

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

MISTER E-LIQUID LLC,

Plaintiff,

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

Case No.
Hon.

Defendants.

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COMPLAINT

Plaintiff Mister E-Liquid, for its Complaint against Governor Gretchen Whitmer and Department of Health and Human Services Director Robert Gordon, (collectively, “Defendants”), state as follows:

NATURE OF THE ACTION

1. This is a civil action against Governor Gretchen Whitmer and Michigan Health and Human Services Director Robert Gordon for declaratory and other relief pursuant to the United States Constitution.

PARTIES, JURISDICTION, AND VENUE

2. Mr. E-Liquid is a Michigan LLC headquartered in Grand Rapids, Michigan.

3. Governor Gretchen Whitmer (“Governor Whitmer”) is the Governor of the State of Michigan.

4. Department of Health and Human Services Director Robert Gordon is the director of the Michigan Department of Health and Human Services.

5. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1343 and 42 U.S.C. § 1983.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1)-(2).

GENERAL ALLEGATIONS

I. Background on Vapor Products

7. Electronic cigarettes (e-cigarettes), 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.

8. 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.

9. Current estimates indicate that 10.8 million adults in the United States now use vapor products,¹ and that this number is growing as cigarette smoking rates fall. Over 500,000 adults in Michigan use vapor products.² Many of these adults are former smokers of traditional combustible tobacco products, who use vapor products to quit smoking.³

10. 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 more than 56,000 people.⁴

11. In Michigan, the vapor industry generates approximately \$608,284,800 for the Michigan economy and has created 4,290 jobs for the Michigan workforce. Vapor businesses in Michigan have paid over \$188,961,400 in wages and benefits to their employees, and have generated \$51,350,900 in state and local taxes.⁵ There are over 200 vapor shops in Michigan

¹ See Mirbolouk, *et al.*, Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016, *Ann Intern Med.* 2018;169(7):429-438 (October 2, 2018), available at <<https://annals.org/aim/article-abstract/2698112/prevalence-distribution-e-cigarette-use-among-u-s-adults-behavioral>>.

² Beth LeBlanc, *Researchers: Flavored e-cig ban could derail smoking cessation efforts*, *Detroit News* (September 11, 2019), <<https://www.detroitnews.com/story/news/politics/2019/09/11/researchers-flavored-e-cig-ban-could-derail-smoking-cessation-efforts/2232213001/>>.

³ About Vaping, *What Is Vaping?*, AMERICAN VAPING ASSOCIATION (2019), <<https://vaping.org/about-us/what-is-vaping/>>.

⁴ See *The Value of Vapor*, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>>.

⁵ See *The Value of Vapor*, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>>.

according to the American Vaping Association.⁶ Many will be forced to shut down because of the Emergency Rules.⁷

II. Health Effects

12. 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 due in part to the fact that 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.⁸

13. 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.⁹

14. Moreover, there is considerable evidence that the overwhelming majority of users of vapor products in the U.S., commonly identified as “vapers,” are now former cigarette

⁶ Beth LeBlanc, *Researchers: Flavored e-cig ban could derail smoking cessation efforts*, Detroit News (September 11, 2019), <<https://www.detroitnews.com/story/news/politics/2019/09/11/researchers-flavored-e-cig-ban-could-derail-smoking-cessation-efforts/2232213001/>>.

⁷ Beth LeBlanc, *Researchers: Flavored e-cig ban could derail smoking cessation efforts*, Detroit News (September 11, 2019), <<https://www.detroitnews.com/story/news/politics/2019/09/11/researchers-flavored-e-cig-ban-could-derail-smoking-cessation-efforts/2232213001/>>.

⁸ 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>>.

⁹ 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/>>.

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.¹⁰

15. 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.”¹¹ Another review of relevant science completed in 2019 found that there is growing evidence showing that e-cigarette emission aerosols are relatively safe compared to tobacco smoke.¹²

16. The head of the Food and Drug Administration (“FDA”) Center for Tobacco Products (CTP), Mitchell Zeller, recently acknowledge – in sworn testimony in federal court proceedings – that some vapor products may 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

¹⁰ 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>>.

¹¹ 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>.

¹² Riccardo Polosa *et al.*, (2019). *The effect of e-cigarette aerosol emissions on respiratory health: a narrative review*, Expert Review of Respiratory Medicine <<https://www.tandfonline.com/doi/full/10.1080/17476348.2019.1649146>>.

serious risk that adults, especially former smokers, who currently use [vapor] products and are addicted to nicotine would migrate to combustible tobacco products”¹³

17. Public health authorities around the world have come to similar conclusions. In April 2016, the Royal College of Physicians (“RCP”) – Britain’s professional association dedicated to setting and improving medical standards and the authors of the original groundbreaking report on the dangers of cigarette smoking in 1962 – issued a report lauding the benefits of vapor products as safer alternatives to combustible tobacco (hereinafter, the “RCP Report”). The RCP Report summarizes the science, public policy, regulation, and ethical issues related to electronic nicotine delivery systems (“ENDS”) products, and concludes that vaping is not a “gateway” to smoking. On the contrary, “the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.”¹⁴

18. Specifically, the RCP Report estimates that vapor products are only 5% as harmful as traditional cigarettes and that the long-term effects of nicotine from vapor are likely to be minimal. This estimate corresponds with the conclusions of Public Health England, a

¹³ 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>>.

¹⁴ Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, Report (April 28, 2016), available at <<https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>>.

department of the British Government, which determined that, based on the current evidence, vapor products are 95% less harmful than traditional cigarettes.¹⁵

19. These studies show that 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.

III. Population Benefits and Youth Concerns

20. 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 2018.¹⁶ 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.¹⁷

21. 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

¹⁵ Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, Report (April 28, 2016), available at <<https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>>.

¹⁶ 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/?>>.

¹⁷ 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/>>.

cigarettes to vapor products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the U.S. alone.¹⁸

22. In Michigan, it is cigarette smoking – not flavored vapor products – that poses a public health crisis. Michigan currently has one of the highest smoking rates in the country, among both youth (10.5%)¹⁹ and adults (19.3%),²⁰ resulting in 16,200 annual deaths.²¹ According to the Michigan Department of Health and Human Safety, this makes cigarette smoking the leading cause of preventable death in Michigan.²²

IV. Role of Flavors

23. Numerous published studies highlight the important role of flavored vapor products for tobacco harm reduction. An extensive online survey of 20,836 American adults who use vapor products found that cigarette smokers who switch to vapor products are doing so increasingly with a variety of fruit and other non-tobacco flavors.²³ These results were buttressed

¹⁸ 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>>.

¹⁹ See CDC, *Youth Risk Behavior Surveillance System* (2017), available at <<https://www.cdc.gov/healthyyouth/data/yrbs/index.htm>>.

²⁰ See CDC, *Behavioral Risk Factor Surveillance System* (2017), available at <<https://www.cdc.gov/brfss/index.html>>.

²¹ *Causes of Preventable Death*, Mich Dep't of Health and Human Servs, *Tobacco Facts for State of Michigan* (2011), <https://www.michigan.gov/documents/mdch/2011-State_of_Michigan_456820_7.pdf>.

²² *Causes of Preventable Death*, Mich Dep't of Health and Human Servs, *Tobacco Facts for State of Michigan* (2011), <https://www.michigan.gov/documents/mdch/2011-State_of_Michigan_456820_7.pdf>.

²³ 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>>.

by another survey of more than 69,000 adult vapers, which similarly found that the vast majority (more than 85%) preferred fruit and dessert flavors compared to tobacco and menthol.²⁴

24. Flavors are crucial to helping adult smokers make the switch and stay away from cigarettes.²⁵ The ability to vape non-tobacco flavors is what drove the development of these products by early entrepreneurs. Vapor products were in fact invented by smokers for smokers looking for less harmful products that do not smell or taste like traditional cigarettes.²⁶ Adult vapers overwhelmingly report that non-tobacco flavors and flavor variability matter to them and help keep them off tobacco.²⁷

25. 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.²⁸ If *only* tobacco-

²⁴ 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>>.

²⁵ 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>>.

²⁶ 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%2023,%202019%20CTP%20Meeting.pdf>.

²⁷ 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>>.

²⁸ 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>>.

flavored e-liquids were permitted, smokers would be less likely to disassociate their habit and addiction from such flavor, and would constantly be at risk of re-triggering an urge to smoke.

26. In 2018, researchers studying the impact of vaping on preventing smoking relapse interviewed dozens of vapers to learn more about their smoking history, prior quit attempts, how they started vaping, preferred flavors and nicotine strength, and whether they had switched to vapor in an attempt to quit smoking.²⁹ These researchers found that vapor products, all of which are flavored, may be a unique harm reduction innovation for smoking relapse prevention, and a viable long-term substitute for smoking, as these products meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related aspects of tobacco addiction. Flavors and smells, the sensory aspect of vapor, were an important factor.

27. Moreover, the availability of flavors may not be the predominant reason 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,³⁰ but with the introduction of high-concentration nicotine-salt based “pod-

²⁹ See Caitlan Notley, et al., The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention, 15 Harm Reduction Journal (2018), <<https://doi.org/10.1186/s12954-018-0237-7>>.

³⁰ 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>. (“Importantly, youth vaping didn’t peak at the same time flavor options did. The vape 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 vaping 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),

system” vapor products (like the Juul)³¹ which gained access to the convenience store distribution network normally reserved for Big Tobacco products.³²

28. FDA has suggested that “open-tank” vapor products are *not* the source of rising underage use.³³ Open-tank products utilize refillable flavored e-liquids, represent about half of the total vapor market,³⁴ 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 the FDA retailer warning letters and No Tobacco Sale Orders for illegal sales to minors.³⁵

https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html?outputType=amp&_twitter_impression=true.

³¹ 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, 11:32 AM), <https://www.wisn.com/amp/article/juul-nicotine-hit-may-be-worst-for-kids-best-for-smokers/27293019?fbclid=IwAR0xF2TgLNshUB2DZDIY30gJ0whezaREGoRMXjWg4cJ9vwpoPHpT4uwVV4k>.

³² 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, Nielsen: C-Store Data Through 1/27/18, 2/24/18, and 10/6/18; WELLS FARGO SECURITIES.

³³ U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, (September 12, 2018)” See <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>.

³⁴ 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, (Sept. 8, 2018).

³⁵ 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-%202619.

V. Reports of Vapor Related Illnesses

29. The media has recently covered incidents of “vaping related” illnesses around the country. These cases are likely the result of aftermarket additives such as being used with illicit tetrahydrocannabinol (THC) and marijuana.³⁶

30. Many vapor products are sold as pods, 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.³⁷

31. The illegal vapor cartridges that contain THC have also been reported to contain significant amounts of vitamin E acetate, which is a diluting and thickening agent that makes cannabis oil more affordable.³⁸

32. 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.³⁹

33. These aftermarket THC oils are bought on the black market and are not available for sale at regulated vapor shops.⁴⁰

³⁶ 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>>.

³⁷ 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/>>.

³⁸ 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/>>.

³⁹ *Id.*

⁴⁰ 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

VI. Plaintiff Mister E-Liquid

34. 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.

35. 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.

36. The company's e-liquid is 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 outside of the state.

37. The wholesale business-to-business side sells manufactured e-liquid to other vape juice retailers across the country and around globe. This wholesale business occurs primarily outside Michigan with both national and global customers, and averages at least into the five figures per month in revenues.

38. In addition to online retail, Mister E-Liquid has retail stores in Michigan located in Belmont, Kentwood, Grand Rapids, Okemos, and Niles, as well as Illinois retail stores in Decatur and Lincoln.

39. Given the short time-frame to comply under the Emergency Rules, this means that by October 1, 2019, Mister E-Liquid's physical locations in Michigan must either: (i) sell off or

<<https://www.usatoday.com/story/news/health/2019/09/23/vaping-illnesses-crisis-teens-black-market-thc-no-regulation/2209009001/>>.

destroy all of their inventory of flavored nicotine vapor products (except tobacco-flavored nicotine vapor products); or (ii) move such inventory out-of-state.

40. Moreover, Mister E-Liquid must sell off, or destroy all inventory of any vapor product (including vapor products without nicotine) that has any “imagery explicitly or implicitly representing a characterizing flavor.”

41. Further, in connection with online-retail, Mister E-Liquid 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.

42. Mister E-Liquid has already shut down their website for wholesale orders and anticipate shutting down the business to consumer side as well.

43. 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.

44. 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.

45. Mister E-Liquid will be forced to shut down, lay off its employees and move its entire operations outside of the State of Michigan.

46. Not only will they be forced to obtain 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.

47. 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 sellers of vapor products and through wholesale retail to online sellers of vapor products;
- c. Mister E-Liquid will be forced to shut down manufacturing in its laboratory and stop taking in new orders; and
- d. Mister E-Liquid will suffer a loss of good will if its business operations are disrupted for even a short period.

VII. Federal Regulation – The Tobacco Control Act

48. 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).

49. 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).

50. 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” 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.

51. 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.

52. 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.⁴¹

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

54. 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).

55. 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).

56. 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

⁴¹ 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>>.

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).

57. 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.*

58. 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).

59. 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).

VIII. Michigan Regulation – Emergency Rules

60. The State of Michigan only recently began to regulate vapor products.

61. 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.⁴²

62. On August 30, 2019, Governor Whitmer signed a Finding of Emergency prepared by the Michigan Department of Health and Human Services (the “Department”).⁴³ This document

⁴² 2019 Public Act 18, MCL 722.641 *et seq.*

⁴³ 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>.

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.

63. 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.⁴⁴

64. 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 products. 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, 2019.⁴⁵

65. 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.

66. Also, in connection with the September 4, 2019 press conference, the Department initially promised that the Emergency Rules would be issued within “a few weeks” and that all

⁴⁴ 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>.

⁴⁵ 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>.

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.

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

68. 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.

69. 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 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.

70. Some provisions of the Emergency Rules also reach beyond retailers and resellers. Specifically, they provide that a "person shall not transport flavored nicotine vapor products intended for delivery to any retailer or reseller in violation of these rules." Rule 2(2). This provision covers all manner of pick-up and delivery services.

71. The Emergency Rules also implicate 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 would 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).

72. 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).

73. Accordingly, to be in compliance, [Plaintiff] must immediately: (i) quarantine all flavored vapor products; (ii) cease all online sales of such products to consumers outside of Michigan; (iii) stop transporting any flavored vapor products to out-of-state destinations; (iv) remove all labeling and advertising that could be considered “fraudulent or misleading; and (v) comply with all labeling and advertising restrictions set forth in 21 C.F.R. § 1140.32.

74. Any “person” who violates the Emergency Rules is 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.

COUNT ONE

**Violation of Commerce Clause
U.S. Const., art. 1, § 8, cl. 3**

75. Plaintiff reasserts and incorporates by reference each of the above paragraphs.

76. Article I, Section 8 of the United States Constitution grants to Congress the exclusive authority to regulate interstate commerce. Under the Dormant Commerce Clause, states are precluded from applying a state statute so that it governs commerce taking place outside of the state or otherwise controls conduct beyond the boundaries of the state. A state statute that results in extraterritorial regulation is *per se* unconstitutional.

77. The Emergency Rules prohibit retailers and resellers of flavored products from selling, offering for sale, giving, transporting, or otherwise distributing, or possessing with intent to sell, give, or otherwise distribute” such products. Rule 2.

78. This provision, however, does not limit its applicability to only Michigan transactions or activity. The sweeping language found in Rule 2 means that in-state retailers and resellers are not only prohibited from selling product to Michigan customers, but also consumers located in other states. In fact, in-state retailers and sellers cannot even maintain stocks sufficient to fill out-of-state orders or transport such product.

79. The Emergency Rules also regulate the content of in-state retailer or reseller websites as they are streamed in other states. 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.”

80. To comply with these marketing restrictions, in-state retailers and resellers, including Plaintiff, must either remove such material from their websites, which means it cannot be seen by consumers and customers in other states, or risk an enforcement action.

81. The Emergency Rules project Michigan's policy choices regarding flavored vaping products on other states that might take a different approach. By preventing in-state retailers and resellers from engaging in sales and marketing activities in other states, the State will have substantially altered the flow of goods across state borders. Moreover, Michigan will have projected its ban on certain products into other states, even those that have adopted public health policies of maximizing adult access to flavored vapor products so that they can move away from their smoking habits.

82. Finally, based on the foregoing, the burden on interstate commerce is clearly excessive in relation to the putative local benefits.

83. Plaintiffs and others who violate these unconstitutional provisions are subject to extensive criminal penalties. Rule 7.

84. The Emergency Rules violate the Commerce Clause and the prohibition on extraterritorial regulation. Thus, the above provisions should be declared unconstitutional and enjoined in their entirety.

COUNT TWO

Federal Preemption U.S. Const., art. VI, cl. 2

85. Plaintiff reasserts and incorporates by reference each of the above paragraphs.

86. Article VI, Clause 2 of the U.S. Constitution declares "the Laws of the United States . . . shall be the supreme law of the land." Under the Supremacy Clause, federal law

preempts state law where: (i) a federal statute does so “expressly” (“express preemption); or (ii) where the state statute prevents “the accomplishment and execution of the full purposes and objectives” of federal law (“obstacle preemption”).

87. The TCA expressly preempts any state laws that regulate “labeling” and “modified risk tobacco products” (“MRTP”) in a manner that is “different from or in addition to” federal regulation under the TCA. 21 U.S.C. § 387p(a)(2)(A).

88. The TCA’s MRTP provision prohibits retailers and distributors from making claims in their labeling or advertising that a product, among other things, presents a lower risk, is less harmful, contains a reduced level of a substance, or reduces exposures to such substances. FDA may approve of an MRTP claims after an extensive review of product data and information. 21 U.S.C. § 387k(b).

89. Rule 2 regulates similar claims because it prohibits “fraudulent or misleading terms or statements” when marketing vapor products where such statements are “likely to induce false or unevicenced belief regarding the properties of the vapor products in a substantial portion of the audience.” Such terms include “clean,” “safe,” “harmless,” and “healthy.” However, Rule 2 is different from or in addition to the MRTP provision because it does not provide retailers and resellers the opportunity to obtain approval to make such claims. As such, Rule 2 is not only expressly preempted, but it also frustrates a policy choice made by Congress not to completely ban MRTP claims, but instead allow them to be made under certain circumstances.

90. Under the TCA, FDA also has adopted various labeling restrictions that limit labels to “only black text on a white background.” 21 C.F.R. § 1140.32. These restrictions only apply to cigarettes and smokeless tobacco. *Id.* During the rulemaking process that led to the

Deeming Rule, FDA explicitly rejected comments asking that these labeling restrictions also be applied to vapor products. 81 Fed. Reg. at 29,041, 29,056.

91. Rule 4 explicitly applies the labeling provisions of 21 U.S.C. § 1140.23 to vapor products, despite the fact that FDA made a conscious decision not to do the same. Accordingly, Rule 4 is preempted under both express and obstacle preemption.

92. These two provisions of the Emergency Provisions should be declared void and unconstitutional.

COUNT THREE

Declaratory Judgment 28 U.S.C. §§ 2201-2202

93. Plaintiff reasserts and incorporates by reference each of the above paragraphs.

94. An actual controversy exists, within the meaning of 28 U.S.C. §§ 2201-2202, between Plaintiff and the State of Michigan regarding the constitutionality of various provisions under the Emergency Rules.

95. Plaintiffs claim that Rule 2 violates the Dormant Commerce Clause and the prohibition on extraterritorial regulation. Plaintiff also claims that Rules 3 and 5 are preempted under the federal TCA and FDA's regulations.

REQUEST FOR RELIEF

96. WHEREFORE, Plaintiff respectfully requests the following relief:

- a. A declaration that Rule 2 violates the Dormant Commerce Clause;
- b. A declaration that Rules 3 and 5 violate the Supremacy Clause;
- c. A temporary, preliminary, and permanent injunction enjoining the enforcement of the challenged Rules;

- d. Attorneys' fees and expenses pursuant to 42 U.S.C. § 1988; and
- e. Such other relief as this Court deems appropriate.

Respectfully submitted,

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