotine replacement therapy] has been proved safe and effective, but there is no safe tobacco product.”<sup>64</sup>

Dr. Siegel’s assertion that flavored e-cigarette regulation will lead to substantial increases in cigarette consumption is not based on a valid analysis.<sup>65</sup> Dr. Siegel cites the experience with the Massachusetts emergency flavored e-cigarette ban, which took effect on September 25, 2019. He compares Massachusetts cigarette pack sales in September, 2018 with those sales in September, 2019 (a 9.8% decline), with the comparable change in October, 2018 vs. October, 2019 (a 4.1% decline). Finding that the rate of decline was greater in the September comparison than in the October comparison, Siegel concludes that the e-cigarette flavor ban must have caused an increase in cigarette consumption in Massachusetts.<sup>66</sup> This conclusion ignores the fact that pack sales fluctuate greatly and the changes observed in September and October in Massachusetts are well

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<sup>63</sup> 2020 SG Report, *supra* note 24, at 23.

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

<sup>65</sup> Siegel Amicus Br at 8-10.

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



within the range of normal variability in such comparisons, which have ranged from 15% declines to 10% increases in monthly year-over-year sales comparisons in Massachusetts over the past two years.<sup>67</sup> Therefore, no causal impact of the Massachusetts emergency rule can be inferred from this data.

Moreover, contrary to Dr. Siegel's assertions,<sup>68</sup> there is no evidence that flavors in e-cigarettes play any role in smoking cessation. While there are surveys showing that many adults enjoy using flavored products, and anecdotal reports of smokers who say flavored e-cigarettes helped them quit, there is no evidence that smokers could not have quit without non-tobacco flavors. There has not been a single randomized controlled trial to assess the impact of flavored vs. non-flavored or tobacco-flavored e-cigarettes on smoking cessation outcomes.

Because the benefits of e-cigarettes are largely anecdotal and speculative, but the risks of e-cigarettes, including addiction and other harms, are well-documented and real, the grant of an injunction harms the public interest.

### **III. Michigan's Emergency Rules Are Necessary Because Other Existing Tobacco Regulations Are Insufficient to Address the Epidemic of E-Cigarette Use Among Kids.**

Plaintiff-Appellants suggest that Michigan's law making it illegal for retailers to sell e-cigarettes to individuals under 18 had an "ameliorative impact" on the youth e-cigarette problem. See Plaintiff-Appellee A Clean Cigarette's Brief in Response to Defendant's Brief on Appeal, at 3-4. Although Michigan's age-restrictions on sale of tobacco products are important and necessary measures to restrict access, they are insufficient on their own to combat the e-cigarette epidemic among youth. Young people entering stores cannot avoid being accosted by an array of e-

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<sup>67</sup> Orzechowski and Walker, The Tax Burden on Tobacco, 1970-2018, <https://chronicdata.cdc.gov/Policy/The-Tax-Burden-on-Tobacco-1970-2018/7nwe-3aj9>.

<sup>68</sup> Siegel Amicus Br, at 5-6.

cigarettes—virtually all with flavors designed to enhance their appeal to youth. Experience demonstrates convincingly that, because flavored e-cigarettes have such a powerful appeal to youth, laws prohibiting sales to minors are simply not enough.

According to the 2018 Monitoring the Future Survey, more than 60% of 10th grade students say it is easy to get vaping devices and e-liquids.<sup>69</sup> Indeed, it is clear that, despite age restrictions, retailers continue to sell these products to minors. In the summer of 2018, the FDA’s undercover enforcement efforts yielded over 1,300 warning letters and fines to brick-and-mortar and online retailers for illegally selling e-cigarettes to minors.<sup>70</sup> According to FY2019 data, Michigan has a sales to minors violation rate of 10%.<sup>71</sup> FDA reported 809 sales to minors violations in 2018 in Michigan, involving the issuance of 532 warning letters, 275 civil money penalties, and 2 no-tobacco sale orders.<sup>72</sup> A study in JAMA Pediatrics found that in California, where the tobacco sales age is 21, 44.7% of tobacco and vape shops sold e-cigarettes to underage decoys.<sup>73</sup>

Given the obvious insufficiency of age restrictions alone, the Emergency Rules prohibiting the sale of flavored e-cigarettes are absolutely necessary to reduce the use of e-cigarettes by Michigan kids.

#### **IV. FDA’s Regulatory Authority Over E-Cigarettes Does Not Limit the State from Taking Further Action to Protect Its Youth from the Harm of E-Cigarettes.**

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<sup>69</sup> University of Michigan, Monitoring the Future Study, *Trends in Availability – Tables 15-17*, 2018, <http://monitoringthefuture.org/data/18data/18drtbl15.pdf> and <http://monitoringthefuture.org/data/18data/18drtbl16.pdf>.

<sup>70</sup> FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, March 13, 2019, <https://www.fda.gov/media/121384/download>.

<sup>71</sup> Michigan Annual Synar Report, FFY 2019, at 39, [https://www.michigan.gov/documents/mdhhs/SYNAR\\_Report\\_2019\\_637850\\_7.pdf](https://www.michigan.gov/documents/mdhhs/SYNAR_Report_2019_637850_7.pdf).

<sup>72</sup> FDA, *Compliance Check Inspections of Tobacco Product Retailers* (through 8/31/2019), [https://www.accessdata.fda.gov/scripts/oc/inspections/oc\\_insp\\_searching.cfm](https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm).

<sup>73</sup> Roeseler, A, et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, JAMA Pediatrics, June 24, 2019.

Contrary to the suggestion of Plaintiff-Appellees,<sup>74</sup> the existence of federal regulatory authority over e-cigarettes does not obviate the need for emergency action by Michigan to stem the tide of vaping among youth.

Although Congress gave FDA broad regulatory authority over tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), the agency has largely failed to use that authority to regulate e-cigarettes. Pub L No 111-31, 123 Stat 1776 (2009)(codified at 21 USC 387-387u). Despite the requirement in the Tobacco Control Act that new tobacco products (i.e., those introduced after February 15, 2007) obtain an FDA order authorizing their marketing, not a single e-cigarette product currently on the market has been reviewed and authorized by the FDA. 21 USC 387j. Thus, it is essential for Michigan and other states to utilize their authority to protect the health of its residents and especially its youth. Moreover, the Tobacco Control Act expressly preserves the power of states to regulate, and even prohibit, the sale of tobacco products. 21 USC 387p.

E-cigarettes were entirely unregulated by FDA until the 2016 issuance of a final rule “deeming” e-cigarettes and other previously unregulated tobacco products subject to FDA regulation. See Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed Reg 28,974 (May 10, 2016) (“Deeming Rule”). Even after the Deeming Rule was issued, FDA’s regulatory power has been severely underutilized. For example, although FDA now has the authority to regulate the methods used in manufacturing, design and testing of vapor products and to mandate new product standards regarding the construction, composition, ingredients and characteristics of vapor products, the agency has issued no regulations requiring

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<sup>74</sup> Pls. Marc Slis and 906 Vapor’s Br In Supp of Mot For Prelim Inj, 11-13 (Pls App at 23-25).

good manufacturing practices for e-cigarettes, nor has it issued a single product standard for e-cigarettes. 21 USC 387(f)(e), 387(g).

Most significantly, FDA has failed to implement the required premarket review of “new tobacco products” (i.e., products marketed after February 15, 2007), in which manufacturers generally would be required to demonstrate that their products are “appropriate for the protection of public health” in order to stay on the market or enter the market. 21 USC 387(j). At the time it issued the Deeming Rule in August 2016, FDA exercised its enforcement discretion to e-cigarettes already on the market, to give their manufacturers a two-year period, until August 2018, to file applications for premarket review. 81 Fed Reg 28,978. Then, in an August 2017 Guidance, FDA announced it would further defer enforcement of the premarket review requirements for e-cigarettes four additional years until 2022. Thus, FDA allowed thousands of flavored e-cigarettes to remain on the market until 2022 without having to even submit an application demonstrating that they met the public health standard in the statute. As the result of a lawsuit brought against FDA by several public health groups, a federal court established a ten-month deadline (until May 2020) for industry marketing applications and a one-year deadline for completion of FDA review. Thus, the premarket review process has been revived, but only by court order, which is subject to a pending appeal. See *Am Acad of Peds* 399 FSupp3d at 487, *appeal docketed*, No. 19-2130 (4th Cir, Oct. 18, 2019).

FDA’s enforcement policy announced on January 2, 2020 is also wholly inadequate to clear the market of the appealing e-cigarette flavors that are widely sold and targeted to youth.<sup>75</sup> The

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<sup>75</sup> FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on Market Without Premarket Authorization, Guidance for Industry (Jan. 2, 2020) (“FDA 2020 Guidance”).

policy only restricts flavors in some cartridge-based e-cigarettes,<sup>76</sup> leaving over 15,000 flavored e-liquids in every imaginable flavor widely available.<sup>77</sup> The policy also exempts all menthol flavored e-cigarettes.<sup>78</sup> Leaving menthol e-cigarettes on the market will not solve the youth e-cigarette epidemic as menthol tobacco products are uniquely appealing to youth. Half (50.1%) of youth who have ever tried smoking initiated with menthol flavored cigarettes<sup>79</sup> and over half (54%) of current youth smokers ages 12-17 smoke menthol cigarettes.<sup>80</sup> There is no reason to believe that menthol e-cigarettes are not equally appealing to kids—especially if they are the only available flavor for cartridge-based products. Data from the 2019 National Youth Tobacco Survey show that over half (57.3%) of high school e-cigarette users use mint or menthol flavored e-cigarettes. This is an increase from just 16% in 2016.<sup>81</sup> Furthermore, the policy also exempts refillable pod

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<sup>76</sup> *Id.* at 3, 9.

<sup>77</sup> Letter from 30 U.S. Senators to FDA re: FDA E-Cigarette Policy, Jan. 13, 2020, <https://www.help.senate.gov/download/01132020-fda-letter-final-pdf> (“In other words, FDA will continue to allow all menthol-flavored e-cigarettes and all flavored e-liquids used in “open tank” e-cigarettes, including those in fruit and candy flavors, as well as single-use products, to remain on the market even though these products have not undergone an FDA review.”); Convenience Stores News, *New Flavored E-Cigarette Cartridge Policy Goes into Effect Feb. 6*, Jan. 10, 2020, [https://csnews.com/new-flavored-e-cigarette-cartridge-policy-goes-effect-feb-6?utm\\_source=omeda&utm\\_medium=email&utm\\_campaign=NL\\_CVN+Backbar&utm\\_keyword=&oly\\_enc\\_id=490219478178C9Y](https://csnews.com/new-flavored-e-cigarette-cartridge-policy-goes-effect-feb-6?utm_source=omeda&utm_medium=email&utm_campaign=NL_CVN+Backbar&utm_keyword=&oly_enc_id=490219478178C9Y) (“Though the FDA’s policy affects flavored cartridges, retailers can still sell e-liquid flavors used in open vaping systems and in disposable single-use vape products.”); Campaign for Tobacco-Free Kids, Administration’s E-Cigarette Policy Leaves Thousands of Flavored E-Cigarettes on the Market, [https://www.tobaccofreekids.org/media/2020/2020\\_01\\_15\\_what-isnt-covered](https://www.tobaccofreekids.org/media/2020/2020_01_15_what-isnt-covered).

<sup>78</sup> FDA 2020 Guidance, *supra* note 75, at 3 (“FDA intends to prioritize enforcement against: Any flavored, cartridge-based ENDS product (other than tobacco- or menthol-flavored ENDS product”).

<sup>79</sup> Ambrose, BK, et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, Journal of the American Medical Association, published online October 26, 2015.

<sup>80</sup> Villanti, A., et al., *Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014*, Tobacco Control, published online October 20, 2016.

<sup>81</sup> Leventhal, AM, et al., *Flavors of e-Cigarettes Used by Youths in the United States*, JAMA, published online November 5, 2019.

systems like Suorin and Smok and disposable e-cigarettes like Puff Bar, Mojo, and Stig,<sup>82</sup> all which are immensely popular among youth.<sup>83</sup> Because FDA’s policy falls far short of clearing the market of flavored e-cigarettes, they will remain widely available to youth.

In light of the absence of effective federal regulation, it is vital for states to take action to protect their residents from the harms of e-cigarettes. Nothing in the Tobacco Control Act prohibits MDHHS from promulgating regulations to prohibit the sale and distribution of flavored e-cigarette products to consumers in Michigan. Section 916 of the Tobacco Control Act specifically preserves broad state and local authority with respect to tobacco products. 21 USC 387(p). Section 916(a)(2)(B), the provision’s “savings clause,” specifically states that the limited preemption in Subparagraph (A) does not apply to the “sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age....” *Id.* Thus, in no sense does the existence of federal regulatory authority over e-cigarettes affect Michigan’s authority to prohibit the sale of flavored e-cigarettes, nor does it diminish the public health importance of doing so.

### CONCLUSION

Michigan was the first state to prohibit the sale of flavored vaping products; seven other states have followed Michigan’s example in initiating restrictions on flavored vaping products to address the youth e-cigarette crisis. At least 200 localities also have passed restrictions or complete prohibitions on the sale of flavored e-cigarettes.<sup>84</sup> Michigan children and families should not be

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<sup>82</sup> FDA 2020 Guidance, *supra* note 75, at 9, Fn 20 (“An example of products that would not be captured by this definition include completely self-contained, disposable products”).

<sup>83</sup> Kaplan, S., *Teens Find a Big Loophole in the New Flavored Vaping Ban*, The New York Times, Jan. 31, 2020.

<sup>84</sup> Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted the Sale of Flavored Tobacco Products*, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

deprived of the benefits of this necessary and appropriate response to the current epidemic. The preliminary injunction delaying implementation of the Emergency Rules addressing the youth vaping crisis should be reversed.

Respectfully submitted,

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Dated: February 3, 2020

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**CERTIFICATE OF SERVICE**

Cassie Poe, being first duly sworn deposes and says that on February 3, 2020, she filed the foregoing Brief of Amici Curiae and this Certificate of Service with the Clerk of the Court using the Court's electronic filing system which will electronically serve all counsel of record.

*/s/ Cassie Poe* \_\_\_\_\_

Cassie Poe

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## ATTACHMENT A

### Description of Amici Curiae

1. **American Heart Association**

The American Heart Association (AHA) is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. In Michigan, AHA has helped advocate for critical tobacco control and prevention policies including the Clean Indoor Air Act, and increasing the age of sale on tobacco from 18 to 21 in both Ann Arbor and Genesee County.

2. **American Indian Veterans of Michigan**

American Indian Veterans of Michigan has worked in Commercial Tobacco Control specifically with all veterans, their organizations and VA's throughout Michigan.

3. **American Lung Association**

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

4. **American Thoracic Society**

The American Thoracic Society (ATS) is a medical profession society comprised of physicians, nurses, respiratory therapists and researchers dedicated to the prevention, detection, treatment, cure and research of respiratory disease, critical care illness and sleep disordered breathing. Members of the ATS are research and clinical experts on the prevention and treatment of nicotine-related diseases and tobacco cessation. Many of our members are currently treating youth and adults suffering from the recent outbreak of e-cigarette vaping associated lung injury (EVALI). For these reasons, the ATS has a compelling interest in the state of Michigan's ban on flavored vaping and e-cigarette products.

5. **Campaign for Tobacco-Free Kids**

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke. Tobacco-Free Kids has a strong interest in ensuring the timely enforcement of Michigan's Emergency Rules because they are essential to curbing the dramatically increasing incidence of youth usage of e-cigarettes in Michigan that threatens to addict a new generation of young people to nicotine and undermine the progress made over decades in curbing tobacco use by adolescents in Michigan and elsewhere.

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**6. Genesee County Prevention Coalition**

The Genesee County Prevention Coalition represents a diverse group of people and organizations working within the community to develop new and effective ways to prevent and reduce mental health and substance use disorders. We believe in our collective and individual responsibility to ensure healthy, safe and productive lives for all Genesee County residents through innovative strategies and community partnerships.

**7. Genesee Health Plan**

Genesee Health Plan (GHP) is a community-initiated non-profit program designed to provide health care coverage to the uninsured residents of Genesee County. At GHP, we have a Health Navigation program designed to assist individuals with chronic disease management including smoking cessation for individuals wanting to make healthy changes with their lifestyle. By conducting assessments with our GHP members, we know that 40% of our members smoke. We have helped over ten thousand Genesee County residents over the last 18 years get the resources they need to start the difficult process of quitting smoking. GHP also has Community Health Workers in each of the Flint Public Schools. Thirty-Four (34%) percent of adults assessed are smokers in the households where the children in the Flint community reside. GHP has also helped these Flint residents get the tools they need to quit smoking.

**8. Hurley Medical Center**

The Hurley Mission: “Clinical Excellence. Service to People.” The mission of Hurley Medical Center is to ensure that we are always ready when someone faces a serious injury, complex illness, or high risk condition. Today, tomorrow, and beyond, we have the dedicated, compassionate professionals, advanced technology, and state-of-the-art facilities to meet the complex health needs of our region. Hurley’s Vision: To be “Leaders in transforming health through academic and clinical excellence, expanding access to innovative care.” “Transforming Health” means that our job is to help Genesee County get healthy and stay that way. At Hurley, our vision is to create a healthier future for every child, adult and senior citizen. We will not only treat people when they are sick or injured and then return them to their homes, but we will find ways to help them stay in their homes living vibrant, healthy, active lives.

**9. Karmanos Cancer Center**

Karmanos Cancer Center is the only National Cancer Institute (NCI)-designated comprehensive cancer center in metro Detroit and one of just 51 centers of its kind in the United States. That means patients can access treatments exclusive to Karmanos as well as clinical trials, cancer prevention programs and multidisciplinary teams of cancer specialists — a comprehensive approach you cannot find at a community hospital.

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**10. Mercy Health & Saint Joseph Mercy Health System**

The Michigan-based health systems of Trinity Health, Mercy Health and Saint Joseph Mercy Health System, are leading health care providers and one of the state’s largest employers. With 20,000 employees serving 23 counties, we provide the full continuum of care for Michigan residents through eight hospitals, including the five hospitals of Saint Joseph Mercy Health System in Ann Arbor, Chelsea, Howell, Livonia and Pontiac, and the three-hospital Mercy Health, operating in Grand Rapids and Muskegon.

**11. Michigan Academy of Family Physicians**

The Michigan Academy of Family Physicians (MAFP) is the largest specialty physician association in the State of Michigan. With more than 4,200 student, resident, active, and life members, MAFP is dedicated to assisting family physicians and their practices as they work to ensure high-quality, cost-effective healthcare for patients of all ages.

**12. Michigan Association for Local Public Health**

The Michigan Association for Local Public Health (MALPH) was founded in 1985 as a private, non-profit, 501(c)(3) state association. The association is organized to represent Michigan's 45 city, county, and district health departments before the state and federal legislative and executive branches of government, to strengthen Michigan's system of local public health.

**13. Michigan Chapter – American Academy of Pediatrics**

The Michigan Chapter of the American Academy of Pediatrics (MIAAP) is a diverse group of over 1,400 pediatricians. Members include general pediatricians, sub-specialists, and academicians. Members are active in promoting the health and well-being of the children in the state of Michigan. The MIAAP is an affiliate of the American Academy of Pediatrics. The mission of the MIAAP is to identify, develop and manage opportunities to improve the health and welfare of children and the practice of pediatric medicine and to provide ongoing Continuing Medical Education opportunities for its members.

**14. Michigan Chapter – March of Dimes**

March of Dimes leads the fight for the health of all moms and babies. We believe that every baby deserves the best possible start. Unfortunately, not all babies get one. We are changing that.

**15. Michigan Council for Maternal & Child Health**

The Michigan Council for Maternal & Child Health (MCMCH) is an advocacy organization which seeks to impact public policy and improve maternal and child health outcomes through prevention programs, access to care and adequate funding. Members include health care systems, public health departments, statewide and local organizations.

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**16. Michigan Council of Nurse Practitioners**

The Michigan Council of Nurse Practitioners (MICNP) is a professional membership association representing all nurse practitioner specialties throughout the state. MICNP seeks to provide nurse practitioners the leadership and resources to improve their practice environment through education of its members and the community, legislative support on issues affecting the profession, and promoting access to nurse practitioner services.

**17. Michigan Health & Hospital Association**

The Michigan Health & Hospital Association (MHA) is the statewide leader representing all community hospitals in Michigan. Established in 1919, the MHA represents the interests of its member hospitals and health systems in both the legislative and regulatory arenas on key issues and supports their efforts to provide quality, cost-effective and accessible care. Our mission is to advance the health of individuals and communities.

**18. Michigan League for Public Policy**

The Michigan League for Public Policy has been around for 107 years. Children have been at the core of the League's mission from day one, as it formed in 1912 in part to address child labor laws and keep kids safe and out of factories. That commitment to kids was boosted further in 1992, when the League became the Kids Count organization in Michigan to monitor and report on child well-being at the state and local level. The League proudly continues to be a policy-minded and data-driven voice for Michigan kids.

**19. Michigan Osteopathic Association**

The Michigan Osteopathic Association (MOA) is the largest statewide osteopathic organization representing osteopathic physicians, interns, residents and medical students in Michigan. Since 1898, the MOA has been dedicated to the promotion of quality patient care and advocating on behalf of physicians and the communities they serve.

**20. Michigan Society of Hematology & Oncology**

The Michigan Society of Hematology and Oncology (MSHO) represents over 90% of the medical oncology, hematology and radiation oncology specialists in Michigan, treating cancer patients across all settings of care. It is the mission of our Society to promote exemplary care for patients with cancer and blood disorders through advocacy, education and research.

**21. Michigan Society for Respiratory Care**

The Michigan Society for Respiratory Care (MSRC) is a not-for-profit professional association dedicated to providing education, advocacy and resources to promote respiratory health in communities throughout Michigan. Founded in 1956 as the Michigan Society for Respiratory Therapy, MSRC is committed to enhancing the quality of respiratory health by ensuring the professional development and growth of its membership. Our mission is to be the leading state professional association for respiratory care. We represent and promote professional excellence, advance the science and practice of respiratory care and serve as an advocate and

resource for our patients, their families, the public, the profession and the respiratory care practitioner. The MSRC is a chartered affiliate of the American Association for Respiratory Care (AARC).

**22. Michigan State Medical Society**

The Michigan State Medical Society (MSMS) is a professional association that represents the interests of over 14,000 Michigan physicians. Organized to protect the public health and to preserve the interests of its members, the mission of MSMS “is to promote a health care environment that supports physicians in caring for and enhancing the health of Michigan citizens through science, quality, and ethics in the practice of medicine.” MSMS has a continuing interest in issues which affect the medical profession and the patients it serves and is an active advocate in the educational, judicial and legislative arenas.

**23. Michigan Thoracic Society**

The purpose of the Michigan Thoracic Society is to support and maintain the highest professional and scientific standards and to collect, interpret and disseminate scientific information concerning all aspects of respiratory and critical care medicine and nursing; to participate actively with medical societies, governmental units, patient advocacy groups and other organizations in the prevention and control of respiratory diseases; to encourage and support professional and technical education in the field of respiratory and critical care medicine, nursing, respiratory therapy and other allied health professions; to encourage and fund research relative to the respiratory system and the quality of life of individuals and communities with respect to respiratory and critical care medicine and nursing; and to develop and disseminate standards of practice in respiratory and critical care medicine.

**24. South Eastern Michigan Indians, Inc.**

South Eastern Michigan Indians, Inc. has worked in Commercial Tobacco Control since 2007 in education, prevention and cessation.

**25. Tobacco Free Michigan**

Tobacco Free Michigan is a coalition of school health specialists, health care providers, prevention specialists, and other tobacco related professionals who work to prevent and reduce tobacco use and its harmful effects in all Michigan communities through education, networking, advocacy, and dissemination of research data, with a specific focus on vulnerable populations heavily targeted by the tobacco industry.

**26. Truth Initiative**

Truth Initiative Foundation, d/b/a Truth Initiative (“Truth Initiative”) is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated

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with tobacco use. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.

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