

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

MISTER E-LIQUID LLC.,

Plaintiffs,

No. 19-CV-00786

v

HON. ROBERT J. JONKER

GRETCHEN WHITMER, Governor and  
ROBERT GORDON, Director of Department of  
Health and Human Services,

MAG. RAY KENT

Defendants.

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**DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFF'S  
MOTION FOR PRELIMINARY INJUNCTION**

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## CONCISE STATEMENT OF ISSUES PRESENTED

1. Whether Plaintiff's motion for a preliminary injunction should be denied where (a) Plaintiff fails to show irreparable harm, (b) Plaintiff cannot demonstrate a substantial likelihood of success on the merits, and (c) a balancing of the equities weighs against granting injunctive relief.
2. Whether the Emergency Rules effectuates a fair and legitimate public interest, and whether the effects of the Emergency Rules on interstate commerce, if any, are only incidental.
3. Whether the Tobacco Control Act (TCA) preempts Michigan's authority to regulate flavored nicotine vapor product as set forth in the Emergency Rules, where the TCA explicitly allows states to enact any law, rule, or regulation that is in addition to, or more stringent than, the requirements under the TCA as it pertains to the sale, distribution, possession, use, or advertising and promotion of tobacco.

## CONTROLLING OR MOST APPROPRIATE AUTHORITY

Issue 1: *United Food & Commercial Workers Union, Local 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 348 (6th Cir. 1998).

Issue 2: *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

Issue 3: Tobacco Control Act, 21 U.S.C. § 387p(a)(1).

## INTRODUCTION

Cotton Candy, Bubble Gum, Gummy Bear. Knowing full well the alluring nature of candy and sweets to children and teens, those in the vaping business are turning millions of young people into addicted customers, while insisting that they are not targeting kids at all.<sup>1</sup> As numerous public health officials recognize, vaping is a public health epidemic. Addressing this crisis through the promulgation of emergency rules is entirely appropriate and justified. Temporarily limiting the sale and distribution of flavored nicotine vapor products in Michigan to halt the pipeline of this rapidly growing problem until those products can be more comprehensively reviewed, studied, and regulated does not warrant the extraordinary issuance of a preliminary injunction.

Despite its claims of irreparable harm, Plaintiff Mister E-Liquid, LLC (E-Liquid) is still able to sell, transport, and distribute flavorless

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<sup>1</sup> See September 10, 2019 New York Times opinion article, Michael R. Bloomberg, et al, Ban Flavored E-Cigarettes to Protect Our Children, <https://www.nytimes.com/2019/09/10/opinion/vape-deaths-children-bloomberg.html> (accessed October 14, 2019)



and tobacco flavored nicotine vapor products, as well as flavored vapor products with no nicotine, under Michigan's Protection of Youth from Nicotine Product Addiction Emergency Rules (Emergency Rules).<sup>2</sup> Not only does E-Liquid fail to establish the legal elements needed for its requested relief, but it fails to appreciate the public benefit that the Defendants have taken to save lives and prevent further proliferation of a public health crisis. Accordingly, Plaintiff's motion should be denied.

## **STATEMENT OF FACTS**

### **A. Vaping among youth is a public health crisis.**

Nationwide, e-cigarette use among middle and high school students increased 900% from 2011-2015. (See Attachment A, August 30, 2019 Michigan Department of Health and Human Services (DHHS) Finding of Emergency (citations to supporting evidence in document)). From 2017 to 2018, e-cigarette use among youth increased 78% among high school students and 48% among middle school students. *Id.* The total number of children who are currently using e-cigarettes rose to 3.6

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<sup>2</sup> On October 15, 2019, Michigan Court of Claims Judge Cynthia Diane Stephens issued an Opinion and Order enjoining the enforcement of the Emergency Rules. The Ruling did not address the federal claims made in the present matter.

million in 2018, 1.5 million more than the previous year. *Id.* From 2015-2016 and 2017-2018, counties across Michigan (cross section of 39 reporting) witnessed between a 30% and 118% increase in use of vapor products among high school students who used an e-cigarette during the past month. *Id.*

The nicotine in e-cigarettes can rewire the brain to crave more of the substance and create a nicotine addiction. Resulting brain changes may have long-lasting effects on attention, learning, and memory. *Id.* Research has also shown that youth who use e-cigarettes are significantly more likely to start smoking combustible cigarettes despite the well-known, documented, and often deadly health consequences such as lung cancer and heart disease. *Id.*

In December 2018, United States Surgeon General Jerome Adams officially declared e-cigarette use among youth in the United States an epidemic. *Id.* Dr. Adams issued an advisory on e-cigarette use among youth, noting that action must be promptly taken to protect the health of young people. *Id.* Dr. Adams was joined by the Secretary of the U.S. Department of Health & Human Services, Alex Azar, who called the

historic increase in e-cigarette use by youth, which has outpaced any other substance, an “unprecedented challenge.” *Id.*

Flavors are a driving force of this epidemic. According to a recent study, 81% of youth e-cigarette users reported using a flavored e-cigarette at first use. *Id.* This study concluded that flavored tobacco products may attract young users and serve as “starter products to regular tobacco use.” Another study revealed that nearly two thirds (63.6%) of current middle and high school tobacco users have used a flavored tobacco product in the past month. *Id.*

The Centers for Disease Control and Prevention (CDC) has concluded that the use of e-cigarettes is unsafe for kids, teens, young adults, pregnant women, and adults who do not currently use tobacco products. Further, the CDC recommends that everyone, youth and adult, refrain from using e-cigarette or vaping products.

The nicotine in e-cigarettes is harmful to young people’s developing brains, and young people who use e-cigarettes are more likely to smoke cigarettes in the future. (See Attachment B, September 25, 2019 testimony of Joneigh S. Khaldun, MD, MPH, FACEP, Chief Medical Executive, State of Michigan, Chief Deputy Director for Health,

DHHS (citations to supporting evidence in document)). The Food and Drug Administration (FDA) has determined that youth who experiment with e-cigarettes are 7.7 times more likely to become established smokers than those who do not experiment. *Id.* E-cigarette aerosol that users breath and exhale can contain harmful substances including nicotine, ultrafine particles, flavoring such as diacetyl, which is a chemical linked to a serious lung disease, volatile organic compounds, cancer-causing chemicals, and heavy metals such as nickel, tin, and lead. *Id.* Recent research has demonstrated that acute exposure to flavored e-liquids or e-cigarette use can exacerbate endothelial dysfunction, which often precedes cardiovascular diseases. *Id.*

E-cigarettes have not been validated or approved by the FDA as a smoking cessation strategy. In one study of adult smokers, those who used e-cigarettes were less likely to have stopped smoking combustible cigarettes, and also smoked more cigarettes than those who did not use e-cigarettes. *Id.* The long-term health effects or efficacy of e-cigarettes for smoking cessation have not been properly evaluated, so any assertions that these products are safe, healthy, or part of a smoking cessation program are not scientifically confirmed.

In sum, there is no dispute that nicotine is a highly addictive chemical; nicotine in e-cigarettes is harmful to young people’s developing brains;<sup>3</sup> young people typically use flavored vapor products when using e-cigarettes for the first time;<sup>4</sup> and young people who use e-cigarettes that contain nicotine are more likely to smoke cigarettes in the future.<sup>5</sup> Further, e-cigarettes are advertised using the same themes and tactics that have been shown to increase youth initiation of other tobacco products, including cigarettes.<sup>6</sup> Yet, it appears that e-cigarette companies have moved beyond the “Joe Camel” cartoon tactics used by tobacco companies to lure children into the nicotine trap. Many children using these products do not even know that flavored e-cigarettes are high in nicotine.<sup>7</sup> Addressing this very real public health crisis to

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<sup>3</sup> CDC, Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html) (accessed October 12, 2019).

<sup>4</sup> Id.

<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> Id.

protect our youth and future through the promulgation of emergency rules was entirely proper and appropriate.

### **B. Promulgation of Emergency Rules**

The Michigan Legislature authorized the DHHS to issue emergency rules if three conditions are met: (1) it finds that preservation of the public health, safety, or welfare requires it; (2) it states in the rule its reasons for that finding; and (3) the governor concurs in the finding of emergency. Mich. Comp. Laws § 24.248 (1). Under those circumstances, the emergency rule is immediately effective and remains so for up to 6 months. *Id.* The Governor may extend the rule for another six months upon if the Governor files a certificate of need for an extension with the Michigan Secretary of State. *Id.* The Legislature did not require a hearing before an agency's finding of an emergency and, made as it is in the context of rulemaking, the finding of an emergency is quasi-legislative in nature. See *Michigan State AFL-CIO v. Sec'y of State*, 230 Mich App 1, 20 (1998). As such, during the temporary period that the emergency rules are in place, the agency may take action to promulgate permanent rules in accordance with the Michigan Administrative Procedures Act. Mich. Comp. Laws § 24.231 to

Mich. Comp. Laws § 24.266. The Legislature may also pass legislation in this area.

On August 30, 2019, DHHS declared a public health emergency as to the youth vaping crisis and recommended the promulgation of emergency rules to address this crisis. (Attachment A). On September 18, 2019, Governor Gretchen Whitmer concurred in DHHS's finding that circumstances creating an emergency have occurred and that the public interest requires the promulgation of emergency rules. (See Attachment C, Emergency Rules). While the Emergency Rules took immediate effect upon filing with the Secretary of State on September 18, 2019, some prohibitions relating to the sale and transport of nicotine flavored vapor products as well as some other provisions were not enforced until 14 days after the Rules were filed with the Secretary of State. *Id.*

On September 30, 2019, this Court denied Plaintiff's motion seeking an ex parte Temporary Restraining Order. (R. 9, PageID.117-121). Also, to date, two bills have already been introduced in the Michigan legislature seeking address flavored nicotine vaping products. (HB 4996 and HB 5019).

## ARGUMENT

The factors used to determine whether to issue a temporary restraining order are the same as those used to determine whether to issue a preliminary injunction, *Ohio Republican Party v. Brunner*, 543 F.3d 357, 361 (6th Cir. 2008), which are:

(1) whether the movant has a “strong” likelihood of success on the merits; (2) whether the movant would otherwise suffer irreparable injury; (3) whether issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of a preliminary injunction.

*United Food & Commercial Workers Union, Local 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 347 (6th Cir. 1998). “These factors are to be balanced against one another and should not be considered prerequisites to the grant of a preliminary injunction.” *Leary v. Daeschner*, 228 F.3d 729, 736 (6th Cir. 2000); *Nader v. Blackwell*, 230 F.3d 833, 834 (6th Cir. 2000). However, “the demonstration of some irreparable injury is a sine qua non for issuance of an injunction.” *Patio Enclosures, Inc. v. Herbst.*, 39 F. App'x 964, 967 (6th Cir. 2002), (citing *Friendship Material, Inc. v. Michigan Brick, Inc.*, 679 F.2d 100, 105 (6th Cir. 1982)). Moreover, “a finding that there is simply no likelihood of success on the merits is usually fatal.” *Gonzales v. Nat'l Bd. of Med.*



*Exam'rs*, 225 F.3d 620, 625 (6th Cir. 2000) (citing *Mich. State AFL-CIO v. Miller*, 103 F.3d 1240, 1249 (6th Cir. 1997)).

**I. Plaintiff fails to show that immediate, substantial and irreparable harm will occur in the absence of injunctive relief.**

To be entitled to injunctive relief, a plaintiff must first show that a failure to issue an injunction or other equitable relief is likely to result in continuing irreparable harm. *Elrod v. Burns*, 427 U.S. 347, 373 (1976); *see also Jones v. Caruso*, 569 F.3d 258, 277 (6th Cir. 2009) (quoting *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)) (“Violations of First Amendment rights constitute per se irreparable injury.”). However, in order for the court to find irreparable harm to be continuing, future harm cannot be speculative. *Reporters Committee for Freedom of Press v. AT & T Co.*, 593 F.2d 1030, 1068 (D.C. Cir. 1979).

A party who has established a constitutional violation is entitled to injunctive relief if (1) the failure to issue the injunction is likely to result in continuing irreparable harm and (2) there is no other adequate remedy at law. *United States v. Miami Univ.*, 294 F.3d 797, 816 (6th Cir. 2002); *Dayton Christian Schs., Inc. v. Ohio Civil Rights Comm'n*,

766 F.2d 932, 961 (6th Cir. 1985) (citations omitted), *rev'd on other grounds*, 477 U.S. 619 (1986).

- A. Plaintiff can (1) sell, distribute, and transport all of its products out of Michigan, (2) sell, distribute, and transport tobacco flavored nicotine vapor product in Michigan, and (3) sell, distribute and transport any flavored vapor product containing no nicotine in Michigan.**

The Emergency Rules only prohibit in-state sales and distribution of flavored *nicotine* vapor products, not all vapor products. The Emergency Rules do not preclude the sale, transport, or distribution of flavored vapor products that do not contain nicotine within Michigan. Further, nicotine vapor products that are unflavored or tobacco flavored may also be sold, transported, and delivered without restriction in Michigan under the Emergency Rules.

Plaintiff argues, in part, that it will suffer irreparable harm because “[f]lavored vapor products are the backbone of this company and a large majority of its product line.” (Pl’s Brief in Supp. of Mtn., R. 5, PageID.87). Without the ability to sell “flavored vapor products,” Plaintiff contends that “it will have to lay off employees and move its operations to another state.” (*Id.*) Further, with respect to marketing

its products, Plaintiff contends that it will suffer irreparable harm because it “will either have to shut down its website or remove (i) all imagery related to characterizing flavors; (ii) any [modified risk tobacco product] MRTP-like marketing claims; and (iii) any reference to flavored vapor products.” (*Id.*). As this Court correctly noted when denying Plaintiff’s motion for an ex parte TRO, “virtually all the harm to which plaintiff points is economic – lost of inventory and revenue.” (R. 9, PageID.119). Plaintiff does not meet its burden of establishing irreparable harm.

First, Plaintiff either misstates or misinterprets the Emergency Rules to the extent it maintains that it is precluded from selling, distributing, or transporting vapor product outside of Michigan. DHHS’s Emergency Rules apply to the sale, distribution, and transportation of product to persons, retailers, or resellers located in Michigan only. Because the Emergency Rules may only regulate conduct directed at the State of Michigan, out-of-state sales, distributions, and marketing, are beyond the purview of the Emergency

Rules.<sup>8</sup> Accordingly, contrary to Plaintiff's assertion, E-Liquid is not required to shutter its manufacturing facilities to the extent it sells its flavored nicotine vapor product (the only product that the Emergency Rules apply to with respect to sales and distributions *in Michigan*) to out-of-state retailers or customers. Inasmuch as Plaintiff contends that about 70% of its revenues are based on out-of-state sales, Plaintiff is unable to establish that it will suffer irreparable injury.

As stated previously, with respect to in-state sales and distributions, the restrictions on selling, transporting, and distributing vapor products under the Emergency Rules only apply to flavored *nicotine* vapor products, not all vapor products. Thus, there is nothing in the Emergency Rules to preclude the sale, transport, or distribution of flavored vapor products that do not contain nicotine within Michigan. Further, nicotine vapor products that are unflavored or tobacco flavored may also be sold, transported, and delivered without restriction in

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<sup>8</sup> To the extent Plaintiff continues to assert confusion about the Emergency Rules, on October 4, 2019, DHHS issued an "Interpretive Statement Regarding Emergency Rules for Protection of Youth from Nicotine Addiction," indicating that "the Rules do not prohibit the transportation of flavored nicotine vapor products to persons outside of the State of Michigan. Such activity is not in violation of the Rules." (Attachment D).

Michigan under the Emergency Rules. Thus, in light of the range of products that Plaintiff can continue to sell, transport, and deliver, both in and out of Michigan, Plaintiff fails to meet its burden of showing irreparable injury.

**B. Plaintiff is not prevented from manufacturing and possessing flavored nicotine vapor products.**

Plaintiff repeatedly, and erroneously, asserts that it must either sell off or destroy its entire inventory of flavored nicotine vapor products under the Emergency Rules, implying that it is precluded under the Rules from manufacturing or possessing such products. The Emergency Rules, however, do not require the destruction of any product, do not make possession of any product a violation of the Rules (provided that the product is not possessed with the intent to sell, give, or otherwise distribute in Michigan),<sup>9</sup> and do not prohibit the manufacture of such products in Michigan. Accordingly, Plaintiff fails to establish irreparable harm to the extent its claims are based on Plaintiff's mistaken assertion that it is precluded under the Emergency Rules

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<sup>9</sup> See Attachment D, which makes clear that the Emergency Rules “do not ... prohibit the mere possession of flavored nicotine vapor product in Michigan.”

from possessing or manufacturing flavored nicotine vapor products in Michigan.

**C. The Emergency Rule’s limits on advertising and marketing vapor products do not create irreparable harm to Plaintiff’s business.**

With respect to the marketing aspects of the Emergency Rules, while Plaintiff may be required to modify its website and/or take other steps to modify its marketing techniques, Plaintiff is not required to discontinue its website or cease all aspects of advertising. Rather, Plaintiff must simply refrain from using “imagery explicitly or implicitly representing a characterizing flavor to sell, offer for sale, give, or otherwise distribute a vapor product” (Rule 2(1)(b)) and may not use “fraudulent or misleading terms or statements to sell, offer for sale, give or otherwise distribute vapor products.” (Rule 3(1)). Again, these Rules apply to the extent the conduct is directed toward those residing in Michigan. There is no doubt any number of ways Plaintiff could alter or modify its on-line advertising or solicitations so as not to target Michigan residents and take reasonable steps to ensure that it is not

selling or delivering flavored nicotine vapor product to Michigan residents.<sup>10</sup>

Moreover, Rule 3(3), which prohibits the use of fraudulent or misleading terms or statements, “does not apply to products for which advertising is exclusively regulated by the Food and Drug Administration.” Accordingly, the Rule specifically acknowledges that, to the extent the FDA regulates the advertising of such products, the Rule does not apply.

In sum, the Emergency Rules are narrowly tailored such that they do not substantially burden or result in irreparable harm to Plaintiff or other manufacturers or distributors of flavored vapor product to the extent such product is not distributed to Michigan residents. Plaintiff’s argument of irreparable injury is premised on an overly broad interpretation of the Rules and does not apply to products that Plaintiff manufactures where those products are intended for out-of-state

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<sup>10</sup> Indeed, Plaintiff appears to have already taken steps to modify its website, which now contains language indicating that “[d]ue to Michigan Flavor ban, we cannot ship products to Michigan from Mister-E Liquid.com. to purchase Michigan-compliant vape juice.” (See Attachment D, E-Liquid’s website, <https://mister-es.com/>, accessed October 12, 2019).

distribution – which appears to be the vast majority of E-Liquid’s business. Accordingly, Plaintiff is unable to meet its burden of showing irreparable harm and its motion should be denied.

**II. Plaintiffs have not established a substantial likelihood of success on the merits because the Emergency Rules do not violate the dormant commerce clause and are not preempted by federal law.**

**A. The Emergency Rules do not violate the dormant commerce clause.**

“The Commerce Clause of the Constitution grants Congress the power ‘[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.’ U.S. Const. art. I, § 8, cl. 3. ‘Although the Clause thus speaks in terms of powers bestowed upon Congress, the Court has long recognized that it also limits the power of the States to erect barriers against interstate trade.’ *Maine v. Taylor*, 477 U.S. 131, 137 (1986); citing *Lewis v. BT Investment Managers, Inc.*, 447 U.S. 27, 35 (1980). However, “[t]he limitation imposed by the Commerce Clause on state regulatory power ‘is by no means absolute,’ and ‘the States retain authority under their general police powers to regulate matters of ‘legitimate local concern,’ even though interstate



commerce may be affected.” *Maine v. Taylor*, 477 U.S. at 138; citing *Lewis*, 447 U.S. at 36.

“When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, [the Supreme Court has] generally struck down the statute without further inquiry. When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, [the Supreme Court has] examined whether the State’s interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. In either situation the critical consideration is the overall effect of the statute on both local and interstate activity.” *Ferndale Laboratories, Inc. v. Cavendish*, 79 F.3d 488, 494 (1996) (internal citations omitted).

The Emergency Rules do not directly regulate or discriminate against interstate commerce and the Rules’ effect do not favor in-state economic interests over out-of-state interests. That is, the Emergency Rules plainly apply equally to retailers and resellers located in and outside of Michigan with respect to the sale or distribution of flavored nicotine vapor product. Indeed, the Emergency Rules apply

evenhandedly, giving no economic advantage to in-state distributors. Thus, because the Emergency Rules incidentally affect interstate commerce and are non-protectionist in nature, a determination of whether the Emergency Rules violate the Commerce Clause should be analyzed under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). “Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such [interstate] commerce is clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142; *Ferndale Laboratories*, 79 F.3d at 495.

Because the Emergency Rules are non-discriminatory, Plaintiffs would have to show that “the burden [they] impose [] upon interstate commerce is clearly excessive in relation to the putative local benefits.” *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 644 (6th Cir. 2010). Under *Pike*, the Rules are constitutional if “there is a rational basis to believe that [their] benefits outweigh any burden that [they] impose[.]” *Id.* at 650.

Michigan has demonstrated much more than a rational basis to believe that the benefits of the Emergency Rules outweigh any burdens they impose. The State of Michigan enacted the Emergency Rules to address the crisis related to the use of flavored vapor products by its youth. The rationale for implementing the Emergency Rules is set forth in the “Finding of Emergency” preamble to those Rules. Michigan’s interest in preventing the documented and dangerous effects of the use of vapor products, and in particular flavored nicotine products, is manifest – Michigan has implemented the Emergency Rules to protect the public health of its inhabitants. “As long as a State does not needlessly obstruct interstate trade or attempt to ‘place itself in a position of economic isolation,’ *Baldwin v. G.A.F. Seeling, Inc.*, 294 U.S. 511, 527 (1935), it retains broad regulatory authority to protect the health and safety of its citizens....” *Ferndale Laboratories*, 79 F.3d at 495; citing *Maine v. Taylor*, 477 U.S. at 151.

As discussed above, the Emergency Rules do not impose a needless obstruction of interstate commerce and treat in-state and out-of-state retailers and resellers evenhandedly. And importantly, Michigan has a compelling interest that is not substantially outweighed

by the minimal, if any, affect that the Rules have on interstate commerce. Simply put, Michigan does not run afoul of the dormant commerce clause by implementation of its temporary Emergency Rules.

**B. The Emergency Rules are not preempted by federal law.**

To the extent the FDA regulates tobacco under the Tobacco Control Act (TCA) – and to the extent that “tobacco products” under the TCA includes the flavored nicotine vapor product that is the subject of DHHS’s Emergency Rules<sup>11</sup> – the TCA permits the states to impose regulation related to such products that is “in addition to, or more stringent than” regulation under the TCA. Specifically, section 387p of the TCA, which is entitled “Preservation of State and local authority,” provides, in relevant part, that:

Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be

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<sup>11</sup> While Plaintiff contends that 21 U.S.C. § 387a(b) gives the FDA the authority to regulate “any other tobacco products that the [FDA] by regulation deems to be subject to” the TCA, as this Court points in its 9/30/19 Order, R. 9, PageID.17, it is questionable, in light of *United States v. Havis*, 927 F.3d 382 (6th Cir. 2019), whether the FDA has the authority under even under this “deeming rule,” to regulate flavored nicotine vapor product. Indeed, Plaintiff’s complaint contends that vapor products do not even contain tobacco. (Compl., ¶ 7, R. 1, PageID.2).

construed to limit the authority of a ... State or political subdivision of a State, ... to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products *that is in addition to, or more stringent than,* requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, .... [21 U.S.C. § 387p(a)(1) (emphasis added).]

In light of 21 U.S.C. § 387p(a)(1), there is no question that DHHS's Emergency Rules are not preempted by the TCA or the FDA's determination that it has authority to regulate vapor product by virtue of "deeming" its authority to regulate such products under 21 U.S.C. § 387a(b).

### **III. The balance of harms and the public interest weighs against the issuance of an injunction.**

As Dr. Joneigh Khaldun, Chief Medical Executive and Chief Deputy Director for Health at DHHS, stated when the Emergency Rules were enacted, "Youth vaping is a public health emergency and has been declared an epidemic by the U.S. Surgeon General. Nicotine in e-cigarettes is harmful to developing brains and has dangerous long-term

health consequences such as heart disease and cancer.”<sup>12</sup> Indeed, as Governor Whitmer noted, Michigan’s recent legislation prohibiting the sale of e-cigarettes and other non-traditional nicotine products to minors, 2019 PA 18, did not go far enough to protect Michigan’s kids from nicotine addiction.<sup>13</sup> Governor Whitmer pointed out that the marketing, packaging, and taste of e-cigarettes was a “bait-and-switch” engineered to “create new nicotine addicts.”<sup>14</sup> To be sure, while the recent amendments to Michigan’s Youth Tobacco Act prohibits both sale of vaping products to minors and possession of vaping products by minors (Mich. Comp. Laws § 722.641, Mich. Comp. Laws § 722.642), it has glaring weaknesses that necessitated the Emergency Rules. States with similar age restrictions on vaping products, which were enacted long before Michigan’s age restrictions, have still seen a skyrocketing growth on youth vaping.<sup>15</sup> Moreover, youth smokers (ages 12–17)

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<sup>12</sup> September 18, 2019 Press Release, [https://www.michigan.gov/mdhhs/0,5885,7-339-73970\\_71692-507760--00.html](https://www.michigan.gov/mdhhs/0,5885,7-339-73970_71692-507760--00.html) (accessed October 14, 2019).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> State-level data show that although 44 out of 50 states had imposed age restrictions by January 1, 2018, e-cigarette use among ninth through twelfth graders increased 78% in 2018 alone. US FDA, 2018

identify social sources, such as friends and classmates, as a common source of e-cigarettes. A 2018 study found that 50% of youth JUUL users (ages 12-17) surveyed, had gotten JUUL from a social source.<sup>16</sup>

If an injunction issues, thousands of additional young people will become addicted to nicotine—among the most addictive drugs known to humanity—due to the availability of flavored nicotine vapor products in Michigan. Protection of this population – most of whom will eventually (and hopefully) grow to become Michigan’s adults – is critical to long-term population health. Setting aside that Plaintiff cannot show irreparable harm and has no likelihood of success on the merits, this fact alone warrants denial of Plaintiff’s motion.

## **CONCLUSION AND RELIEF REQUESTED**

For the reasons set forth above, Plaintiff fails to meet the requirements for injunctive relief and its motion should be denied.

Defendants Governor Gretchen Whitmer and DHHS Director Robert

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NYTS Data: A Startling Rise in Youth E-cigarette Use  
<https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use> (accessed October 14, 2019)

<sup>16</sup> Truth Initiative, “Where are kids getting JUUL?” May 29, 2018, <https://truthinitiative.org/news/where-are-kids-getting-juul>. (accessed October 14, 2019).

Gordon respectfully request that this Honorable Court deny Plaintiff's motion for preliminary injunction and dismiss the complaint against them in its entirety, together with any other relief the Court determines to be appropriate under the circumstances.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

In accordance with L.Civ.R. 7.2, the brief was produced on a computer using Microsoft Office 365 ProPlus, and does not exceed 10,800 words, including headings, footnotes, citations and quotations.

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