

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

MISTER E-LIQUID LLC,

Plaintiffs,

v.

GOVERNOR GRETCHEN WHITMER, and  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES DIRECTOR ROBERT GORDON,

Defendants.

**PLAINTIFF MISTER E-LIQUID'S BRIEF IN SUPPORT OF MOTION FOR A  
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

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## INTRODUCTION

On September 4, 2019, Governor Gretchen Whitmer announced that her administration had unilaterally decided to ban flavored nicotine vapor products, claiming that the State of Michigan (“State” or “Michigan”) needed to immediately address an increase in underage use of e-cigarettes. On September 18, 2019, the Department of Health and Human Services (“DHHS”) filed emergency rules, entitled “Protection of Youth from Nicotine Product Addiction Emergency Rules” (the “Emergency Rules”), with the Secretary of State. Ex. A.

Effective immediately, the Emergency Rules outlawed the sale of flavored nicotine vapor products, while restricting the advertisement of all vapor products. By statute, the Emergency Rules were immediately “effective on filing.” MCL 24.248(1). Indeed, the Emergency Rules specify that they took “effect upon filing with the Secretary of State....” Nevertheless, in some parts, the Emergency Rules purport to delay the effective date of certain aspects (without any cited authority do to so) for 14 days.

Further, while Governor Whitmer initially announced on September 4, 2019 that the Emergency Rules would be issued “in the next few weeks,” and that businesses would have thirty days thereafter to comply,<sup>1</sup> it appears that the planned timeline was then accelerated for some reason because they were issued just two weeks after the September 4 press conference, and retailers and resellers subject to the rules were given only fourteen days to comply.

The Emergency Rules aim to prevent underage use of e-cigarettes in the State of Michigan. However, their actual scope is much broader and unconstitutionally so. Various provisions reach beyond the State’s borders and regulate sales of flavored vapor products by

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<sup>1</sup> Emma Keith & Kathleen Gray, *Michigan becomes first state to ban flavored e-cigarettes, cites dangers of vaping*, Detroit Free Press (September 4, 2019), at <https://tinyurl.com/y2lrvdpe>.

Plaintiff Mister E-Liquid and other in-state retailers and resellers to their out-of-state customers, and otherwise control internet marketing content from Michigan-based websites that is streamed into other states. And the State did not stop there. The Emergency Rules also encroach onto the authority of the U.S. Food and Drug Administration's ("FDA") regulation of vapor products by imposing additional regulations on Plaintiff and other in-state retailers and resellers where the federal government has already acted. Accordingly, various portions of the Emergency Rules violate the U.S. Constitution's Dormant Commerce Clause, and its prohibition on extraterritorial regulation, and are preempted by federal tobacco control laws.

Temporary and preliminary relief are warranted here because: (i) Plaintiff is likely to prevail on the merits of its constitutional claims; (ii) Plaintiff will suffer immediate, irreparable harm if the Emergency Rules remain in effect; (iii) Plaintiff's potential harm greatly outweighs that of the Defendants (collectively the State of Michigan); and (iv) the public interest will be served if Defendants are compelled to maintain the status quo.

## **I. BACKGROUND**

### **A. E-Cigarettes or Vapor Products**

Electronic cigarettes ("e-cigarettes" or "vapor products"), including the "e-liquid" used in them, are commonly referred to as "vapor products" and are intended for adult tobacco product users and cigarette smokers. Vapor products do not contain tobacco and there is no combustion or smoke. Rather, the aerosol (vapor) produced by a vapor device is created when a battery activates a heating coil (contained in an atomizer) that vaporizes a flavored e-liquid solution.

E-liquids are manufactured using three or four primary ingredients – propylene glycol (PG) and/or vegetable glycerin (VG), flavorings, and liquid nicotine. Nicotine is used in most, but not all, e-liquids. The nicotine, in turn, may be derived from tobacco or non-tobacco sources, or produced synthetically in a lab. There is no such thing as an "unflavored" finished e-liquid.

All flavors, including tobacco, must be chemically added to the base PG/VG solution to create a characterizing flavor. Unlike cigarettes or other tobacco-containing products, there is simply no “natural” tobacco or other flavors inherent to e-liquids.<sup>2</sup>

A recent economic impact analysis found, among other things, that: (i) the vapor industry generates \$24,457,512,300 for the U.S. economy; (ii) vapor businesses paid over \$7,897,889,500 in wages and benefits to their employees; and (iii) there are approximately 11,469 vapor shops across the country that employ over 56,000 people.<sup>3</sup> In Michigan, the vapor industry generated approximately \$608,284,800 for the Michigan economy in 2018 and created 4,290 jobs for the Michigan workforce. Vapor businesses in Michigan paid over \$188,961,400 in wages and benefits to their employees in 2018, and generated \$51,350,900 in state and local taxes.<sup>4</sup>

The adult consumer base is growing as well. Current estimates indicate that 10.8 million adults in the United States now use vapor products,<sup>5</sup> and that this number is growing as cigarette smoking rates fall.

## **B. Health Effects**

A large and growing body of scientific evidence indicates that vapor products do not pose the same health risks and are substantially less harmful than traditional cigarettes. This is

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<sup>2</sup> See Dr. Michael Siegel, The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary, *Glantz and Colleagues Essentially Call for a Ban on Electronic Cigarettes: Banning Flavors Would Ban All Existing E-Cigarette*, <<http://tobaccoanalysis.blogspot.com/2014/06/glantz-and-colleagues-essentially-call.html>> (posted July 19, 2018)(accessed September 24, 2019).

<sup>3</sup> See Vapor Technology Association, *The Value of Vapor*, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>> (accessed September 24, 2019).

<sup>4</sup> See Vapor Technology Association, *The Value of Vapor*, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>> (accessed September 24, 2019).

<sup>5</sup> See Mirbolouk M, Charkhchi P, Kianoush S, et al, *Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System*, *Ann Intern Med*, 2018, 169(7):429-438, available at <<https://annals.org/aim/article-abstract/2698112/prevalence-distribution-e-cigarette-use-among-u-s-adults-behavioral>> (accessed September 24, 2019).

partially because e-liquids do not contain tobacco and do not result in combustion by-products, like particulate matter (tar) and many other carcinogens and harmful substances.<sup>6</sup> Research suggests that because e-liquids and the resulting vapor do not contain many of the toxic chemicals found in cigarette smoke, the use of these non-combustible, nicotine-containing products is safer than combustible tobacco and is expected to result in a vast reduction in tobacco-related disease and death over time.<sup>7</sup> Moreover, there is considerable evidence that the overwhelming majority of “vapers” in the U.S. are now former cigarette smokers who have turned to vapor products as a smoke-free alternative to reduce or quit smoking, and to avoid the significant health hazards associated with traditional cigarettes.<sup>8</sup>

In 2018, the National Academies of Science, Engineering and Medicine (“NASEM”) completed an exhaustive review of the peer-reviewed literature on vapor products and found sufficient literature to conclude, in pertinent part, that “[l]aboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.”<sup>9</sup> The head of the Food and Drug Administration (FDA) Center for Tobacco Products (CTP), Mitchell Zeller, recently acknowledged—in sworn testimony in federal court proceedings—that some vapor products may

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<sup>6</sup> Linda Bauld, *The evidence keeps piling up: e-cigarettes are definitely safer than smoking*, The Guardian (December 29, 2017), <<https://www.theguardian.com/science/sifting-the-evidence/2017/dec/29/e-cigarettes-vaping-safer-than-smoking>> (accessed September 24, 2019).

<sup>7</sup> See John Britton, *Electronic cigarettes and the precautionary principle*, The BMJ Opinion (September 20, 2019), <<https://blogs.bmj.com/bmj/2019/09/20/john-britton-electronic-cigarettes-and-the-precautionary-principle/>> (accessed September 24, 2019).

<sup>8</sup> Paul Blair, *New CDC Data, More Than 9 Million Adults Vape Regularly in the United States*, Americans for Tax Reform (November 9, 2015), <<https://www.atr.org/new-cdc-data-more-9-million-adults-vape-regularly-united-states>> (accessed September 24, 2019).

<sup>9</sup> See National Academies of Science, Engineering and Medicine: Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems, *THE PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES* (Kathleen Stratton *et al.* eds., 2018), available at <<https://tinyurl.com/ya4w37kb>> (accessed September 24, 2019).



reduce harm and help some addicted smokers end combustible tobacco use. He further noted that “[d]ramatically and precipitously reducing availability of [vapor] products” – in the way the Emergency Rules propose – “could present a serious risk that adults, especially former smokers, who currently use [vapor] products and are addicted to nicotine would migrate to combustible tobacco products.”<sup>10</sup> A growing number of scientific and public health experts in the U.S. and around the world agree that vaping is significantly less harmful than smoking cigarettes and a valuable tool for tobacco harm reduction efforts for adult tobacco users.

### **C. Population Benefit & Youth Concerns**

Vapor products were introduced for the purpose of offering an alternative to smoking tobacco. Vapor products were first marketed in the U.S. over 12 years ago, beginning in mid-2007, when the adult smoking rate was approximately 19.8%. Since then, the national smoking rate has continued to fall dramatically to an all-time low (14%) in 2018.<sup>11</sup> A recent federal study, the National Survey on Drug Use and Health, determined that the accelerated decline in smoking observed over the last several years is likely attributable to smokers switching to vapor products.<sup>12</sup> As cigarette smokers switch to vapor products, in Michigan and around the world, lives are being saved. A Georgetown University study determined that switching from traditional

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<sup>10</sup> Declaration of Mitchell Zeller, *American Academy of Pediatrics v Food and Drug Admin*, No 8:18-cv-00883-PWG (D Md 2019) at ¶ 15, available at <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Zeller%20Declaration%2C%206-12-19.pdf> .

<sup>11</sup> See *Smoking rate in U.S. hits all-time low, CDC says*, CBS NEWS (June 19, 2018) available at <https://www.cbsnews.com/news/smoking-rate-in-u-s-hits-all-time-low/> (accessed September 24, 2019).

<sup>12</sup> See Jacob Sullum, *Vaping May Be Driving Down Smoking, Says Federal Survey Report*, Reason (August 21, 2019), <https://reason.com/2019/08/21/vaping-may-be-driving-down-smoking-says-federal-survey-report/> (accessed September 24, 2019).

cigarettes to vapor products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the U.S. alone.<sup>13</sup>

In Michigan, it is cigarette smoking, rather than flavored vapor, that poses a public health crisis. Michigan currently has one of the highest smoking rates in the country, among both youth (10.5%)<sup>14</sup> and adults (19.3%)<sup>15</sup>, resulting in 16,200 annual deaths.<sup>16</sup> According to the Michigan Department of Health and Human Safety, this makes cigarette smoking the leading cause of preventable death in Michigan.<sup>17</sup>

#### **D. Role of Flavors**

Numerous published studies highlight the important role of flavored vapor products for tobacco harm reduction. An extensive online survey of 20,836 adult American vapers found that cigarette smokers who switch to vapor products are doing so increasingly with a variety of fruit and other non-tobacco flavors.<sup>18</sup> These results were buttressed by another survey of more than 69,000 adult vapers, which similarly found that the vast majority (>85%) preferred fruit and

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<sup>13</sup> See Levy DT, Borland R, Lindblom EN, *et al.*, *Potential deaths averted in USA by replacing cigarettes with e-cigarettes*, *Tobacco Control* 2018; 27:18-25 (January 27, 2018), available at <<https://tobaccocontrol.bmj.com/content/27/1/18>> (accessed September 24, 2019).

<sup>14</sup> See CDC, *Youth Risk Behavior Surveillance System* (2017), available at <<https://www.cdc.gov/healthyyouth/data/yrbs/index.htm>>.

<sup>15</sup> See CDC, *Behavioral Risk Factor Surveillance System* (2017), available at <<https://www.cdc.gov/brfss/index.html>> (accessed September 24, 2019)..

<sup>16</sup> Mich Dep't of Health and Human Servs, *Tobacco Facts for State of Michigan*, Causes of Preventable Death (2011), <[https://www.michigan.gov/documents/mdch/2011-State\\_of\\_Michigan\\_456820\\_7.pdf](https://www.michigan.gov/documents/mdch/2011-State_of_Michigan_456820_7.pdf)> (accessed September 24, 2019).

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

<sup>18</sup> See Christopher Russell, *et al.*, *Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA*, 15 *Harm Reduction Journal* (2018), available at <<https://doi.org/10.1186/s12954-018-0238-6>> (accessed September 24, 2019).

dessert flavors compared to tobacco and menthol.<sup>19</sup> Flavors are crucial to helping adult smokers make the switch and stay away from cigarettes.<sup>20</sup> The ability to vape non-tobacco flavors is what drove the development of these products by early entrepreneurs. Vapor products were invented by smokers, for smokers looking for less harmful products that do not smell or taste like traditional cigarettes.<sup>21</sup>

Adult vapers overwhelmingly report that non-tobacco flavors and flavor variability matter to them and help keep them off tobacco.<sup>22</sup> These non-tobacco flavors have been shown to help smokers disassociate their habit and nicotine addiction with the tobacco and smoke flavors associated with cigarettes. While some smokers may initially try tobacco flavors to mimic the cigarettes they are accustomed to, the availability of multiple e-liquid flavors is what keeps them from reverting to cigarette use, particularly as their taste and olfactory senses return after years of smoking.<sup>23</sup> If *only* tobacco-flavored e-liquids were permitted, smokers would be less likely to

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<sup>19</sup> See Konstantinos Farsalinos, *Submitting to the FDA the Findings of the Largest Ever Survey on E-Cigarette Flavors Use by US Vapers, E-Cigarette Research: Blog (August 11, 2018)*, <<http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav>> (accessed September 24, 2019).

<sup>20</sup> See Jacob Sullum, *Survey Shows Adults Who Use E-Cigarettes To Quit Smoking Prefer Supposedly Juvenile Flavors*, *Forbes* (July 17, 2014), <<https://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/#95fb8a48fc1e>> (accessed September 24, 2019).

<sup>21</sup> See SFATA letter to FDA CTP Director, Mitch Zeller, dated February 11, 2009, available at <[https://www.khlaw.com/Files/38993\\_SFATA%20Response%20to%20January%202023,%202019%20CTP%20Meeting.pdf](https://www.khlaw.com/Files/38993_SFATA%20Response%20to%20January%202023,%202019%20CTP%20Meeting.pdf)> (accessed September 24, 2019).

<sup>22</sup> See Konstantinos Farsalinos, *et al*, *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, 10(12) *Int. J. Environ. Res. Public Health* 7272-7282 (2013), available at <<https://www.mdpi.com/1660-4601/10/12/7272>> (accessed September 24, 2019).

<sup>23</sup> See Vennemann & Berger, *The association between smoking and smell and taste impairment in the general population*, 255(8) *J of Neurology* 1121—6 (2008), available at: <<https://www.ncbi.nlm.nih.gov/pubmed/18677645>> (accessed September 24, 2019).

disassociate their habit and addiction from such flavor, and would constantly be at risk of re-triggering an urge to smoke.

Moreover, the availability of flavors may not be the predominant factor underlying the recent increase in youth experimentation. The sudden surge in past-30-day use in teenagers observed in 2018 coincided not with the introduction of flavors, which have always been available<sup>24</sup>, but with the introduction of high-concentration nicotine-salt based “pod-system” vapor products (like the Juul)<sup>25</sup> which gained access to the convenience store distribution network normally reserved for Big Tobacco products.<sup>26</sup>

It is not the open system vapor products sold at small vapor shops that constitute a problem for minors. The FDA has indicated that “open-tank” vapor products are *not* the source

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<sup>24</sup> See Amelia Howard, *Flavors make vaping more palatable, help cigarette smokers kick the habit*, The Inquirer (September 21, 2019), <[https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html?outputType=amp&\\_twitter\\_impression=true](https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html?outputType=amp&_twitter_impression=true)> (accessed September 24, 2019) (“Importantly, youth vaping didn’t peak at the same time flavor options did. The vapor flavor market expanded until 2016, after which the FDA prohibited new products from being introduced without marketing approval. There were an estimated 7,764 flavors available on e-cigarette brand websites in 2013. By 2016 that estimate had more than doubled to 15,586. If flavors cause youth to vape, we’d expect youth vaping to have increased steadily with the proliferation of flavors. CDC data show vaping rates among youth increased every year between 2011 (when the behavior was first measured) and 2015. But in 2016, right when the United States vapor market reached “peak flavor,” national data showed youth vaping decline for the first time. This low rate remained stable in 2017. Increases in 2018 and 2019 happened when the flavor market was frozen in its 2016 state.”). See also Thomas Farley, *Pro/Con: As vaping-related illnesses rise, should flavored e-cigarettes be banned? Opinion*, The Inquirer (September 21, 2019), <[https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html?outputType=amp&\\_twitter\\_impression=true](https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html?outputType=amp&_twitter_impression=true)> (accessed September 24, 2019).

<sup>25</sup> While Juul is available in a handful of non-tobacco and non-menthol flavored pods, what is unique about the e-liquid used in the product is the high concentration (i.e., up to 50 mg) of protonated nicotine, commonly referred to as nicotine salts, in its pre-filled pods. It is this high level of nicotine salt in the Juul which creates the “powerful buzz” that drives repeated use, rather than its flavors. See Haley Egle, *Juul nicotine hit may be 'Worst for kids, best for smokers'*, WISN ABC (Apr. 29, 2019) <<https://www.wisn.com/amp/article/juul-nicotine-hit-may-be-worst-for-kids-best-for-smokers/27293019?fbclid=IwAR0xF2TgLNShUB2DZDIY30gJ0whezaREGoRMXjWg4cJ9vwpoPHpT4uwVV4k>> (accessed September 24, 2019).

<sup>26</sup> A review of Nielson data from 2017-18 indicates that the reported surge in underage e-cigarette use corresponds almost exactly with JUUL’s rise to dominance of the convenience store channel. See Bonnie Herzog, *Nielson: C-Store Data Through 1/27/18, 2/24/18, and 10/6/18*; WELLS FARGO SECURITIES.

of rising underage use.<sup>27</sup> Open-tank products utilize refillable flavored e-liquids, represent about half of the total vapor market,<sup>28</sup> and are primarily sold in independent vapor shops and online, rather than in convenience stores, pharmacies and gas stations – the recipients of the majority of FDA retailer warning letters and No Tobacco Sale Orders (NTSOs) for illegal sales to minors.<sup>29</sup>

### **E. Vapor-Related Recent Illnesses**

The media has recently covered incidents of “vaping related” illnesses around the country. These cases are likely the result of aftermarket additives to illicit tetrahydrocannabinol (THC) and marijuana.<sup>30</sup> Many vapor products are sold as pods that are filled with the flavor and liquid that will be transformed into the vapor. Some users are adding their own oils to these pods, including THC.<sup>31</sup> The illegal vapor cartridges that contain THC have also been reported to

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<sup>27</sup> U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gotlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, (September 12, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm> (accessed September 24, 2019).

<sup>28</sup> The vapor industry is very diverse and complex. Closed-system and pod-based e-cigarettes (like JUUL) make up roughly 57.5% of the \$6.6 billion U.S. vapor products market, with open-system vapor products (e.g., tanks, mods, e-liquids, etc.) making up approximately 42.4% in 2018, according to Wells Fargo. See Bonnie Herzog, *Nielsen: Tobacco All Channel Data Through 9/8*, WELLS FARGO SECURITIES, (September 8, 2018) available at < <https://11bxcx1bcuig1rfxaq3rd6w9-wpengine.netdna-ssl.com/wp-content/uploads/2018/02/Nielsen-Tobacco-All-Channel-Report-Period-Ending-9.08.18.pdf> > (accessed September 24, 2019).

<sup>29</sup> U.S. Food and Drug Administration, *FDA pursues order barring specific retailers from selling tobacco products as part of its continuing efforts to target youth tobacco use* (February 7, 2019) [https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm?utm\\_source=Eloqua&utm\\_medium=email&utm\\_term=stratcomms&utm\\_content=pressrelease&utm\\_campaign=CTP%20News%3A%20NTSO%20-%20202619](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=pressrelease&utm_campaign=CTP%20News%3A%20NTSO%20-%20202619) (accessed September 24, 2019).

<sup>30</sup> Michelle Minton, *Update: Big Picture in ‘Vaping-Linked’ Lung Poisonings*, Competitive Enterprise Institute (September 16, 2019), available at <<https://cei.org/blog/update-big-picture-vaping-linked-lung-poisonings>> (accessed September 24, 2019).

<sup>31</sup> Lena Sun, *What we know about mysterious vaping linked illnesses*, The Washington Post (September 7, 2019), at <<https://www.washingtonpost.com/health/2019/09/07/what-we-know-about-mysterious-vaping-linked-illnesses-deaths/>> (accessed September 24, 2019).

contain significant amounts of vitamin E acetate, which is a diluting and thickening agent that makes cannabis oil more affordable.<sup>32</sup>

In most cases of reported illness, authorities have found vitamin E acetate from cannabis samples in the patients' lungs. This rogue oil might not completely transform into vapor, and instead travels into the lungs causing harm.<sup>33</sup> These aftermarket THC oils are bought on the black market and are not available for sale at regulated vapor shops.<sup>34</sup>

#### **F. Federal Regulation of Vapor Products**

The Tobacco Control Act (the "TCA") was adopted on June 22, 2009, and amended the Food, Drug and Cosmetic Act to give the FDA authority to regulate the "manufacture, marketing, and distribution of tobacco products." Pub. L. No. 111-31, § 3(1), 123 Stat 1776, 1781 (2009). For purposes of the TCA, the term "tobacco product" is defined to mean, in part, "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 USC § 321(rr).

The FDA was initially charged under the TCA with regulating "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." In addition, the FDA was given authority to regulate "any other tobacco products that [the FDA] by regulation deems to be subject to this chapter." 21 USC § 387a(b). On August 8, 2016, the FDA's "Deeming Rule"

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<sup>32</sup> Paige Minfield Cunningham, *The Health 202: Vaping illnesses sparked the e-cig crackdown. But marijuana is likely to blame*, The Washington Post (September 18, 2019), at <<https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/09/18/the-health-202-vaping-illnesses-sparked-the-e-cig-crackdown-but-marijuana-is-likely-to-blame/5d812a6a88e0fa7bb93a8b9c/>> (accessed September 24, 2019).

<sup>33</sup> *Id.*

<sup>34</sup> Jayne O'Donnell, *Sketchy THC vape products. Sneaky teens. How patchwork regulations on e-cigarettes led to health crisis*, USA Today (September 23, 2019), at <<https://www.usatoday.com/story/news/health/2019/09/23/vaping-illnesses-crisis-teens-black-market-thc-no-regulation/2209009001/>> (accessed September 24, 2019).

became effective, extending the TCA's requirements to vapor products that contain or are intended to be used with tobacco-derived ingredients such as nicotine. 81 Fed Reg 28,975.

Under the TCA, the FDA has regulatory authority over the entire supply chain. Among other provisions, the TCA: (i) prohibits the sale of adulterated and contaminated products; (ii) prohibits the sale of misbranded products; (iii) requires manufacturers to submit health studies and ingredient information; (iv) requires manufacturers to register their facilities with FDA; and (v) imposes advertising and labeling restrictions. 21 U.S.C. §§ 387c, 387d, 387e, 387f(d). The TCA also requires manufacturers of vapor products to obtain pre-market authorization to market their products. 21 U.S.C. § 387j. Currently, under an FDA compliance policy, vapor products that were on the market as of August 2016 may be sold, but must submit pre-market applications to the agency by May 2020.

Under the TCA, flavored vapor products may be marketed subject to the other provisions of the statute. FDA has published an Advanced Notice of Proposed Rulemaking ("ANPRM"), 83 Fed. Reg. 12994 (Mar. 21, 2018), requesting studies and information regarding the role of flavors in tobacco products, including vapor products. More recently, FDA announced that it would soon be finalizing a Guidance Document potentially revising the current compliance policy for non-tobacco flavored vapor products.<sup>35</sup>

For purposes of this lawsuit, the following provisions of the TCA are relevant to Plaintiff's constitutional claims.

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<sup>35</sup> Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, Press Release (September 11, 2019), available at < <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non>>.

The TCA, as applied to vapor products, prohibits the sale of what are called “modified risk tobacco products” (“MRTP”) without prior FDA authorization. 21 U.S.C. § 387k. An MRTP is a tobacco product that is sold or distributed for use to “reduce harm or the risk of tobacco-related disease.” 21 U.S.C. § 387k(b)(1).

In particular, any person, including retailers and distributors, must secure FDA authorization to make MRTP claims in their labeling or advertising. These include, but are not limited to, statements that “represent[] explicitly or implicitly” that the:

- a. product presents a lower risk of tobacco-related disease or is less harmful than one or more commercially marketed tobacco products;
- b. the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
- c. the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance. 21 U.S.C. § 387k(b)(2)(A)(i-ii).

To secure FDA approval to make an MRTP claim, the retailer or distributor must submit an extensive application demonstrating that the product significantly reduces tobacco related harm in individual users, and that it will benefit the health of the population as a whole. MRTP claim approval from FDA can take several years. 21 U.S.C. § 387k(g).

The TCA also contains a federal preemption clause. In general, the clause allows states to adopt laws or regulations applying to vapor products that are “in additional to, or more stringent than, requirements established” under the statute. 21 U.S.C. § 387p(a)(1). These may include restrictions or prohibitions on the “sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of” vaping products. *Id.*



However, the clause preempts state requirements that are “different from, or in addition to, any requirement under the” TCA relating to, among other things, “labeling” and “modified risk tobacco products.” 21 U.S.C. § 387k(2)(A). The clause then sets forth exceptions where state requirements relate to, among other things, the “advertising and promotion of” vapor products. 21 U.S.C. § 387k(2)(B).

### **G. Michigan Regulation of Vapor Products**

The State of Michigan only recently began to regulate vapor products. On June 4, 2019, Governor Whitmer signed Senate Bills 106 and 155 into law, which prohibit the sale of e-cigarettes and other non-traditional nicotine products to minors.<sup>36</sup>

On August 30, 2019, Governor Whitmer signed a Finding of Emergency prepared by the Michigan Department of Health and Human Services (the “Department”).<sup>37</sup> This document concluded that a ban on all non-tobacco flavored vapor products was necessary to respond to increasing rates of vaping among underage users in Michigan. On September 4, 2019, Governor Whitmer held a press conference to announce that her administration would unilaterally ban all flavored nicotine vapor products, except tobacco-flavored nicotine vapor products.<sup>38</sup>

Finally, on September 18, 2019, the DHHS filed emergency rules entitled “Protection of Youth From Nicotine Product Addiction” (the “Emergency Rules”) banning the possession, sale, and distribution of all flavored nicotine vapor products, except tobacco-flavored nicotine vapor

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<sup>36</sup> 2019 Public Act 18, MCL 722.641 *et seq.*

<sup>37</sup> Mich Dep’t of Health and Human Servs, *Finding of Emergency* (2019) available at <[https://www.michigan.gov/documents/mdhhs/Finding\\_of\\_Emergency\\_MDHHS\\_665031\\_7.pdf](https://www.michigan.gov/documents/mdhhs/Finding_of_Emergency_MDHHS_665031_7.pdf)>.

<sup>38</sup> Press Release, *Governor Whitmer Takes Bold Action to Protect Michigan Kids from Harmful Effects of Vaping*, Office of the Governor (Sept. 4, 2019) <[https://www.michigan.gov/whitmer/0,9309,7-387-90499\\_90640-506450--,00.html](https://www.michigan.gov/whitmer/0,9309,7-387-90499_90640-506450--,00.html)>.

products. Ex. A. The Emergency Rules also impose advertising and other restrictions for all vapor products – including those with/without nicotine and/or flavors. Governor Whitmer signed the Emergency Rules on September 18, 2019.<sup>39</sup>

Pursuant to MCL 24.248(1), the Emergency Rules were immediately “effective on filing.” MCL 24.248(1). Indeed, the Emergency Rules themselves also specify that they took “effect upon filing with the Secretary of State....” Nevertheless, in some parts, the Emergency Rules purport to delay the effective date of certain aspects for 14 days.

Also, in connection with the September 4, 2019 press conference, the Department initially indicated that the Emergency Rules would be issued within “a few weeks” and that all affected parties would have 30 days thereafter to come into compliance with the new restrictions. Instead, the Emergency Rules were issued just two weeks after the press conference and provided only 14 days for everyone in Michigan to come into compliance.

For purposes of this lawsuit, the following provisions of the Emergency Rules are relevant to Plaintiff’s constitutional claims.

The ban on flavored vapor products applies broadly, to both “retailers” and “resellers.” The term “retailer” means “any person or entity that operates a business engaging in the sale of vapor products.” Rule 1(1)(d). The term “reseller” means “any person who purchases tobacco products or vapor products and intends to distribute such product(s) for resale in the State of Michigan.” Rule 1(1)(e). These definitions would capture, among others, vape shops, distributors, and manufacturers who also sell banned products.

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<sup>39</sup> Mich Dep’t Health and Human Servs, *Emergency Rules: Protection of Youth From Nicotine Product Addiction* (September 18, 2019) (attached as Exhibit B) and available at <[https://www.michigan.gov/documents/mdhhs/Emergency\\_vaping\\_rules\\_-\\_signed\\_by\\_Gov-Director\\_9.18.19\\_666139\\_7.pdf](https://www.michigan.gov/documents/mdhhs/Emergency_vaping_rules_-_signed_by_Gov-Director_9.18.19_666139_7.pdf)>.

The ban applies up and down the supply chain. Retailers and resellers shall not “sell, offer for sale, give, transport, or otherwise distribute, nor possess with intent to sell, give, or otherwise distribute a flavored nicotine vapor product.” Rule 2(1)(a). This ban applies not only to sales from brick-and-mortar stores, but also does not exclude online sales, whether to in-state or out-of-state customers. The Emergency Rules specifically provide that they apply “with equal force to retailers and resellers utilizing online and other remote sales methods that are intended to deliver flavored nicotine vapor products to this state.” Rule 5.

The Emergency Rules also cover advertising and labeling issues. One provision prohibits retailers and resellers from “either directly or indirectly, [using] fraudulent or misleading terms or statements to sell, offer for sale, give, or otherwise distribute vapor products.” Rule 3(1). Such statements include “those that are likely to induce false or unevicenced beliefs regarding the properties of the vapor products in a substantial portion of the audience.” These types of statements include terms like “clean,” “safe,” “harmless,” and “healthy.” Rule 3(2). The provision exempts any “products for which advertising is exclusively regulated by the Food and Drug Administration.” Rule 3(3).

Another provision applies federal labeling and advertising restrictions “set forth at 21 CFR 1140.32” to vapor products. Rule 4. Under federal law, those regulations only apply to “cigarettes and smokeless tobacco.” Subject to certain exceptions, the federal rules restrict all advertising and labeling to “only black text on a white background.” 21 C.F.R. § 1140.32(a).

Finally, any “person” who violates the Emergency Rules is subject to extensive criminal penalties. They would be found guilty of a misdemeanor and subject to imprisonment for not more than 6 months or a fine of not more than \$200, or both. Additional provisions provide for calculating multiple or cumulative violations. Rule 7.

## **H. Plaintiff Mister E-Liquid**

Mister E-Liquid is an e-liquid manufacturer, retailer, and wholesaler whose corporate headquarters is located in Grand Rapids, Michigan. This location is comprised of not only the corporate offices, but also the company's warehouse and laboratory. The company employs approximately 75 employees and has an employee retention rate of 95.67%, with many of the staff members having been with the business since shortly after the company was formed. Pease Aff., Ex. B at ¶¶ 3-4.

Mister E-Liquid-manufactures e-liquids in an industry-leading ISO Certified 14644 Class 6 cleanroom, with strict policies in place to ensure the quality of the facility, staff, and product. The company's products are sold online to its U.S. and global customer base, shipping to most countries around the world. Mister E-Liquid receives approximately 3,000 online orders a month on its website, with 70% of these orders originating in other states. *Id.* at ¶¶ 5, 7.

The wholesale business-to-business side sells manufactured e-liquid to other retailers across the country and around globe. This wholesale business occurs primarily outside Michigan with both national and global customers, and averages at least five figures per month for U.S.-based sales. In addition to online retail, Mister E-Liquid has five retail stores in Michigan located in Belmont, Kentwood, Grand Rapids, Okemos, and Niles, as well as Illinois retail stores in Decatur and Lincoln. *Id.* at ¶¶ 8-9.

Given the short time-frame to comply, this means that by October 1, 2019, Mister E-Liquid's physical locations in Michigan must either: (i) sell off or destroy all of their inventory of flavored nicotine vapor products (except tobacco-flavored nicotine vapor products); or (ii) move such inventory out-of-state. *Id.* at ¶ 13. The company must also sell off, destroy, or move all inventory of any vapor product (including vapor products without nicotine) that has any

“imagery explicitly or implicitly representing a characterizing flavor.” *Id.* In fact, the company is making plans, in the absence of a temporary injunction, to move all finished product out of the state by September 20, 2019. *Id.* at ¶ 14.

Further, as to online-retail, the company must rewrite and re-format websites to remove references to the flavored nicotine vapor products (except tobacco-flavored nicotine vapor products) that they are non-longer able to manufacture and sell. It must also remove any characterizing flavor imagery or marketing claims that the State of Michigan views as fraudulent or misleading as to the characteristics of any remaining product. In fact, the company has already shut down its website for wholesale orders and anticipates shutting down the consumer side as well. To the extent that the company censors, customers in other states and around the world will not have access to that information. It is not possible for Mister E-Liquid to have two web sites, one for Michigan and another for everybody else. *Id.* at ¶¶ 14-15.

Looking forward, if this ban were to remain in effect, it would require Mister E-Liquid to completely shut down production and manufacturing of vape juice as the Emergency Rules prohibit the sale of flavored vapor products to both in-state and out-of-state customers. With the manufacture of flavored vape as the backbone of the company, Mister E-Liquid simply cannot survive in Michigan without being able to manufacture flavored nicotine vapor products. The company will be forced to shut down, lay off its employees and move its entire operations outside of the State of Michigan. Not only will they be forced to secure a new facility outside of the state but they will also be forced to incur the considerable expense of once again engineering a laboratory sufficient to obtain the third party certification necessary to ensure that it is compliant with the ISO 14644 Standard. *Id.* at ¶¶ 17-20.

Even if the Emergency Rules only go into effect for a short time and are subsequently vacated or amended, Mister E-Liquid will still suffer irreparable harm because:

- a. Mister E-Liquid would potentially lose \$500,000 worth of inventory or be forced to move such product out-of-state;
- b. Mister E-Liquid will likely lose revenue from decreased online sales of vapor products and through wholesale retail to online sellers of vapor products;
- c. Mister E-Liquid will not be able to sell any product from a Michigan location to out-of-state customers;
- d. Mister E-Liquid will be forced to shut down manufacturing in its laboratory and stop taking in new orders; and
- e. Mister E-Liquid will suffer a loss of good will if its business operations are disrupted for even a short period of time.

*Id.* at ¶ 22.

## **ARGUMENT**

### **I. Legal Standard**

“The same factors are considered in determining whether to grant a request for either a temporary restraining order or a preliminary injunction.” *Michigan State A. Philip Randolph Inst. v. Johnson*, 209 F. Supp. 3d 935, 942 (E.D. Mich. 2016). The four factors that must be balanced and considered before the court may issue either type of injunctive relieve include: (i) the likelihood of the plaintiff's success on the merits; (ii) whether the plaintiff will suffer irreparable injury without the injunction; (iii) the harm to others which will occur if the injunction is granted; and (iv) whether the injunction would serve the public interest. *Id.*

**II. This Court Should Temporarily and Preliminarily Enjoin The Challenged Provisions Of The Emergency Rules Because Plaintiff Has Satisfied All Four Injunctive Relief Factors**

**A. Plaintiff Has A Strong Likelihood Of Success On The Merits**

**1. The Emergency Rules Violate The Dormant Commerce Clause**

Plaintiff and other vapor businesses in Michigan face extraordinary criminal penalties for violating the Emergency Rules, including incarceration. Yet the State did not see fit to limit the geographical scope of the regulation to those violations involving only Michigan entities and consumers. Instead, businesses may be fined and individuals imprisoned for doing business with out-of-state consumers and marketing online to potential customers outside the State. This is shocking example of regulatory overreach that is clearly not permitted under the Constitution. As discussed below, the offending provisions must therefore be enjoined.

The Commerce Clause not only explicitly grants Congress the exclusive authority to regulate commerce among the States, U.S. Const., art. 1, § 8, cl. 3, but also impliedly limits a State’s ability to “directly” regulate interstate commerce. *Brown –Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 578-79 (1986). Under this so-called “Dormant Commerce Clause,” the Sixth Circuit asks, in part, whether a state regulation is *per se* invalid. Specifically, a state law is *per se* invalid if it is a “direct regulation of interstate conduct (i.e., controls extraterritorial conduct).” *McLemore v. Gumucio*, 2019 U.S. Dist. LEXIS 122525, at \*11 (M.D. Tenn. 2019). This is because the Dormant Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (internal citations omitted).

Further, “a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid,

regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.” *Id.* Extraterritorial concerns arise when a statute “(i) shifts the costs of regulation onto other states, permitting in-state lawmakers to avoid the costs of their political decisions, (ii) has the practical effect of requiring out-of-state commerce to be conducted at the regulating state’s direction, or (iii) alters the interstate flow of the goods in question.” *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 102-03 (2d Cir. 2003). “The practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.” *Healy*, 491 U.S. at 336.

**a. Out-Of-State Sales**

The Emergency Rules run afoul of the extraterritorial doctrine because, at a minimum, they prevent a Michigan retailer, including Plaintiff, from selling and transporting product to out-of-state customers. A “retailer” is defined as “any person or entity that operates a business engaging in the sale of vapor products.” Rule 1(1)(d). A retailer cannot “sell, offer for sale, give, transport, or otherwise distribute, nor possess with intent to sell, give, or otherwise distribute a flavored nicotine product.” Rule 2(1)(a). Significantly, there is no geographical limitation on



where such sales may be made.<sup>40</sup> The provision can therefore be read as not only banning the sale of products to Michigan customers but also customers outside the State.<sup>41</sup>

Moreover, several other provisions make it even more difficult for in-state retailers, as a practical matter, to sell out-of-state. Rule 2(1)(a) prohibits retailers from “transporting” or “possessing with intent to sell” any flavored vapor products. This means that in-state retailers cannot even maintain sufficient stock for sales made in other states or transport any such goods. *See also* Rule 2(2) (“a person shall not transport flavored nicotine vapor products intended for delivery to any retailer or reseller in violation of these rules”).

The Sixth Circuit has explicitly held that a state law has extraterritorial effect if it prohibits in-state manufacturers or sellers from selling product to out-of-state customers. In *Am. Beverage Ass’n v. Snyder*, 735 F.3d 362 (6<sup>th</sup> Cir. 2013), the court considered Michigan’s bottle refund law. Consumers had figured out a way to buy bottles without paying the 10-cent deposit but then redeeming the bottles for that amount (i.e., fraudulent redemptions). Consumers would purchase bottles outside the state that were marked as refundable in Michigan (e.g., buy them across the border in Ohio) where the bottle deposit was not collected by the retailer. The consumer would then cross back over into Michigan and get a refund. *Id.* at 367.

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<sup>40</sup> The definition of “retailer” contrasts with the definition covering “resellers.” The latter specifically limits the Emergency Rules’ applicability to only those resellers (i.e., distributors) to those who “intend[]” to resell product “in the State of Michigan.” Rule 1(1)(e). However, in essence, any “reseller” automatically becomes a “retailer” upon a subsequent sale.

<sup>41</sup> This restriction would apply to online or mail order sales by Michigan retailers. Nothing in Rule 2(1)(a) explicitly exempts such sales to customers in other states. It is true that Rule 5 provides that “[t]hese rules apply with equal force to retailers and resellers utilizing online and other remote sales methods that are intended to deliver flavored nicotine vapor products to this state.” But that provision has no language otherwise limiting the geographical application of the Emergency Rules or removing such transactions from regulation.

In response, Michigan passed a law that required a unique marking clearly indicating that a bottle was subject to the State bottling law and, for purposes of this lawsuit, also prohibited in-state and out-of-state bottlers from selling those drink products outside of Michigan (and in a few other states). *Id.* at 367. This effectively prevented fraudulent redemptions. Consumers could no longer buy Michigan bottles in other states and then return them in Michigan for a refund amount that was never paid.

The Sixth Circuit held that the ban on sales to other states constituted unlawful extraterritorial regulation. Specifically, the court noted that “whether a beverage manufacturer is located in Michigan or outside of the state, it must still comply with the statute’s requirements.” *Id.* at 371. It concluded that the bottling regulation “not only requires beverage companies to package a product unique to Michigan but also allows Michigan to dictate where the product can be sold.” *Id.* at 376. In reality, it prevented in-state bottlers from making sales in other states. As such, Michigan “project[ed] its regulatory regime into the jurisdiction of another state.” *Id.*

Interestingly, the court also pointed out that the State had failed to consider less intrusive alternatives that would have allowed such transactions. For example, Michigan could have relied on “vigorous enforcement” to prevent fraudulent redemptions, limited the number of bottles that an individual could be returned, or required proof of purchase showing “that the container was sold and purchased in the state.” *Id.* at 375.

Michigan has done the same thing here. No Michigan retailer or distributor, including Plaintiff, can even market, let alone sell, flavored vapor products to consumers in other states. The ban requires other states to play by Michigan’s rules. It shifts the burdens of the Emergency Rules and the state’s policy choices onto consumers and businesses in other states who had no say in their adoption. Yet the accompanying Finding of Emergency fails to offer any justification

as to why Michigan has any interest in regulating sales to out-of-state consumers. Nor do they indicate that the State spent any time considering alternatives, whether standing alone or in combination, that could have achieved its goal of preventing underage access to flavored vapor products. This is particularly surprising as Michigan just banned the sale of e-cigarettes to minors, the aggressive enforcement of which could achieve the same purposes.

**b. Online Sales**

The Emergency Rules also violate the Dormant Commerce Clause and the extraterritorial principle because they restrict out-of-state content on the internet. Federal courts routinely enjoin attempts by states to censor commercial and non-commercial information streamed online.

“Because the internet does not recognize geographic boundaries, it is difficult, if not impossible, for a state to regulate internet activities without 'project[ing] its legislation into other States.’”

*Backpage.com, LLC v. Cooper*, 939 F. Supp. 2d 805, 841 (M.D. Tenn. 2013) (citing *Am.*

*Booksellers Found. v. Dean*, 342 F.3d 96, 103 (2d Cir. 2003); *McLemore v. Gumucio*, 2019 U.S.

Dist. LEXIS 122525, \*11 (M.D. Tenn. July 23, 2019). It is a well-established that the construct

of geography is “a virtually meaningless construct on the Internet.” *Am. Libraries Ass'n v.*

*Pataki*, 969 F. Supp. 160, 169 (S.D.N.Y. 1997).

Indeed, the reality is that an internet content provider cannot dictate who has access to an internet site. “No user could reliably restrict her communications only to [a single state’s] recipients. Moreover, no user could avoid liability . . . simply by directing his or her communications elsewhere, given that there is no feasible way to preclude [citizens in the regulated state] from accessing” the web site. *Id.* at 171. As a result, the content provider is presented with a “Hobson’s choice that imposes an unreasonable restriction on interstate commerce” – either “self-censor or risk prosecution.” *Id.* at 180. This includes instances where in-state content providers are effectively prohibited from streaming internet content outside the

state. *See, e.g., Am. Bookstores*, 342 F.3d at 99, (finding in-state website operator had standing and granting injunction because Vermont prevented plaintiff from providing links to other sites containing indecent material harmful to minors); *Am. Libraries Ass'n*, 969 F. Supp. at 161-63, 171 (case involving New York-based internet content providers and enjoining New York statute prohibiting transmission of indecent material over the internet that could be viewed by underage users where the statute “would apply to communications between New Yorkers and parties outside the State”).

The Emergency Rules fail for the same reason. Rule 2(1)(b) prohibits the “[u]se of imagery explicitly or implicitly representing a characterizing flavor to sell, offer for sale, give, or to otherwise distribute a vapor product.” Rule 3 also makes unlawful the use of what the State considers “fraudulent or misleading” terms in marketing efforts to describe a product’s characteristics, including “clean,” “safe,” “harmless,” and “healthy.” To the extent an in-state retailer operates a website, the Emergency Rules force them to remove any offending material, thus preventing potential customers across the country (and indeed the world) from viewing such content, or otherwise risk criminal prosecution. Again, as with the overall ban on sales, Michigan did not offer any rationale for regulating online content in other states or how that would further the goals of protecting the State’s youth. Nor did Michigan consider less intrusive alternatives so that in-state retailers could maintain access to their websites in other states.

Finally, the Dormant Commerce Clause protects against regulatory inconsistencies that might arise where one State’s statute is projected” into another State’s jurisdiction. *Healy*, 491 U.S. at 336-37. To allow otherwise “would be arbitrarily to exalt the public policy of one state over that of another.” *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 667-68 (7<sup>th</sup> Cir. 2010). Here, if other states adopted statutes similar to Michigan’s in which in-state retailers could not

sell to customers located out-of-state, the free-flow of products across state borders would be substantially hampered. Indeed, states like Iowa that have decided that its adult smokers should have full access to vapor products in an effort to move away from more dangerous cigarettes would be increasingly subject to bans on products adopted by other states.<sup>42</sup>

## **2. The Emergency Rules Are Preempted By Federal Law**

The State of Michigan continued to reach well beyond its regulatory authority through several provisions in the Emergency Rules that clearly encroach on FDA's domain. Under the TCA, Plaintiff and others are subject to an extensive regulatory scheme governing all aspects of vapor products, with specific areas carved out solely for federal control. This provides the regulated community with predictability and avoids a patchwork of confusing states laws that threaten individuals and businesses with extensive civil and criminal liability. As shown below, these provisions are preempted under the TCA and cannot be lawfully enforced.

Any preemption analysis begins with the Supremacy Clause of the U.S. Constitution. Article VI of the Constitution states that "the Laws of the United States . . . shall be the supreme law of the land." U.S. Const. art. VI, cl. 2. When determining whether a federal statute preempts state law, courts look specifically to the intent expressed by Congress when adopting the statute as the "ultimate touchstone" of preemption analysis. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Such intent may be explicitly stated in the federal statute or implicitly contained in the statute's structure and purpose. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

There are generally two types of preemption. "Express preemption" occurs when there is an explicit command from Congress stating a clear intention to preempt state law.

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<sup>42</sup> Letter from Thomas J. Miller, Iowa Attorney General, to Alex M. Azar, II, Secretary, U.S. Department of Health and Human Services (July 24, 2019) (stressing need for adult access to vaping products to promote public health), <https://tinyurl.com/y67ghz23>.

*Cipollone*, 505 U.S. at 16; *State Farm Bank, FSB v. Reardon*, 539 F.3d 336, 341-342 (6<sup>th</sup> Cir. 2008). “Conflict preemption” arises where state law prevents “the accomplishment and execution of the full purposes and objectives” of federal law. This is often called “obstacle preemption.” Under this form of preemption courts look specifically to the goals underlying a given regulatory scheme and ask whether the state law would frustrate the federal agency’s efforts to reach those goals. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 881 (2000); *Robbins v. New Cingular Wireless PCS, LLC*, 854 F.3d 315, 319 (6<sup>th</sup> Cir. 2017). Both types of preemption are implicated by several provisions of the Emergency Rules.

Rule 3 of the Emergency Rules prohibits retailers and resellers from “either directly or indirectly, [using] fraudulent or misleading terms or statements to sell, offer for sale, give, or otherwise distribute vapor products.” Rule 3(1). Such statements include “those that are likely to induce false or unevicenced beliefs regarding the properties of the vapor products in a substantial portion of the audience.” According to the Rule, these include terms like “clean,” “safe,” “harmless,” and “healthy.” Rule 3(2). There is no opportunity under the Rule for retailers or resellers to obtain approval to make such a claim. The provision exempts any “products for which *advertising* is exclusively regulated by” FDA. Rule 3(3) (emphasis added).

The TCA’s preemption section, however, specifically states that “[n]o State or political subdivision of a State may establish . . . any requirement which *is different from, or in addition to*, any requirement under [the Tobacco Control Act] . . . relating to . . . *modified risk tobacco products*. 21 U.S.C. §387p(a)(2)(A) (emphasis added). As discussed above, the MRTP provision requires retailers and resellers to secure FDA’s approval before they sell products that are explicitly marketed as “reduc[ing] harm or the risk of tobacco-related disease.” 21 U.S.C. § 387k(b)(1). Labeling and advertising may not include any unapproved claims, whether they are made “explicitly or

implicitly” that the product somehow presents a lower risk, is less harmful, contains fewer hazardous substances, or is free of such substances. 21 U.S.C. § 387k(b)(2)(A)(i-ii). FDA will only approve these claims after a retailer or reseller submits, among other things, extensive testing data and information substantiating the reduced risk. 21 U.S.C. § 387k(g).

The Emergency Rules regulate MRTP claims otherwise governed by the TCA and thus are expressly preempted. Like the MRTP provisions, Rule 3 covers marketing statements that could mislead consumers into believing, whether “directly or indirectly,” that a vapor product is safer or less risky than it really is. Indeed, the terms “clean,” “safe,” “harmless,” and “healthy” would be quintessential MRTP claims. However, Rule 3 is “different from or in addition to” the MRTP provision now applied to vapor products. While FDA can approve such claims following a scientific review, the State has outright banned them, no questions asked.

Moreover, Rule 4’s clause exempting claims appearing in “advertising” that are otherwise “exclusively regulated by” FDA does not save this provision from preemption. MRTP claims also cover “the label [and] labeling.” 21 U.S.C. § 387k(b)(2)(i). “Labeling” is defined under the TCA as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m). “Label” means a “display of written, printed, or graphic matter upon the immediate container of any article[.]” 21 U.S.C. § 321(k). Thus, the State is also prohibited from regulating MRTP claims on product labels, in addition to any advertising materials.

Further, Rule 3 is preempted in its entirety under obstacle preemption. As the Supreme Court held in *Geier*, state or local regulations that “prevent or frustrate the accomplishment of a federal objective” are preempted. 529 U.S. at 873; *see also Robbins*, 854 F.3d at 319 (“obstacle preemption” is where “the state law is an obstacle to the accomplishment and execution of the

full purposes and objectives of Congress”) (citation and internal quotation omitted). Congress did not ban MRTP claims in the TCA. Rather, it made a clear policy choice that some claims should be permitted. Regulated entities must have an opportunity to demonstrate that their claims are justified. But under Rule 3, the State simply assumes that a claim is fraudulent or misleading. Retailers and resellers have no chance to prove otherwise without risking an enforcement action. This clearly frustrates the balance struck by Congress in the MRTP provision.

Similarly, Rule 4 of the Emergency Rules is expressly preempted and directly frustrates express policy choices made by FDA. The State applies FDA labeling and advertising restrictions set forth in 21 C.F.R. § 1140.32 to vapor products. Those regulations require that any retailer or distributor use only “black text on a white background” for labeling and advertising. There are, however, various exceptions for advertising (such as in publications with a primarily adult readership). During the rulemaking process, when FDA was considering deeming vapor products, various stakeholders commented that Section 1140.32 should apply to e-cigarettes. 81 Fed. Reg. at 29,041, 29,056. FDA explicitly rejected those requests and decided not to apply those labeling and advertising restrictions to vapor products. *Id.* As such, Section 1140.32 only covers cigarettes and smokeless tobacco. 21 C.F.R. § 1140.32.

Accordingly, Rule 4 is expressly preempted because it is “different from or in addition” to labeling and advertising regulations that have been adopted by FDA and applied to e-cigarettes. While the TCA’s saving provision spares “advertising” from preemption (21 U.S.C. § 387p(a)(2)(B)), the statute’s preemption provision clearly covers “labeling” (21 U.S.C. § 387p(a)(2)(A)). At a minimum, therefore, the State is prohibited from applying the print and color restrictions to vapor product labels. Moreover, Rule 4 is completely preempted as it frustrates a policy choice made by FDA regarding the proper scope of labeling and advertising



restrictions for newly deemed products. FDA made a conscious decision not to regulate retailers and resellers in this manner. Rule 4 directly contradicts this intent.

**B. Plaintiff Will Suffer Irreparable Harm**

Plaintiff Mister E-Liquid, as well as other retailers and resellers in the State, will undoubtedly suffer substantial irreparable harm. Even if the Emergency Rules are only in effect for six months, their enforcement will give Mister E-Liquid no choice but to close its Michigan operations, including its headquarters, manufacturing facilities, and five retail outlets. Flavored vapor products are the backbone of this company and a large majority of its product line. Accordingly, it will have to lay off employees and move its operations to another state, which would necessitate the building of an entirely new production facility. Ex. B at ¶¶ 18-21.

Significantly, the company will be prohibited from remaining in Michigan and surviving on revenues from online sales to customers in other states. The Emergency Rules prevent the company from doing so, and even make it unlawful for Mister E-Liquid to maintain stocks in Michigan sufficient to service out-of-state customers or transport that product to locations outside the State. The lost revenue, even with a temporary ban on flavored vapor products, will be significant. The company receives about 70% of its revenues on out-of-state online sales, with the total for wholesale amounting to at least five figures per month. *Id.* at ¶¶ 7, 22.

Moreover, to comply with the various marketing restrictions, Mister E-Liquid will either have to shut down its website or remove: (i) all imagery related to characterizing flavors; (ii) any MRTP-like marketing claims; and (iii) any references to flavored vapor products. In fact, the company has already shut down its website for wholesale and may do so on the retail side. To the extent the company decides to censor its website, out-of-state customers would have no access to that marketing or information. Mister E-Liquid has no way to operate a website for Michigan only and another for those outside the State. *Id.* at ¶¶ 15-16.

At a minimum, even if the Emergency Rules go into effect for a short time and are subsequently vacated and enjoined, Mister E-Liquid will still suffer irreparable harm:

- a. Mister E-Liquid would potentially lose \$500,000 worth of inventory or have to move it out-of-state at great expense to the company;
- b. Mister E-Liquid will lose substantial revenue on out-of-state online sales;
- c. Mister E-Liquid will not be able to sell any flavored vapor products from a Michigan location to out-of-state customers;
- d. Mister E-Liquid will be either forced off-line or have to censor content;
- e. Mister E-Liquid will be forced to shut down manufacturing in its laboratory and stop taking new orders (in fact, the company stopped taking wholesale orders on September 24, 2019); and
- f. Mister E-Liquid will suffer loss of goodwill even for a short period.

**C. Harm To Plaintiff Will Outweigh Harm To The State Without A Temporary and Preliminary Injunction**

Mister E-Liquid and others regulated by the Emergency Rules would also suffer harm that clearly outweighs any harm to the State. *Nexus Gas Transmission*, 757 Fed. Appx. at 495 (the third factor requires the court to “balance the harm that [plaintiff] would face absent an injunction against that which [defendant] would face if we uphold the injunction”) (citation and internal quotations omitted). In fact, the State would suffer no harm in this instance. “[I]f the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, no substantial harm to others can be said to inhere in its enjoinder.” *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6<sup>th</sup> Cir. 2001) (quotation omitted); *see also Planned Parenthood Assn. v. Cincinnati*, 822 F.2d 1390, 1400 (6<sup>th</sup> Cir. 1987) (finding city does not experience substantial harm by being unable to enforce unconstitutional law).

**D. The Public Interest Will Be Served With An Injunction**

Finally, the public interest would serve the public interest on several grounds. First, the Sixth Circuit has stated that “it is always in the public interest to prevent the violation of a party’s constitutional rights.” *G & V Lounge v. Michigan Liquor Control Comm’n*, 23 F.3d 1071, 1079 (6<sup>th</sup> Cir. 1994) (citations omitted). Second, given that Michigan has no interest in addressing issues associated with youth outside its own borders, an injunction would not implicate public health and safety in Michigan. Third, enjoining enforcement of the various provisions will actually allow adult smokers in other states to continue to have access to products that they may have been relying on to stay away from more harmful cigarettes.

**CONCLUSION**

Plaintiff hereby requests that this Court enter an order enjoining the Emergency Rules from remaining in effect. A proposed Order is attached hereto for the Court’s convenience.

September 27, 2019

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 27, 2019, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system. I also served Plaintiff's Complaint and Motion for Temporary Restraining Order with supporting brief by email to the following:

Governor Gretchen Whitmer:

Governor Gretchen Whitmer  
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Before filing this suit (starting at approximately 2:30 p.m.), I also called—and either spoke with, or left messages for—the following individuals as a courtesy to notify them that this case would be filed today and inquire whether they wanted the pleadings sent to any other email address, fax number, etc.:

Mark Totten  
Chief Legal Counsel for Governor Whitmer

Mr. Ray Howd  
Attorney General's Office  
Division Chief for the Health, Education & Family Services Division

(The receptionist who answered for Mr. Howd informed me that Assistant Attorney General Darren Fowler was on duty to accept such calls. I spoke with Mr. Fowler, who asked me to send him a courtesy copy of the pleadings once filed, which I did—but, at his request, I am not publicly revealing his email address here)

Mr. Matthew Rick  
Department of Health and Human Services  
Acting Director of Legal Affairs

By: /s/ Kevin M. Blair