

STATE OF MICHIGAN
IN THE SUPREME COURT

MARC SLIS and 906 VAPOR,

Plaintiff-Appellees,

v.

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

Defendant-Appellants.

Supreme Court Case No. 160431

Court of Appeals Case No. 351211

Court of Claims Case No. 2019-000152-MZ

A CLEAN CIGARETTE CORPORATION, a
Michigan Corporation,

Plaintiff-Appellee,

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.

Court of Appeals Case No. 351212

Court of Claims Case No. 2019-000154-MZ

BRIEF OF AMICI CURIAE PUBLIC HEALTH AND MEDICAL ORGANIZATIONS

KERR, RUSSELL AND WEBER, PLC
Daniel J. Ferris (P69633)
Attorneys for Amici Curiae
500 Woodward Avenue, Suite 2500
Detroit, MI 48226-3427
(313) 961-0200; FAX (313) 961-0388
dferris@kerr-russell.com

Of counsel:
Dennis Henigan
Swati Rawani
Campaign for Tobacco-Free Kids
1400 Eye St., NW
Washington, D.C. 20005

TABLE OF CONTENTS

INDEX OF AUTHORITIES..... ii

STATEMENT OF QUESTION PRESENTED iii

INTRODUCTION AND STATEMENT OF INTEREST OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. The State of Michigan Faces A Vaping Crisis Among Youth..... 3

II. Vaping Products Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth..... 6

III. 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..... 11

IV. E-Cigarettes Have Not Been Approved as a Smoking Cessation Drug or Device in the U.S. 12

V. Michigan’s Emergency Rules Are Necessary Because Other Existing Tobacco Regulations Are Insufficient to Address the Epidemic of E-Cigarette Use Among Kids..... 13

CONCLUSION..... 15

INDEX OF AUTHORITIES

Cases

Am Acad of Pediatrics v FDA,
 unpublished opinion of the United States District Court for the District of Maryland,
 issued July 12, 2019 (Docket No. 18-cv-00883) 5

M & S, Inc v Attorney General,
 165 Mich App 301 (1987)..... 2

Statutes

MCL 24.248 2

MCL 333.2226(d) 2

Rules

MCR 7.312(H)(4) 1

Regulations

81 Fed Reg 28,988 10

81 Fed Reg 29,028 13

81 Fed Reg 29,032 10

81 Fed Reg 29,037 13

STATEMENT OF QUESTION PRESENTED

This brief amicus curiae will address the question whether a preliminary injunction issued to prevent enforcement of the Michigan Protection of Youth from Nicotine Product Addiction Emergency Rules would harm the public interest.

INTRODUCTION AND STATEMENT OF INTEREST OF AMICI CURIAE

Amici curiae are filing this brief in opposition to the motion for a preliminary injunction against the Michigan Protection of Youth from Nicotine Product Addiction Emergency Rules (“Emergency Rules”). The amici are the following 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 Association for Local Public Health, Michigan Chapter – American Academy of Pediatrics, Michigan Chapter – March of Dimes, Michigan Council for Maternal & Child Health, 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., and Truth Initiative.¹

A description of these organizations is provided in Attachment A.

Amici respectfully submit this brief in opposition to Plaintiff-Appellees’ motions for preliminary injunction. By this filing, amici seek to demonstrate that a preliminary injunction against Michigan’s Emergency Rules would be contrary to the public interest because it would deprive residents of the state, and particularly its young people, of the demonstrable public health benefits of prohibiting the sale of flavored vapor products.²

¹ Pursuant to MCR 7.312(H)(4), 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.

² 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.

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 save lives. 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

In determining whether to issue a preliminary injunction against the enforcement of a regulation or statute, courts must determine whether the injunction would be in the public interest. *See M & S, Inc v Attorney General*, 165 Mich App 301 (1987) (finding issue of an injunction would harm public interest). An injunction against the Emergency Rules would be 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.³

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

³ Amici curiae are disappointed that Plaintiff-Appellees would 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. Amici curiae believe that Plaintiff-Appellees' interpretation of the law runs contrary to the most basic social values.

from 2017 to 2019, to 27.5 percent of students, or more than 1 in 4 high schoolers.⁴ Altogether, 5 million middle and high school students used e-cigarettes in 2019 – an increase of nearly 3 million users in two years.⁵ The Emergency Rules constitute a proper and appropriate use of the State’s emergency authority to protect the health of Michigan’s children by ending the sale of flavored vaping products and thereby reducing the use of highly-addictive e-cigarettes by Michigan youth.

ARGUMENT

I. The State of Michigan Faces A Vaping Crisis Among Youth.

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 2017.⁶ Kids are not just experimenting with e-cigarettes, but 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

⁴ 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.

⁵ 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>.

⁶ FDA, *supra* note 4.

30 days.⁷ Alarming, 1 in 9 of all high school seniors (11.7%) report that they vaped nicotine nearly daily, a strong indication of addiction.⁸

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.⁹ Between the years 2015-16 and 2017-18, counties across Michigan witnessed between a 30% and 118% increase among 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.¹⁰

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, Acting Commissioner of the FDA, “Years of progress to combat youth use of tobacco – to prevent lifetimes of addiction to nicotine – is now threatened by an

⁷ 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/>.

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

⁹ 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>.

¹⁰ 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; 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>.

epidemic of e-cigarette use by kids.”¹¹ 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.”¹² A U.S. District Court recently declared e-cigarettes to constitute a “clear public health emergency.”¹³

The increasing number of vaping related pulmonary illnesses around the country only heightens the concern about initiation of vaping by youth.¹⁴ 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 recently noted, “To be honest, they look like the kind of change you would expect to see in an unfortunate worker in an industrial accident 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.”¹⁵

Indeed, as of October 15, 1,479 confirmed or probable cases of acute lung illness associated with the use of e-cigarette or vaping products have been reported to CDC and 33 deaths have been

¹¹ 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>.

¹² 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>.

¹³ *Am Acad of Pediatrics v FDA*, unpublished opinion of the United States District Court for the District of Maryland, issued July 12, 2019 (Docket No. 18-cv-00883), p 6 (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.”)

¹⁴ Abbot, B., *What We Know About Vaping-Related Lung Illness*, The Wall Street Journal, Oct. 3 2019.

¹⁵ Grady, D., *Lung Damage From Vaping Resembles Chemical Burns, Report Says*, The New York Times, Oct. 2, 2019.

confirmed in 24 states.¹⁶ As of October 15, the Michigan Department of Health and Human Services has reported 1 death¹⁷ and 36 vaping-associated lung injury cases in Michigan.¹⁸ The known vaping associated illnesses in Michigan have afflicted teens and other young people, with the youngest victim being 16 years old.¹⁹

These statistics establish that Michigan, like other states across the nation, faces a vaping crisis among youth which must be addressed. As explained more fully below, any injunction delaying implementation of the Emergency Rules would deprive this State of a vital tool to bring this epidemic under control. An injunction thereby would seriously harm the public interest.

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

In recent years, tobacco companies have significantly stepped up 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

¹⁶ 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 (last updated October 8, 2019).

¹⁷ Michigan Department of Health and Human Services Press Release, Oct. 4, 2019, https://content.govdelivery.com/attachments/MIDHHS/2019/10/04/file_attachments/1298633/Vaping%20NR.pdf

¹⁸ Michigan Department of Health and Human Services Press Release, Communicable Disease Information and Resources, https://www.michigan.gov/mdhhs/0,5885,7-339-71550_5104_53072---,00.html.

¹⁹ 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 on "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;

users, almost all of whom are under age 18.²⁰ 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.²¹ 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.²² 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.”²³

The data confirms that flavors play a major role in youth initiation and continued use of e-cigarettes. The 2016 Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.²⁴ Data from

²⁰ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.

²¹ 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/>.

²² 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.

²³ Ramanathan, L, *We killed the cigarette. What we got in return is mango-flavored nicotine in 'party mode,'* Washington Post, August 8, 2018, 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

²⁴ 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

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.”²⁵ The PATH study also found that 97% of current youth e-cigarette users had used a flavored e-cigarette in the past month.²⁶ The 2019 NYTS found that 63.9% of high school e-cigarette users use mint or menthol flavors, an increase from 51.2% in 2018.²⁷ Mint and menthol flavors are about as popular as fruit flavors among high school e-cigarette users.²⁸

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 e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”²⁹ 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. The researchers estimate that this translates to over 43,000 current

Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

²⁵ 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>.

²⁶ *Id.*

²⁷ 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.

²⁸ *Id.*

²⁹ 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>.

youth cigarette smokers who might not have become smokers without e-cigarettes.³⁰ 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.³¹

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.³² While e-cigarettes can be used for non-nicotine products, including marijuana, more than two-thirds of youth e-cigarette users report using e-cigarettes exclusively for nicotine-containing products.³³ Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development.³⁴ Nicotine also impacts the cardiovascular system.³⁵ The Surgeon General concluded that, “The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth,

³⁰ 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.

³¹ *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.

³² *Supra* note 29.

³³ CDC, *Characteristics of Electronic Cigarette Use Among Middle and High School Students—United States, 2015*, MMWR, 65(50-51): 1425-1429, <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051a2.pdf>.

³⁴ 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.

³⁵ 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 Prevention, Office on Smoking and Health, 2010 <http://www.ncbi.nlm.nih.gov/books/NBK53017/>.

including in e-cigarettes, is unsafe.”³⁶ 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.³⁷

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.³⁸ 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.³⁹

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.

³⁶ 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.

³⁷ See Mot. to Dismiss and Opp. to Mot. for Pre. Inj., *Vapor Tech Assoc v Food and Drug Administration et al*, United States District Court for the Eastern District of Kentucky, filed October 11, 2019, (Docket No. 19-cv-00330), p 11, citing 81 Fed Reg at 28,988 (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. *Id.* at 11-12, citing 81 Fed Reg 29,032, 29,036 (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).

³⁸ *Id.*

³⁹ 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.

III. 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, that cites one group’s unscientific assertion that e-cigarettes are 95% safer than traditional cigarettes. 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 public journals have also sharply criticized the scientific reliability of the “95% safer” claim. E.g., Editorial, *E-cigarettes: Public Health England’s evidence-based confusion*, *The Lancet*, vol. 386, at 829 (Aug. 29, 2017) (“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.”). An exercise of this type does not represent a rigorous scientific analysis of relative product harms.

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

Although Plaintiff-Appellees assert that flavored e-cigarettes facilitate smoking cessation,⁴⁰ 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...”⁴¹ The same NASEM report cited by Plaintiff-Appellees also concluded, “Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”⁴² 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.”⁴³ 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.⁴⁴

⁴⁰ See e.g., Plaintiff-Appellees Marc Slis and 906 Vapor’s Br. In Support of Mot. for Temp. Res. Order, Sep. 27, 2019, pp. 5-6.

⁴¹ U.S. Preventive Services Task Force, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women*: U.S. Preventive Services 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>.

⁴² *Supra* note 29.

⁴³ 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.

⁴⁴ 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

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).⁴⁵ NASEM found that dual use of cigarettes and e-cigarettes “is not a proven method for combustible tobacco cigarette cessation.”⁴⁶ 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.

Moreover, 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.

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

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-cigarettes—virtually all with flavors designed to enhance their appeal to youth. Experience

⁴⁵ 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

⁴⁶ *Supra* note 29, at 18-24.

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.⁴⁷ 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.⁴⁸ According to FY2019 data, Michigan has a sales to minors violation rate of 10%.⁴⁹ 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.⁵⁰ 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.⁵¹

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.

⁴⁷ 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>.

⁴⁸ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, March 13, 2019, <https://www.fda.gov/media/121384/download>.

⁴⁹ Michigan Annual Synar Report, FFY 2019, at 39, https://www.michigan.gov/documents/mdhhs/SYNAR_Report_2019_637850_7.pdf.

⁵⁰ FDA, *Compliance Check Inspections of Tobacco Product Retailers* (through 8/31/2019), https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm.

⁵¹ Roeseler, A, et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, JAMA Pediatrics, June 24, 2019.

CONCLUSION

Michigan is the first state to prohibit the sale of flavored vaping products and eight 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.⁵² Michigan children and families should not be deprived of the benefits of this necessary and appropriate response to the current epidemic. A preliminary injunction delaying implementation of the Emergency Rules addressing the vaping crisis would not be in the public interest and should be denied.

Respectfully submitted,

KERR, RUSSELL AND WEBER, PLC

By: /s/ Daniel J. Ferris

Daniel J. Ferris (P69633)

Attorneys for Amici Curiae

500 Woodward Avenue, Suite 2500

Detroit, MI 48226-3427

(313) 961-0200; FAX (313) 961-0388

dferris@kerr-russell.com

Dated: October 25, 2019

⁵² Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted the Sale of Flavored Tobacco Products*, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

CERTIFICATE OF SERVICE

Cynthia J. Villeneuve, being first duly sworn deposes and says that on October 25, 2019, 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/ Cynthia J. Villeneuve
Cynthia J. Villeneuve

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.

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.

10. Mercy Health & St. 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 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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).

20. 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.

21. 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.

22. South Eastern Michigan Indians, Inc.

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

23. 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 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.