

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF HOUGHTON

MARC SLIS, and 906 VAPOR,

Plaintiffs,

Case No. 19-17278-C2

v.

Hon. Charles R. Goodman

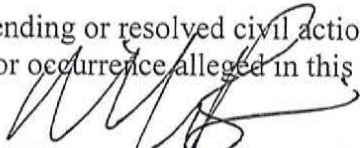
STATE OF MICHIGAN; and DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Defendants.

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There is no other pending or resolved civil action arising out of
the transaction or occurrence alleged in this Complaint.



Michael S. Burink (P70517)

COMPLAINT

Plaintiffs Marc Slis and 906 Vapor, LLC, for their Complaint against the State of Michigan, and the Department of Health and Human Services, (collectively, "Defendants"), state as follows:

FILED
IN THE CIRCUIT COURT
COUNTY OF HOUGHTON MICHIGAN

SEP 25 2019

DEPUTY CLERK

NATURE OF THE ACTION

1. This is a civil action against the State of Michigan and the Department of Health and Human Services for declaratory and other relief pursuant to Michigan law, including the Administrative Procedures Act, Public Act 306 of 1969, MCL 24.201 *et seq.*

PARTIES, JURISDICTION, AND VENUE

2. Marc Slis is the owner and operator of 906 Vapor, LLC, a Michigan limited liability company with its principal place of business in Houghton, Michigan.

3. The State of Michigan (the “State”) includes all departments and agencies of the State, including the Defendant Department of Health and Human Services (“DHHS”).

4. Jurisdiction is proper in this Court pursuant to MCL 600.631 and/or MCL 24.264.

5. Venue is proper in this Court pursuant to MCL 600.1615.

GENERAL ALLEGATIONS

6. Marc Slis is the owner and operator of a retail store called 906 Vapor, LLC (“906 Vapor”), which is located at 321 Shelden Avenue; Houghton, Michigan 49931.¹

7. 906 Vapor sells a variety of vapor products, including some with nicotine and some without nicotine, and some with non-tobacco flavors.²

8. 906 Vapor has been in the business of selling vapor products since 2015.³

I. General Background About Vapor Products

9. 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.

¹ See Slis Affidavit (Exhibit A) at ¶ 2.

² *Id.* at ¶ 3.

³ *Id.* at ¶ 4.

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.

10. 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.

11. 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.⁴

12. Current estimates indicate that 10.8 million adults in the United States now use vapor products,⁵ and that this number is growing as cigarette smoking rates fall. A recent economic impact analysis found, among other things, that (1) the vapor industry generates \$24,457,512,300 for the U.S. economy, (2) vapor businesses paid over \$7,897,889,500 in wages and benefits to their employees, and (3) there are approximately 11,469 vapor shops across the country that employ more than 56,000 people.⁶

⁴ See Dr. Michael Siegel, *Glantz and Colleagues Essentially Call for a Ban on Electronic Cigarettes: Banning Flavors Would Ban All Existing E-Cigarettes*, The rest of the story: tobacco and alcohol news analysis and commentary, (July 19, 2018, 12:15 PM), <<http://tobaccoanalysis.blogspot.com/2014/06/glantz-and-colleagues-essentially-call.html>> (accessed September 24, 2019).

⁵ 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>> (accessed September 24, 2019).

⁶ See *The Value of Vapor*, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>> (accessed September 24, 2019).

13. In Michigan, the vapor industry generated approximately \$608,284,800 for the State's 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.⁷

II. Health Effects

14. A large and growing body of scientific evidence indicates that vapor products, while not beneficial to health, 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

15. Research suggests that because e-liquids and the resulting vapor do not contain 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

16. 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

⁷ See The Value of Vapor, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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/>> (accessed September 24, 2019).

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

17. 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

18. 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 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>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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

19. 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

20. 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>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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

21. 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 Benefit & Youth Concerns

22. 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

23. 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 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

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>> (accessed September 24, 2019).

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/?>> (accessed September 24, 2019).

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/>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

24. 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

25. 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 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

¹⁹ See CDC, Youth Risk Behavior Surveillance System (2017), available at <<https://www.cdc.gov/healthyyouth/data/yrbs/index.htm>> (accessed September 24, 2019).

²⁰ See CDC, Behavioral Risk Factor Surveillance System (2017), available at <<https://www.cdc.gov/brfss/index.html>> (accessed September 24, 2019).

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> (accessed September 24, 2019).

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> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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),

26. 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

27. 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-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.

<<http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

28. 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 and pleasurable aspect.

29. 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,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>> (accessed September 24, 2019).

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> (accessed September 24, 2019). (“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), <<https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen->

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

30. The 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,

smoking-20190921.html?outputType=amp&__twitter_impression=true> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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)” <<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>> (accessed September 24, 2019).

There are two broad categories of vapor devices – closed and open systems. Closed systems, including “cigalikes” designed to look like a traditional cigarette, as well as newer “pod-systems,” are pre-filled with e-liquid, which is not intended to be manipulated by the consumer. Open-system devices, on the other hand, permit consumers to refill an empty tank with the e-liquid of their choice – e.g., with a preferred flavor – that is purchased separately in a glass bottle or plastic container. Open-system products are primarily sold in small adult-only “vape shops” like 906 Vapor, rather than in convenience stores and gas stations, which typically sell traditional tobacco products and pod-systems manufactured by Big Tobacco-affiliated companies.

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).

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 (NTSOs) for illegal sales to minors.³⁵

V. Vapor Related Recent Illnesses

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

32. 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

33. 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

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-%20202619> (accessed September 24, 2019).

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>> (accessed September 24, 2019).

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/>> (accessed September 24, 2019).

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/>> (accessed September 24, 2019).

34. 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

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

VI. Federal Regulation of Vapor Markets

36. The U.S. Food and Drug Administration (the "FDA") first began regulating vapor products in the same manner as traditional tobacco products (e.g., cigarettes) in 2016.

37. The FDA was initially charged under the Tobacco Control Act (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."⁴¹

38. On August 8, 2016, the FDA used this "Deeming Rule" to extend the TCA's requirements to vapor products that contain or are intended to be used with tobacco-derived ingredients such as nicotine.⁴²

39. Under the TCA, the FDA has regulatory authority over the entire supply chain. This means that vapor products are now subject to, among other regulations:

- a. Prohibitions on the sale of adulterated or contaminated tobacco products;⁴³

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 <<https://www.usatoday.com/story/news/health/2019/09/23/vaping-illnesses-crisis-teens-black-market-thc-no-regulation/2209009001/>> (accessed September 24, 2019).

⁴¹ 21 USC § 387a(b).

⁴² 81 Fed Reg at 28,975.

- b. Prohibitions on the sale of misbranded tobacco products;⁴⁴
- c. Requirements that manufacturers submit health information (e.g., health studies, ingredient reports) regarding each tobacco product;⁴⁵
- d. Requirements that manufacturers register their production facilities with the FDA;⁴⁶
- e. Restrictions on advertising the sale and distribution of tobacco products;⁴⁷
- f. Promulgated good manufacturing practices;⁴⁸
- g. Tobacco product standards (e.g., flavor restrictions) adopted through notice-and-comment rulemaking;⁴⁹
- h. Requirements that manufacturers establish and maintain records;⁵⁰ and
- i. Prohibitions on manufacturers and retailers distributing free samples of tobacco products, except free samples of smokeless tobacco (i.e., chewing tobacco), which may be distributed in “qualified adult-only facilities.”⁵¹

40. Manufacturers must submit substantial information to the FDA, including scientific research findings on the ability of the product to reduce risk or exposure, data and information on how consumers actually use the product, and post market surveillance studies. The manufacturer must show that there is a significant reduction in risk of tobacco-related disease and the FDA must take into account, on a population level, the health benefit to users of

⁴³ 21 USC § 387b.

⁴⁴ 21 USC § 387c.

⁴⁵ 21 USC § 387d.

⁴⁶ 21 USC § 387e.

⁴⁷ 21 USC § 387f(d).

⁴⁸ 21 USC § 387f(e).

⁴⁹ 21 USC § 387g(a).

⁵⁰ 21 USC § 387(i).

⁵¹ 21 USC § 387a-1(a).

tobacco products and those who do not use such products (the “public health benefit” standard).⁵²

41. The TCA also requires manufacturers of any “new tobacco product” to obtain pre-market authorization prior to commercial sale. A “new tobacco product” is defined to mean, in part, “any tobacco product ... that was not commercially marketed in the United States as of February 15, 2007,” known as the Grandfather Date. 21 U.S.C. § 387j. Any tobacco product that was on the market “as of” the Grandfather Date is exempt from the FDA pre-market review.⁵³

42. Because there are no grandfathered vapor products, the entire product category is considered “new” and subject to FDA premarket review. For deemed tobacco products on the market as of August 8, 2016, however, the Deeming Rule established a “compliance policy” permitting such products to remain on the market absent an FDA marketing authorization for a period of time before premarket applications are due. The premarket application deadline for deemed products has shifted numerous times, and is currently set for May 11, 2020.⁵⁴

43. With respect to flavors, the FDA has explicitly permitted the marketing of flavored vapor products, as a “special rule” in the TCA prohibiting characterizing flavors other than tobacco and menthol only applies to cigarettes.⁵⁵ In March 2018, the FDA 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

⁵² 21 USC § 387k.

⁵³ 21 USC §§ 387e(j), 387j(a).

⁵⁴ See *American Academy of Pediatrics v Food and Drug Admin*, No 8:18-cv-00883-PWG (D Md 2019).

⁵⁵ 21 USC § 387g(a)(1)(A).

vapor products. More recently, the FDA announced that it would soon be finalizing a Guidance Document potentially revising the current compliance policy for non-tobacco flavored vapor products.⁵⁶

44. Beyond the FDA, vapor products are also subject to a number of federal requirements including, among other things, child-resistant packaging under the Child Nicotine Poison Prevention Act (CNPPA), which is administered by the Consumer Product Safety Commission, numerous environmental and hazardous waste disposal laws, as well as false and misleading advertising and marketing restrictions under Section 5 of the Federal Trade Commission Act.⁵⁷

VII. Michigan Regulation of Vapor Markets & Emergency Rules

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

46. On January 16, 2016, Governor Snyder vetoed legislation aimed at banning the sale of vapor products to minors.⁵⁸ This was Michigan's first legislative or regulatory action on e-cigarettes and vapor products.

⁵⁶ 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>> (accessed September 24, 2019).

⁵⁷ See FDA Newsroom, *E-Liquids Misleadingly Labeled or Advertised as Food Products*, (content current as of September 25, 2018), available at <<https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm>> (accessed September 24, 2019).

⁵⁸ Kathleen Gray, *Snyder vetoes e-cigarette bills, says not tough enough*, Detroit Free Press (January 16, 2015) <<https://www.freep.com/story/news/local/michigan/2015/01/16/snyder-vetoes-bills-banning-cigarette-use-sale-minors/21860557/>> (accessed September 24, 2019).

47. After three years with no further legislation or regulation, 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.⁵⁹

48. On August 30, 2019, Governor Whitmer signed a Finding of Emergency prepared by the Michigan Department of Health and Human Services.⁶⁰

49. 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.⁶¹

50. 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 nicotine⁶² and/or flavors. Governor Whitmer signed the Emergency Rules on September 18, 2019.⁶³

⁵⁹ 2019 Public Act 18, MCL 722.641 *et seq.*

⁶⁰ 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> (accessed September 24, 2019).

⁶¹ 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> (accessed September 24, 2019).

⁶² As explained further below, the Emergency Rules are invalid and overbroad as applied to non-nicotine vapor products because the Rules themselves claim that it is nicotine that is causing the alleged emergency.

⁶³ Mich Dep’t Health and Human Servs, *Emergency Rules: Protection of Youth From Nicotine Product Addiction* (September 18, 2019) (attached as Exhibit B), available at <https://www.michigan.gov/documents/mdhhs/Emergency_vaping_rules_-_signed_by_Gov-Director_9.18.19_666139_7.pdf> (accessed September 24, 2019).

51. Upon information and belief, the Emergency Rules are only the second time that the Department has promulgated emergency rules under MCL 24.248 and circumvented the usual procedural safeguards as required by the state Administrative Procedures Act.

52. 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 (correctly) 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.

53. Also, in connection with the September 4, 2019 press conference, the DHHS initially promised 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, which means, *inter alia*, that 906 Vapor must (a) sell off, return, or destroy all of its inventory of flavored nicotine vapor products (except tobacco-flavored nicotine vapor products); (b) rearrange its store layouts to ensure that advertisements for any vapor product (including those with/without nicotine and with/without flavor) are at least 25 feet away from the cash register, candy, food, and soft drinks; and (c) sell off, return, or destroy all of its inventory of vapor products (including those without nicotine) that has any “imagery explicitly or implicitly representing a characterizing flavor.”

54. The Emergency Rules do not ban or impose any restrictions on any traditional “tobacco products” (flavored or unflavored),⁶⁴ even though the Rules’ preamble claims that nicotine is what has caused the alleged emergency.

55. In fact, the Emergency Rules entirely ignore the fact that the cigarette smoking rate for Michigan adolescents is approximately twice the nationwide rate for adolescents (10.5 percent to 5.8 percent),⁶⁵ while adolescent vapor usage in Michigan is approximately half the national rate (14.8 percent to 27.5 percent).⁶⁶

56. The Emergency Rules fail to take into consideration the impact banning flavored vapor products will have on the overall Michigan population, and, specifically, adult vapers, but instead focuses on the use of vapor products by minors, which is already illegal.⁶⁷

57. Over 500,000 adults in Michigan use vapor products.⁶⁸ Many of these adults are former smokers of traditional combustible tobacco products, who use vapor products to quit smoking.⁶⁹

⁶⁴ As noted in the Emergency Rules, “tobacco product” is a term of art, as defined in MCL 722.644(f), meaning “a product that contains tobacco and is intended for human consumption, including, but not limited to, a cigarette, noncigarette smoking tobacco, or smokeless tobacco” And “vapor product” means “a noncombustible product . . . that can be used to produce vapor from nicotine or any other substance, and the use or inhalation of which simulates smoking.” MCL 722.644(h). “Vapor product” specifically does not include a product regulated as a drug or device by the FDA, such as “tobacco products.”

⁶⁵ *The Toll of Tobacco in Michigan*, CAMPAIGN FOR TOBACCO-FREE KIDS (2019), <<https://www.tobaccofreekids.org/problem/toll-us/michigan>> (accessed September 25, 2019).

⁶⁶ *Id.*

⁶⁷ Both the federal Tobacco Control Act and the Michigan Youth Tobacco Act prohibit the sale of vapor products to minors under 18 years old. See MCL 722.641 *et seq.*, 21 USC § 387, *et seq.*

⁶⁸ *Id.*

⁶⁹ About Vaping, *What Is Vaping?*, AMERICAN VAPING ASSOCIATION (2019), <<https://vaping.org/about-us/what-is-vaping/>> (accessed September 24, 2019).

58. There are over 200 vapor shops in Michigan according to the American Vaping Association.⁷⁰ Many will be forced to shut down because of the Emergency Rules.⁷¹

59. Plaintiffs will be forced to shut down if Defendants' Emergency Rule is not invalidated.

CAUSES OF ACTION

60. This is an original action seeking declaratory and other relief related to the actions of Defendants, whose Emergency Rules are invalid and violate Plaintiffs' rights under Michigan law, including the Michigan Administrative Procedures Act. As outlined in more detail below, Plaintiffs assert the following causes of action:

- a. Declaratory judgment that the Emergency Rules are ultra vires;
- b. Declaratory judgment that the Emergency Rules are procedurally invalid, because, *inter alia*:
 - i. There is no emergency to justify deviating from the very important, usual procedural safeguards required by the Administrative Procedures Act (APA);
 - ii. Even if the circumstances warrant some urgent response, the DHHS cannot justify skipping *all* the usual procedural safeguards in the APA; and
 - iii. Even if the circumstances constitute a true emergency, the alleged threat only affects a small subgroup of the general public, which is insufficient, as a matter of law, to justify deviating from the usual APA procedural safeguards.

⁷⁰ 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/>> (accessed September 24, 2019).

⁷¹ *Id.*

c. Declaratory judgment that the Emergency Rules are substantively invalid because, *inter alia*, (i) they do not comply with the legislative intent of the enabling statute; and (ii) the Emergency Rules are arbitrary and capricious.

COUNT I
DECLARATORY JUDGMENT
EMERGENCY RULES ARE ULTRA VIRES

61. Plaintiffs repeat and re-allege herein each of the foregoing paragraphs.

62. This Court has the authority to issue a declaratory judgment pursuant to MCR 2.605 because there is an actual case and controversy between the parties about whether the Emergency Rules are ultra vires.

63. This Court should decide whether the Emergency Rules are ultra vires because Plaintiffs have a right under MCL 600.631 to seek judicial review of any “order, decision, or opinion of any state . . . agency” that adversely affects Plaintiffs.

64. In addition, or alternatively, this Court should decide whether the Emergency Rules are ultra vires because Plaintiffs have a right under MCL 24.264 to seek a declaratory judgment concerning “the validity or applicability of a rule . . . that . . . interferes with or impairs, or imminently threatens to interfere with or impair, the legal rights or privileges of the plaintiff.”⁷²

65. The Department claims to have rule-making authority pursuant to MCL 333.2233, one of the three enabling statutes cited in the Emergency Rules. MCL 333.2233(1) provides that

⁷² A leading treatise, whose reasoning has been adopted by the Court of Appeals, explains that the provision in MCL 24.264 ostensibly requiring a plaintiff to request an agency ruling before seeking judicial review only applies where a plaintiff wants to litigate the *applicability of a rule to certain facts*. See Mich Admin Law, §§ 8:11 (Declaratory judgments under Michigan Administrative Procedures Act); 8:13 (Challenges to statutes, orders, and validity of rules); *Michigan Farm Bureau v Dep't of Env'tl Quality*, 292 Mich App 106, 119 n 7, 807 NW2d 866, 877 n 7 (2011).

the Department “may promulgate rules necessary or appropriate to implement and carry out the duties or functions vested by law in the department.”

66. Critically, however, MCL 333.2233(2) specifies that “[i]f the Michigan supreme court rules that sections 45 and 46 of the administrative procedures act of 1969 ... are unconstitutional, and a statute requiring legislative review of administrative rules is not enacted within 90 days after the Michigan supreme court ruling, the department shall not promulgate rules under this act.”

67. On June 20, 2000, the Michigan Supreme Court held that sections 45 and 46 of the APA were unconstitutional. *Blank v Dep’t of Corrections*, 462 Mich 103, 611 NW2d 530 (2000).

68. The Legislature did not enact “a statute requiring legislative review of administrative rules” within 90 days after the decision in *Blank*.

69. Thus, according to the plain language of MCL 333.2233, the Legislature has directed that “the department shall not promulgate rules under this act.” Indeed, the Court of Appeals has already upheld the nullification of a different agency’s rules based on identical language in that agency’s enabling statute. See *Verizon v Mich PSC*, 263 Mich App 567, 689 NW2d 709 (2004).

70. The Emergency Rules are therefore ultra vires and should be deemed invalid by this Court.

Wherefore Plaintiffs respectfully request that the Court issue a declaratory judgment invalidating the Emergency Rules as ultra vires, and for any other appropriate relief.

COUNT II
DECLARATORY JUDGMENT
EMERGENCY RULES ARE PROCEDURALLY INVALID

71. Plaintiffs repeat and re-allege herein each of the foregoing paragraphs.

72. This Court has the authority to issue a declaratory judgment pursuant to MCR 2.605 because there is an actual case and controversy between the parties about whether the Emergency Rules are procedurally valid.

73. This Court should decide whether the Emergency Rules are procedurally valid because Plaintiffs have a right under MCL 600.631 to seek judicial review of any “order, decision, or opinion of any state . . . agency” that adversely affects Plaintiffs.

74. In addition, or alternatively, this Court should decide whether the Emergency Rules are procedurally valid because Plaintiffs have a right under MCL 24.264 to seek a declaratory judgment concerning “the validity or applicability of a rule . . . that . . . interferes with or impairs, or imminently threatens to interfere with or impair, the legal rights or privileges of the plaintiff.”

75. “Ordinarily, agencies must follow the notice-and-participation rule-making procedures contained in the APA.” *Mich State AFL-CIO v Sec’y of State*, 230 Mich App 1, 6; 583 NW2d 701 (1998).

76. MCL 24.248(1) allows an agency, in certain circumstances, to promulgate an emergency rule and thereby circumvent some or all of the usual procedural safeguards in the APA, but only if: (1) the agency “finds that preservation of the public health, safety, or welfare requires promulgation of an emergency rule without following the notice and participation procedures required by section 41 and 42;” (2) the agency “states in the rule the agency’s reasons for that finding”; and (3) “the governor concurs in the finding of emergency.” *Mich State AFL-CIO v Sec’y of State*, 230 Mich App 1, 21; 583 NW2d 701 (1998).

77. Where an agency fails to promulgate an emergency rule in compliance with the relevant procedures set forth in the APA, the rule is “invalid and may be stricken by a court...”

Mich State AFL-CIO, 230 Mich App at 24.

78. The Emergency Rules are procedurally invalid because, *inter alia*:

- a. There is no true emergency to justify deviating from the very important, usual procedural safeguards required by the APA;
- b. Even if the circumstances warrant some urgent response, the DHHS cannot justify skipping *all* the usual procedural safeguards in the APA; and
- c. Even if the circumstances constitute a true emergency, the alleged threat only affects a small subgroup of the general public, which is insufficient, as a matter of law, to justify deviating from the usual APA procedural safeguards.

79. Defendants provided the public no official notice of the Emergency Rules before they were promulgated on September 18, 2019. Governor Whitmer’s press release on September 4, 2019 was devoid of details and did not provide businesses or consumers with sufficient details.

80. Defendants provided no opportunity for comment on the Emergency Rules. Plaintiffs, other businesses, consumers, and associations have had no opportunity to provide Defendants with alternative viewpoints, solutions, or studies.

81. Defendants have provided only 14 days for Plaintiffs to comply with the Emergency Rules which means, *inter alia*, that 906 Vapor must (a) sell off, return, or destroy all of its inventory of flavored nicotine vapor products (except tobacco-flavored nicotine vapor products); (b) rearrange its store layout to ensure that advertisements for any vapor product (including those with/without nicotine and with/without flavor) are at least 25 feet away from the cash register, candy, food, and soft drinks; and (c) sell off, return, or destroy all of its inventory

of any vapor product (including those without nicotine) that has any “imagery explicitly or implicitly representing a characterizing flavor.”

82. The Emergency Rules will likely cause Plaintiffs to go out of business—which is especially arbitrary and capricious because stores selling combustible tobacco products (flavored and unflavored) remain unaffected by the Emergency Rules.

Wherefore Plaintiffs respectfully request that the Court issue a declaratory judgment that the Emergency Rules are procedurally invalid, and for any other appropriate relief.

COUNT III
DECLARATORY JUDGMENT
EMERGENCY RULES ARE SUBSTANTIVELY INVALID

83. Plaintiffs repeat and re-allege herein each of the foregoing paragraphs.

84. This Court has the authority to issue a declaratory judgment pursuant to MCR 2.605 because there is an actual case and controversy between the parties about whether the Emergency Rules are substantively valid.

85. This Court should decide whether the Emergency Rules are substantively invalid because Plaintiffs have a right under MCL 600.631 to seek judicial review of any “order, decision, or opinion of any state . . . agency” that adversely affects Plaintiffs.

86. In addition, or alternatively, this Court should decide whether the Emergency Rules are substantively invalid because Plaintiffs have a right under MCL 24.264 to seek a declaratory judgment concerning “the validity or applicability of a rule . . . that . . . interferes with or impairs, or imminently threatens to interfere with or impair, the legal rights or privileges of the plaintiff.”

87. Under the APA, this Court must “set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 USC § 706(2)(A); see also MCL 24.306(e).

88. Courts defer to an agency's findings of fact only if they are supported by "substantial evidence." 49 USC § 46110(c); see also MCL 24.306(d).

89. "[A] fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Amerijet Int'l, Inc v Pistole*, 753 F3d 1343, 1350 (DC Cir 2014) (internal citation and quotation omitted).

90. In determining the substantive validity of an agency's emergency rules, this Court must analyze three factors: "(1) whether the rule is within the subject matter of the enabling statute; (2) whether it complies with the legislative intent underlying the enabling statute; and (3) whether it is arbitrary and capricious." *Blank v Dep't of Corrections*, 222 Mich App 385, 406; 564 NW2d 130 (1997), *aff'd in part*, 462 Mich 103 (2000); see also *Chesapeake & O R Co v Pub Serv Com'n*, 59 Mich App 88, 98-99; 228 NW2d 843 (1975); *Thomas Bros, Inc v Sec'y of State*, 90 Mich App 179, 185-186; 282 NW2d 273 (1979).

91. The Emergency Rules are substantively invalid because they are not within the subject matter of the DHHS's enabling statute, MCL 333.2201 *et. seq.*

92. Alternatively, to the extent that Defendants may claim that they have delegated authority to promulgate the Emergency Rules, that argument fails because, *inter alia*, the very general "authority to promulgate rules to safeguard properly the public health" in MCL 333.2226, and/or the conclusory "emergency" language in MCL 24.248(1)—especially when considered together—represent, at best, an unconstitutional delegation of power without any reasonable standards or guidance by the legislature about what constitutes a true emergency, what "public health, safety, or welfare" means, etc. See, e.g., *Blue Cross & Blue Shield of Michigan v Governor*, 422 Mich 1, 51; 367 NW2d 1 (1985).

93. The Emergency Rules are also substantively invalid because they do not comply with the legislative intent underlying the DHHS's enabling statute, MCL 333.2201 *et. seq.*

94. A statute that grants power to an administrative agency must be strictly construed and the administrative authority drawn from such statute must be granted plainly, because doubtful power does not exist. *Lake Isabella Dev, Inc v Vill of Lake Isabella*, 259 Mich App 393, 675 NW2d 40 (2003).

95. The Emergency Rules are also substantively invalid because they are arbitrary and capricious. For example:

- a. The Emergency Rules ban all flavored nicotine vapor products, except tobacco-flavored nicotine products, even though the supposed cause of the alleged emergency is nicotine—and the most prevalent source of nicotine (“tobacco products”) are unaffected by the Emergency Rules. Likewise, the Emergency Rules provide no reasonable explanation for excluding tobacco-flavored nicotine vapor products from the otherwise exhaustive general ban on all flavored nicotine vapor products.
- b. The Emergency Rules impose advertising and other restrictions on all vapor products, regardless of flavor and including non-nicotine vapor products, even though the Emergency Rules are supposedly intended to mitigate the alleged emergency posed by youth access to nicotine. In other words, the Emergency Rules do not even attempt to justify declaring an emergency for non-nicotine vapor products, and thus, at a minimum, the DHHS must follow the usual APA safeguards if it wishes to promulgate rules imposing restrictions on non-nicotine vapor products.

- c. Defendants failed to consider alternative solutions as required by the APA, such as increasing penalties for selling to minors, and/or modifying existing tobacco laws and/or regulations to cover nicotine vapor products.
- d. Defendants also failed to consider alternative viewpoints as required by the APA, such as the harm to adults who use flavored nicotine vapor products to quit or reduce use of traditional combustible or smokeless tobacco, and/or the harm to the vapor industry, and state and local economies, including all those who will lose jobs if the Emergency Rules are not vacated.
- e. Defendants failed to consider potential solutions that would address the purported emergency but minimize accordant harms to retail establishments and adult citizens (among other portions of the general public outside the narrow subgroup that the DHHS claims need protected).
- f. Defendants failed to consider potential consequences of banning regulated flavored vapor products, such as consumers being driven to the black market, where they would encounter illicit THC cartridges that are the apparent source of illnesses around the country.⁷³

Wherefore Plaintiffs respectfully request that the Court issue a declaratory judgment that the Emergency Rules are substantively invalid, and for any other appropriate relief.

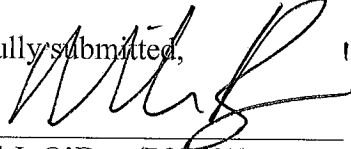
⁷³ Paige Minfield Cunningham, *The Health 202: Vaping illnesses sparked the e-cig crackdown. But marijuana is likely to blame*, The Washington Post (September 18, 2019), at <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/09/18/the-health-202-vaping-illnesses-sparked-the-e-cig-crackdown-but-marijuana-is-likely-to-blame/5d812a6a88e0fa7bb93a8b9c/> (accessed September 24, 2019).

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that the Court:

- A. Issue a declaratory judgment that the Emergency Rules violate Michigan law, including the Administrative Procedures Act.
- B. Grant Plaintiffs such other and further relief as this Court deems just and proper.

Respectfully submitted,



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Dated: September 25, 2019

Attorneys for Plaintiffs

EXHIBIT A

(Slis Affidavit)

STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF HOUGHTON

MARC SLIS and 906 VAPOR, LLC,

Plaintiffs,

v.

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

Defendants.

AFFIDAVIT OF MARC SLIS

NOW COMES Marc Slis, being first duly sworn, stating as follows:

1. I have personal knowledge of the facts set forth herein and, if called as a witness, would be competent to testify as to such facts.
2. I am an owner and operator of a retail store called 906 Vapor, LLC (“906 Vapor”), which is located at 321 Shelden Avenue; Houghton, Michigan 49931.
3. 906 Vapor sells a variety of vapor products, including some with nicotine and some without nicotine, and some with non-tobacco flavors.
4. 906 Vapor has been in the business of selling vapor products since 2015.
5. On September 4, 2019, Governor Whitmer held a press conference to announce that her administration would ban all flavored nicotine vapor products, except tobacco-flavored nicotine vapor products.
6. On September 18, 2019, the Department of Health and Human Services (“DHHS”) issued 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.

7. In connection with the Governor's September 4, 2019 press conference, the State initially promised 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 affected parties were given only 14 days to come into compliance, which means, *inter alia*, that 906 Vapor must (a) sell off, return, or destroy all of its inventory of flavored nicotine vapor products (except tobacco-flavored nicotine vapor products); (b) rearrange its layout to ensure that advertisements for any vapor product (including those with/without nicotine and with/without flavor) are at least 25 feet away from the cash register, candy, food, and soft drinks; and (c) sell off, return, or destroy all inventory of any vapor product (including vapor products without nicotine) that has any "imagery explicitly or implicitly representing a characterizing flavor."

8. At least 80% of 906 Vapor's current inventory is banned under the Emergency Rules.

9. The Emergency Rules fail to take into consideration the impact banning flavored vapor products will have on the overall Michigan population, including adult former smokers like me.

10. The Emergency Rules claim that banning all flavored vapor products is necessary to protect minors from nicotine, but selling nicotine vapor products to minors is already illegal, and 906 Vapor routinely checks identification before selling vapor products to any customers who appear to be less than 30 years old.

11. 906 Vapor has never been cited for selling vapor products to minors. Indeed, to the best of my knowledge, 906 Vapor has never sold any vapor products to minors.

12. In every year since 906 Vapor opened for business in 2015, less than 5% of its sales involved tobacco-flavored vapor products. 906 Vapor simply cannot survive without being able to sell flavored nicotine vapor products.

13. If the Emergency Rules go into effect, 906 Vapor will be forced to shut down and lay off its employee.

14. Even if the Emergency Rules only go into effect for a short time and are subsequently vacated or amended, 906 Vapor still suffer irreparable harm because:

- a. 906 Vapor will be forced to remove and/or destroy over 80% of its current inventory;
- b. 906 Vapor will likely lose customers to online sellers of vapor products; and
- c. 906 Vapor will suffer a loss of good will if its business operations are disrupted for even a short period.

15. On the other hand, in my opinion, Defendants and the public at large will not suffer any harm if this Court temporarily stays enforcement of the Emergency Rules. Defendants can still enforce existing laws that prohibit selling vapor products to minors.

16. Further, affiant sweareth naught.

SIGNATURE PAGE FOLLOWS

>

>

Date: 9/24/19

Marc K. Slis

Marc Slis

Sworn and subscribed before me
this 24 day of September, 2019

Sandra A Manninen

Notary Public

Houghton County, Michigan

My comm. exp. 6-4-2020

SANDRA A MANNINEN
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF HOUGHTON
My Commission Expires June 4, 2020
Acting in the County of Houghton

EXHIBIT B



DEPARTMENT OF HEALTH AND HUMAN SERVICES
BUREAU OF HEALTH AND WELLNESS, PUBLIC HEALTH ADMINISTRATION
PROTECTION OF YOUTH FROM NICOTINE PRODUCT ADDICTION
EMERGENCY RULES

Filed with the Secretary of State on

These rules take effect upon filing with the Secretary of State and shall remain in effect for 6 months.

By authority conferred on the Department of Health and Human Services by the sections 2221, 2226, and 2233 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, and 333.2233, Executive Reorganization Order No. 2015-1, MCL 400.227, and section 48 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.248.

FINDING OF EMERGENCY

For the reasons below, the Michigan Department of Health and Human Services finds that the State of Michigan faces a vaping crisis among youth and recommends the promulgation of emergency rules to address this crisis.

Since 2014, e-cigarettes (also known as vapor products) have been the most commonly used tobacco product among youth in the U.S.¹ Nationwide, e-cigarette use among middle and high school students increased 900% from 2011-2015.² From 2017 to 2018, e-cigarette use among youth increased 78% among high school students and 48% among middle school students.³ The total number of children who are currently using e-cigarettes rose to an astonishing 3.6 million in 2018, 1.5 million more than the previous year alone.⁴ From the years 2015-2016 and 2017-2018, counties across Michigan (cross section of 39 reporting) witnessed between a 30% and 118% increase in use among high school students who used an e-cigarette during the past month.⁵

¹ U.S. Surgeon General's Advisory on E-Cigarette Use among Youth, available at <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

² Surgeon General's Advisory see footnote 1; citing Wang TW, Gentzke A, Sharapova S, et al. Tobacco Use Among Middle and High School Students – United States, 2011-2017. MMWR Morbidity and Mortality Weekly Report. 2018;67(22):629-633.

³ See <https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use> citing the most recent National Youth Tobacco Survey (NYTS) data.

⁴ See Footnote 3.

⁵ Michigan Profile for Healthy Youth Survey by MDE & MDHHS, 39 County Data from 2015-2016 and 2017-2018 for e-cigarette usage among high schoolers.

E-cigarettes use an e-liquid that may contain nicotine, in addition to a combination of flavoring, propylene glycol, vegetable glycerin, and other ingredients.⁶ They may also contain toxic chemicals such as formaldehyde, acrolein, acrylonitrile, propylene oxide, crotonaldehyde and acetaldehyde (also found in cigarette smoke), as well as metal particles such as nickel, lead, and chromium, which can be inhaled into the lungs.⁷

The nicotine in e-cigarettes can rewire the brain to crave more of the substance and create a nicotine addiction. Resulting brain changes may have long-lasting effects on attention, learning, and memory.⁸ Research has also shown that youth who use e-cigarettes are significantly more likely to start smoking combustible cigarettes despite the well-known, documented, and often deadly health consequences such as lung cancer and heart disease.⁹

In December of 2018, the United States Surgeon General Jerome Adams officially declared e-cigarette use among youth in the United States an epidemic.¹⁰ Dr. Adams issued an advisory on e-cigarette use among youth, noting that action must be promptly taken to protect the health of young people.¹¹ Dr. Adams was joined by the Secretary of the U.S. Department of Health & Human Services, Alex Azar, who called the historic increase in e-cigarette use by youth, which has outpaced any other substance, an “unprecedented challenge.”¹²

According to a recent study, 81% of youth e-cigarette users reported using a flavored e-cigarette at first use.¹³ This study concluded that flavored tobacco products may attract young users and serve as “starter products to regular tobacco use.” Another study

⁶ <https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends#references>

⁷ <https://www.fda.gov/tobacco-products/ctp-newsroom/think-e-cigs-cant-harm-teens-health>

⁸ See footnote 6, referencing Abreu-Villaca, Y., Seidler, F. J., Tate, C. A., & Slotkin, T.A. (2003). Nicotine is a neurotoxin in the adolescent brain: critical periods, patterns of exposure, regional selectivity, and dose thresholds for macromolecular alterations. *Brain Res*, 979 (1-2), 114-128.

⁹ <https://www.fda.gov/tobacco-products/ctp-newsroom/think-e-cigs-cant-harm-teens-health>, referencing Berry KM, Fetterman JL, Benjamin EJ, Bhatnager A, Barrington-Trimis JL, Leventhal AM, Stokes A. Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths. *JAMA Netw Open*. 2019;2(2)e187794. Doi: 10.1001/jamanetworkopen.2018.8894.

¹⁰ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

¹¹ Id.

¹² <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-for-e-cigarette-press-conference.html>

¹³ Villanti AC, Johnson AL, Ambrose BK, et al. Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013-2014). *Am J Prev Med*. 2017;53(2):139-151. doi:10.1016/j.amepre.2017.01.026. <https://www.ncbi.nlm.nih.gov/pubmed/28318902>.

revealed that nearly two thirds (63.6%) of current middle and high school tobacco users have used a flavored tobacco product in the past month.¹⁴

This epidemic can therefore be attributed in large part to the appeal of flavored vapor products to youth as well as the advertising and promotional activities by companies that glamorize use of nicotine products nationwide.

Rule 1. (1) As used in these rules:

(a) "Characterizing flavor" means a taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product, vapor product, or alternative nicotine product, or any byproduct produced thereof. This includes, but is not limited to, tastes or aromas relating to food or drink of any sort; menthol; mint; wintergreen; fruit; chocolate; vanilla; honey; candy; cocoa; dessert; alcoholic beverages; herbs; or spices.

(b) "Flavored vapor product" means any vapor product that imparts a characterizing flavor.

(c) "Flavored nicotine vapor product" means any vapor product that contains nicotine and imparts a characterizing flavor.

(d) "Retailer" means any person or entity that operates a business engaging in the sale of tobacco products or vapor products.

(e) "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.

(2) The terms defined in the youth tobacco act, 1915 PA 31, MCL 722.641 to 722.645, have the same meaning when used in these rules.

Rule 2. (1) Beginning 14 days after these rules are filed with the secretary of state, a retailer or reseller shall not:

(a) Sell, offer for sale, give, transport, or otherwise distribute, nor possess with intent to sell, give, or otherwise distribute a flavored nicotine vapor product.

(b) Use imagery explicitly or implicitly representing a characterizing flavor to sell, offer for sale, give, or otherwise distribute a vapor product.

(2) Beginning 14 days after these rules are filed with the secretary of state, a person shall not transport flavored nicotine vapor products intended for delivery to any retailer or reseller in violation of these rules.

¹⁴ Dai H. Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017. *JAMA Pediatr.* Published online January 07, 2019;173(3):282-284. doi:10.1001/jamapediatrics.2018.4595.

Rule 3. (1) Beginning 14 days after these rules are filed with the secretary of state, a retailer or reseller shall not use, either directly or indirectly, fraudulent or misleading terms or statements to sell, offer for sale, give, or otherwise distribute vapor products.

(2) As used in this rule, "fraudulent or misleading terms or statements" include those that are likely to induce false or unevidenced beliefs regarding the properties of the vapor products in a substantial portion of the audience. Fraudulent or misleading terms include, but are not limited to, "clean;" "safe;" "harmless;" and "healthy."

(3) This rule does not apply to products for which advertising is exclusively regulated by the Food and Drug Administration.

Rule 4. Beginning 14 days after these rules are filed with the secretary of state, the restrictions on advertising set forth at 21 CFR 1140.32 apply with equal force to vapor products. Violations of 21 CFR 1140.32 are violations of this rule.

Rule 5. These 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.

Rule 6. (1) Beginning 14 days after these rules are filed with the secretary of state, advertisements for vapor products shall not be placed:

(a) Within 25 feet of the point of sale. Where this cannot be achieved, advertisements must be placed at the greatest possible distance from the point of sale.

(b) Within 25 feet of candy, foodstuff, or soft drinks. Where this cannot be achieved, advertisements must be placed at the greatest possible distance from candy, foodstuff, and soft drinks.

(c) In such a manner that the advertisement can be readily seen by a person standing outside of the building at a distance of 25 feet.

Rule 7. (1) A person who violates any provision of these rules is guilty of a misdemeanor, punishable by imprisonment for not more than 6 months, or a fine of not more than \$200, or both, as set forth by section 2261 of the public health code, 1978 PA 368, MCL 333.2261.

(2) Violations of rule 2 are calculated on a per-item and per-transaction basis and may be punished cumulatively.

(3) Violations of rules 3, 4, and 6 are calculated daily, with each 24-hour period during which the violation occurs constituting a separate violation.

Rule 8. If any rule or subrule of these rules, in whole or in part, is found to be invalid by a court of competent jurisdiction, such decision will not affect the validity of the remaining portion of these rules.

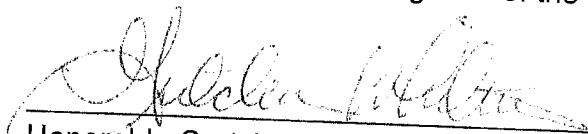
MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES



Robert Gordon
Director

Date:

Pursuant to Section 48(1) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.248(1), I hereby concur in the finding of the Department of Health and Human Services that circumstances creating an emergency have occurred and the public interest requires the promulgation of the above rules.



Honorable Gretchen Whitmer
Governor

Date: