

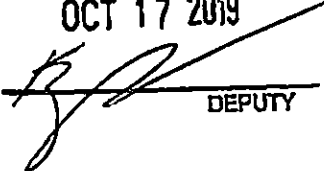
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FILED
PAIGE TRAUTWEIN, CLERK

OCT 17 2019


DEPUTY

MONTANA TWENTY-FIRST JUDICIAL DISTRICT COURT, RAVALLI COUNTY

<p>MONTANA SMOKEFREE ASSOCIATION, INC.; FREEDOM VAPES, LLC., LIBERTY SMOKE, INC.; AND UBLAZE VAPOR, LLC</p> <p>Petitioners,</p> <p>vs.</p> <p>MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; Sheila Hogan, in her official capacity as the Director of the Montana Department of Public Health and Human Services and STEPHEN C. BULLOCK, in his official capacity as Governor of the State of Montana.</p> <p>Respondents.</p>	<p>Cause No. DV-19-388/1</p> <p>Dept. No. 2 Jennifer B. Lint</p> <p>PETITION FOR JUDICIAL REVIEW OF MONTANA DEPARTMENT OF PUBLIC OF HEALTH AND HUMAN SERVICES TEMPORARY EMERGENCY RULES</p>
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COMES NOW, Petitioners, Montana Smoke Free Association, Freedom Vapes, LLC,

Liberty Smoke, Inc. and Ublaze Vapor, LLC., by and through their attorneys, and for their Petition for Judicial Review and supporting affidavits attached as Exhibits 1-3, in this matter against Respondents, Montana Department of Public Health and Human Services (“DPHHS”) and Sheila Hogan, in her official capacity as the Director (“Director”) of the DPHHS, and Stephen M. Bullock, in his official capacity as Governor of the State of Montana (“Governor”), respectfully set forth and allege as follows:

PRELIMINARY STATEMENT

1. This is a special proceeding, pursuant to the Montana Administrative Procedures Act, specifically § 2-4-702(2), MCA, which requests the Court review the October 8, 2019 decision of the DPHHS to adopt Temporary Emergency Rules (“Emergency Rules”) which prohibit: (1) the sale, offering for sale, giving, or otherwise distributing flavored Electronic Nicotine Delivery System (“ENDS”) products and cannabis products to persons within Montana and (2) the transporting within Montana flavored ENDS products and cannabis products intended for sale or distribution within Montana by any person. Exhibit 4. The Emergency Rules were implemented upon the Governor’s directive. DPHHS has invoked § 2-4-303, MCA as the basis for adopting and enforcing the Emergency Rules.

2. Petitioners seek: (i) a declaratory judgment that Respondents have improperly enacted the Emergency Rules by emergency executive action in excess of constitutional, statutory and administrative authority; (ii) a judgment annulling the Emergency Rule; and (iii) a temporary restraining order, a preliminary injunction and a permanent injunction preventing Respondents from enforcing the Emergency Rules.

3. The Emergency Rules which impose a ban on flavored e-liquid ENDS products enacted by Respondents exceed their statutory authority, are arbitrary and capricious, fail to articulate sufficient statutory grounds upon which to predicate emergency executive action, and

fail to comply with the Montana Administrative Procedure Act (“MAPA”). Petitioners are all Montana bricks-and-mortar open system ENDS product retailers and each will be irreparably harmed by imminent enforcement of the Emergency Rules, as they will be forced to shut down their business operations entirely or face significant criminal penalties for non-compliance.

4. Indeed, virtually all of the over 20 businesses that comprise Montana’s open system ENDS products retail industry confront the same imminent fate. The balance of equities also favors Petitioners, as they merely seek to preserve the status quo in order for the Respondents to be required to consider less restrictive and onerous means of seeking to reduce youth access to, and use of, ENDS products and addressing recent incidents of pulmonary ailments alleged caused by the illegal use of illegal black market products.

5. Moreover, the Emergency Rules will directly affect members of the general public in Montana who utilize open system flavored ENDS e-liquid products as part of their combustible tobacco cessation efforts.

6. The Emergency Rules therefore affect the Petitioners’ respective legal rights, and ability to conduct business. Accordingly, this is a “contested case” as defined by § 2-4-102(4), MCA. This Petition is timely filed, within 30 days of the DPHHS’s adoption of the Emergency Rules and in the appropriate jurisdiction and venue as provided by § 2-4- 702(2)(a), MCA because the DPHHS conducts business in Ravalli County and at least one of the Petitioners’ affected businesses is located in Ravalli County.

7. For these reasons, as explained in greater detail below, the Court should temporarily preliminarily enjoin enforcement of the Emergency Rules pending a determination on this Petition and should ultimately enter a declaratory judgment and permanent injunction that the Emergency Rules are *ultra vires*, void, and unenforceable.

PETITIONERS

8. Petitioner, Montana Smoke Free Association (“MSFA”) is a Montana not-for-profit corporation. MSFA is a trade association whose more than twenty members throughout the State of Montana are dedicated to developing and selling high quality open system ENDS products that provide adult consumers with a safer alternative to traditional combustible cigarettes. MSFA’s members include open system ENDS product manufacturers and brick-and-mortar retailers. MSFA and its members are committed to the concept of tobacco harm reduction through the use of ENDS products by adult consumers while seeking to ensure that ENDS products are marketed towards adults only and are not accessible to minors.

9. In its role as the Montana state open system ENDS product trade association, MSFA has a vital interest in ensuring that any regulation of ENDS products imposed by the DPHHS is consistent with state constitutional and administrative law requirements.

10. MSFA has standing to bring this suit because: (a) its members would otherwise have standing to sue in their own right; (b) the interests that MSFA seeks to protect are germane to the organization’s purpose of ensuring the continued availability in Montana of high quality flavored ENDS products to adult consumers that are former smokers; and (c) neither the claims asserted nor the relief requested require the participation of individual members in the lawsuit. *E.g., New Hope Lutheran Ministry v. Faith Lutheran Church of Great Falls, Inc.*, 374 Mont. 229, 236, 328 P.3d 586, 593 (Mont. 2014); *United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552-57 (1996).

11. Freedom Vapes is a Montana limited liability company having its principal office in Hamilton, Montana. Freedom Vapes also owns and operates three (3) bricks-and-mortar open system ENDS product retail stores in Hamilton, Montana, Bozeman, Montana and Belgrade,

Montana.

12. Petitioner, Liberty Smoke, LLC, d/b/a Liberty Vapor (“Liberty Vapor”) is a Montana corporation having its principal office in Missoula, Montana. Liberty Vapes also owns and operates a bricks-and-mortar open system ENDS product retail store located in Missoula, Montana.

13. Petitioner, Ublaze Vapor, LLC. (“Ublaze Vapor”) is a Wyoming limited liability company authorized to conduct business in Montana. Ublaze Vapor owns and operates a bricks-and-mortar open system ENDS product retail store located in Billing, Montana.

14. Freedom Vapes, Liberty Vapor and Ublaze Vapor utilize age identification protocols in the operation of its retail businesses as a condition of customers entering their stores and as a condition of consummating a purchase of any ENDS products. As such, the ENDS product retail businesses owned and operated by the Petitioners are adult-only establishments as they do not admit or serve anyone under the legal age to purchase and consumer ENDS products.

15. MSFA and its member retail stores, including Freedom Vapes, Liberty Vapor and Ublaze Vapor, also have the distinction of not ever having been cited for failing to properly age-identify customers or selling ENDS products to minors.

RESPONDENTS

16. DPHHS is an executive agency of Montana state government as defined under §§ 2-3-102(1) and 2-4-102, MCA. DPHHS has its principal office located at 111 North Sanders, Room 301, Helena MT 59620.

17. The Director is the Director of the DPHHS. The Director has her principal office located at 111 North Sanders, Room 301, Helena MT 59620.

18. Respondent, Stephen C. Bullock (“Governor”) is the Governor of the State of

Montana and as such is the head of the Executive Branch of the Government of the State of Montana. In his official capacity, the Governor is charged with the implementation and enforcement of the challenged provisions of the Temporary Emergency Rules, and DPHHS acted on the Governor's directive in adopting the Temporary Emergency Rules.

19. The Respondents are acting, and have acted, under color of state law with respect to the enactment, enforcement and/or supervision of the enforcement of the provisions of the Emergency Regulation challenged herein by the Petitioners.

ENDS (E-VAPOR) PRODUCTS

20. The Petitioners all operate business enterprises which manufacture and/or sell ENDS products and related products associated with the open system market segment, as described below, including flavored e-liquid ENDS products.

21. ENDS products represent a technology which has been marketed and sold in the United States since approximately 2009. ENDS products are not traditional cigarettes, as they do not use tobacco and there is no combustion or smoke emitted as a result of their use and consumption.

22. Rather, ENDS products produce an aerosolized vapor which is created when a lithium battery activates a heating coil (called an atomizer) which in turn results in the vaporization of an e-liquid solution. ENDS products have the same purpose and functional utility – they allow the user to inhale the aerosolized vapor through a mouthpiece (called “vaping”), with the aerosol providing a flavor and physical sensation to the consumer similar to that of smoking a cigarette.

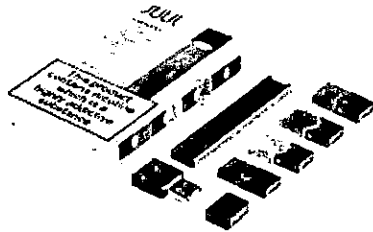
23. The stakeholders in the ENDS products industry have segregated themselves into two distinctive market segments: the “open system” segment and “closed system” segment.

24. The ENDS products purveyed in the closed system market segment contain a small

rechargeable lithium battery that produces a relatively low amount of vapor, and a small, built-in cartridge holding pre-filled and disposable e-liquid cartridges or pods.

25. The closed system ENDS cartridges and pods generally only offer a limited variety of flavor choices. Closed system ENDS products generally require e-liquids which contain a high concentration of nicotine, measured in milligrams per milliliter. This is the case because the batteries used in the products generate a low capacity of power thus requiring e-liquids with a higher nicotine concentration in order to provide a satisfactory consumer experience. Thus, it is common that closed system e-liquid cartridges and pods to contain nicotine concentrations as high as 50 mg/ml, a quantity equivalent to the total nicotine contained in a pack of cigarettes.

26. The following are examples of closed system ENDS products:



27. Simply stated, the closed system ENDS products are akin to one-size-fits-all products which allow consumers little, if any, customization options.

28. In general, closed system ENDS products have been manufactured and distributed by legacy tobacco companies such as Altria Group (*MarkTen*® brand),¹ Reynolds American (*VUSE*® brand), and Imperial Brands (*Blu*® brand). The most popular closed system ENDS product, by market share, is the *Juul*® brand which manufactured and distributed by Juul Labs,

¹ Altria discontinued the manufacture of the *MarkTen*® brand in late 2018.

Inc. In late 2018, legacy tobacco company Altria Group purchased a 35% share of Juul Labs, Inc. for approximately \$13 billion dollars.

29. The products purveyed in the closed system market segment comprise approximately fifty-eight percent (58%) of the total ENDS products market in the United States.²

30. On the other hand, open system ENDS devices are somewhat larger in size than their closed system counterparts and utilize: (a) a higher-powered rechargeable lithium battery, either replaceable or self-contained within the device, than their closed system counterparts and (2) an interchangeable and refillable e-liquid tank. When used in conjunction with each other, these two elements allow open system ENDS devices to produce relatively more vapor than closed system ENDS devices.

31. The following are examples of open system ENDS devices:



and the following are examples of open system ENDS e-liquids:

² 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).



32. Because open system ENDS products generate a greater quantity of power *vis-à-vis* closed system products, they generally require e-liquids which contain a significantly lower concentration of nicotine. Typically, open system e-liquid products contain nicotine in varying concentrations at 3 mg/ml increments ranging from 0 mg/ml to 12 mg/ml.

33. Open system ENDS products exist because of the ingenuity of former consumers of the early generations of closed system ENDS product who sought a better vaping experience. The birth and growth of the open system ENDS products market can be traced to a grassroots movement by the consumers who were dissatisfied by the low device power and the poor quality of e-liquids available in early closed system products. This movement resulted in the development of open system ENDS devices, components and e-liquids designed for use in such devices.

34. These consumers designed and produced competing open system ENDS devices which utilized a more enhanced technology calculated to generate more device power. These open system ENDS devices utilize larger, sometimes multiple, re-chargeable lithium batteries, contain computer chips which allow consumers to independently regulate both the thermal and wattage parameters of their devices and allow consumers to utilize larger atomizers. The result of these technological advances has allowed open system ENDS product consumers to customize their devices to their particular personal preferences.

35. In conjunction with the advent of open system ENDS devices, consumers began experimenting with creating new and better quality e-liquid products for their personal use. The result of this experimentation has been an abundance of thousands of open system ENDS product e-liquid brands and flavors. If an open-system ENDS product consumer has a particular flavor or taste preference, there is likely an e-liquid to satisfy such preference.

36. The e-liquid products used in both closed system ENDS products and open system ENDS products are manufactured using a mixture of three or four primary ingredients – vegetable glycerin, propylene glycol, flavorings, and liquid nicotine. The purpose of propylene glycol and vegetable glycerin, the base e-liquid ingredients, is mainly to act as a carrier for other ingredients and to produce visible vaporized aerosol when evaporated.³ The flavorings in e-liquids are the same flavoring agents used in foods or tobacco products, with numerous e-liquid flavors marketed today. The e-liquid products manufactured for use in both closed system ENDS devices and open system ENDS devices do not contain marijuana, THC, or Vitamin E Acetate.

37. The similarities between the e-liquids used in the closed system ENDS products and open system ENDS products end there. This is the case because closed system ENDS products and open system ENDS products utilize a completely different technology with respect to the manner in which e-liquids are delivered and consumed.

38. Closed system e-liquids like those depicted in Paragraph 26 above utilize sealed and pre-filled pods or cartridges which are designed to be discarded and replaced upon consumption. Closed system e-liquid products are generally limited to approximately less than twenty (20) flavor options and are available only in high nicotine concentrations of a single

³ Propylene glycol and vegetable glycerin are classified by the United States Food and Drug Administration (“FDA”) and the Flavor and Extracts Manufacturer Association (“FEMA”) as additives that are “Generally Recognized As Safe” (“GRAS”) for use in food.

quantity or two quantities.

39. Further, it is also common that the e-liquids used in closed system cartridges and pods contain benzoic acid as an additional ingredient in order to enhance the speed and intensity of the body's uptake of nicotine.

40. Open system e-liquid products as depicted in Paragraph 31 above, on the other hand, are manufactured and sold in bottles of varying sizes (typically in 30ml, 60ml, 90ml or 120ml bottles) and are offered in virtually thousands of flavors.

HEALTH BENEFITS OF ENDS PRODUCTS

41. Not surprisingly, the rise in popularity of ENDS products has resulted in a closely corresponding reduction in the consumption and use of traditional combustible tobacco products in the United States. In fact, both the adult and youth smoking rates in the United States are at all-time lows.⁴

42. A large and growing body of scientific evidence indicates that ENDS products, while not completely harmless, do not pose the same harms and health risks, and are substantially less harmful, than traditional combustible tobacco products. This is due in part to the fact that the e-liquids used in ENDS products do not contain tobacco and do not result a combustion process which produces smoke and the numerous harmful by-products, like the emission of particulate matter (tar) and many other carcinogens and harmful substances.⁵

43. Research further suggests that e-liquids and the resulting aerosol vapor emitted from the ENDS devices do not expose the users, or those in close proximity, to the emission of the

⁴ See Smoking rate in US 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 October 10, 2019).

⁵ 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-theevidence/2017/dec/29/e-cigarettes-vaping-safer-than-smoking>> (accessed October 10, 2019).

numerous toxic chemicals found in the smoke of combustible tobacco. As a result, the use of these non-combustible ENDS products is safer than combustible tobacco as a means of nicotine delivery. This is expected to result in a vast reduction in tobacco-related disease and death over time.⁶

44. Moreover, there is considerable evidence that the overwhelming majority of consumers of ENDS products in the United States, commonly identified as “vapers,” are now former cigarette smokers who have turned to the several generations of ENDS products as a smoke-free alternative to reduce or outright quit smoking, and to avoid the significant health hazards associated with combustible tobacco products.⁷

45. In 2018, the National Academies of Science, Engineering and Medicine completed an exhaustive review of the peer-reviewed literature on ENDS products. Such study concluded, in pertinent part, from such literature 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.”⁸

46. A further review of relevant science completed in 2019 concluded the existence of growing evidence showing that ENDS product emission aerosols are relatively safe compared to combustible tobacco smoke.⁹

⁶ 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-cigarettesand-the-precautionary-principle/>> (accessed October 10, 2019).

⁷ 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 October 10, 2019).

⁸ 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 October 10, 2019).

⁹ 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 October 10, 2019).

47. Mitchell Zeller, the Director of the Center for Tobacco Products at the Food and Drug Administration (“FDA”), recently acknowledged in sworn testimony in a federal court proceeding that some ENDS products may reduce harm and help some addicted smokers end combustible tobacco use. Director Zeller further noted in his sworn testimony that “[d]ramatically and precipitously reducing availability of [vapor] products” in the fashion embodied in the Emergency Regulation “could present a serious risk that adults, especially former smokers, who currently use [ENDS] products and are addicted to nicotine would migrate to combustible tobacco products”¹⁰

48. Public health authorities around the world have come to similar conclusions. In April 2016, the British Royal College of Physicians (“RCP”), the world’s oldest professional medical society, authored and issued a report (the “RCP Report”) lauding the benefits of ENDS products as safer alternatives to combustible tobacco. The RCP Report summarized the science, public policy, regulation, and ethical issues related to ENDS products and concluded that utilizing such products is not a “gateway” to smoking. On the contrary, the RCP Report concluded that “the available evidence indicated that [ENDS products] 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.”¹¹

49. Specifically, the RCP Report estimated that ENDS products are only 5% as harmful as combustible tobacco products and that the long-term effects of nicotine from aerosolized vapor

¹⁰ Declaration of Mitchell Zeller, *American Academy of Pediatrics v Food and Drug Admin*, No 8:18-cv-00883-PWG (D. Md. 2019) at 115, available at <<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Zeller%20Declaration%2C%206-12-19.pdf>> (accessed October 10, 2019).

¹¹ 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 October 10, 2019).

are likely to be minimal. This estimate corresponds with the conclusions of Public Health England, Great Britain's analog to the FDA, which determined that ENDS products are at least 95% less harmful than combustible tobacco products.¹²

50. Both the RCP Report and Public Health England study show that a growing number of scientific and public health experts in the United States and around the world agree that the use of ENDS products is significantly less harmful than smoking combustible tobacco products and a valuable tool for tobacco harm reduction efforts for adult tobacco users.

FEDERAL REGULATION OF ENDS PRODUCTS

51. The Family Smoking Prevention and Tobacco Control Act of 2009 (the "TCA") initially charged the FDA with regulating "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." In addition, provided in the TCA that it was delegating authority to the FDA to regulate "any other tobacco products that [the FDA] by regulation deems to be subject to this chapter."¹³

52. The FDA first began regulating ENDS products in the same manner as traditional tobacco products (*e.g.*, cigarettes) in May 2016 upon the publication of what is colloquially known as the "Deeming Rule"¹⁴ to be effective on August 8, 2016 with respect to ENDS products that

¹² *Id.*

¹³ 21 USC § 387a(b).

¹⁴ The constitutionality of Congress' delegation of deeming authority to the FDA is presently at issue in *Big Time Vapes, Inc. vs. Food and Drug Admin*, No 1:19-cv-00531-HSO-JCG (D. Miss. 2019) [separation of powers grounds]. The constitutionality of the manner in which the FDA implemented the Deeming Rule is also presently at issue in *Mooce Juice vs. Food and Drug Admin*, No. 18-cv-00203-CRC (D.D.C. 2018) [Appointments Clause grounds].

contain or are intended to be used with tobacco-derived ingredients such as nicotine.¹⁵

53. Because of the Deeming Rule, all ENDS products are now subject to, among other regulations:

- a. Prohibitions on the sale of adulterated or contaminated tobacco products;¹⁶
- b. Prohibitions on the sale of misbranded tobacco products;¹⁷
- c. Requirements that manufacturers submit health information (*e.g.*, health studies, ingredient reports) regarding each tobacco product;¹⁸
- d. Requirements that manufacturers register their production facilities with the FDA;¹⁹
- e. Restrictions on advertising the sale and distribution of tobacco products;²⁰
- f. Promulgated good manufacturing practices;²¹
- g. Tobacco product standards (*e.g.*, flavor restrictions) adopted through notice-and-comment rulemaking;²²
- h. Requirements that manufacturers establish and maintain records;²³ and
- i. Prohibitions on manufacturers and retailers distributing free samples of tobacco products, except free samples of smokeless tobacco (*i.e.*, chewing

¹⁵ 81 Fed Reg at 28,975.

¹⁶ 21 USC § 387b.

¹⁷ 21 USC § 387c.

¹⁸ 21 USC § 387d.

¹⁹ 21 USC § 387e.

²⁰ 21 USC § 387f(d).

²¹ 21 USC § 387f(e).

²² 21 USC § 387g(a).

²³ 21 USC § 387(i).

tobacco), which may be distributed in “qualified adult-only facilities.”²⁴

54. As a result of the Deeming Rule, ENDS product manufacturers must submit substantial information to the FDA. Such information includes scientific research findings on the ability of ENDS products to reduce risk or exposure, data and information on how consumers actually use the products, and post-market surveillance studies. The ENDS product manufacturers must also demonstrate to the FDA that there is a significant reduction in risk of tobacco-related disease and the FDA must also take into account, on a population level, the health benefit to users of tobacco products and those who do not use such products (the “public health benefit” standard).²⁵

55. The TCA also requires the manufacturer of any “new tobacco product” to obtain pre-market authorization prior to commercial sale. The TCA defines a “new tobacco product” as, in part, “any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007” (the Grandfather Date).²⁶ Any tobacco product that was on the market in the United States as of the Grandfather Date is exempt from the pre-market review requirements.²⁷

56. There are no grandfathered ENDS products, and the entire product category is considered “new” and thus subject to the FDA premarket review requirements set forth in the TCA. 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 for a period of time before premarket applications were due.

²⁴ 21 USC § 387a-1(a).

²⁵ 21 USC § 387k.

²⁶ 21 U.S.C. § 387j.

²⁷ 21 USC §§ 387eG), 387j(a).

57. The FDA has shifted the premarket application deadline for deemed products numerous times since August 2016 and the deadline is currently set for May 11, 2020.²⁸

58. The FDA has explicitly permitted the marketing of flavored vaped ENDS products, as a “special rule” in the TCA prohibiting characterizing flavors other than tobacco and menthol as only applying to cigarettes.²⁹ In March 2018, the FDA published an Advanced Notice of Proposed Rulemaking, 83 Fed Reg 12994 (Mar. 21, 2018), which solicited the submission of studies, information and public comments regarding the role of flavors in tobacco products, including ENDS 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 ENDS products established by the Maryland District Court.³⁰

59. Beyond the FDA, ENDS products are also subject to a number of federal regulatory requirements including, among other things, child-resistant packaging under the Child Nicotine Poison Prevention Act, as administered by the Consumer Product Safety Commission, numerous environmental and hazardous waste disposal laws, as well as false and misleading advertising and

²⁸ The May 11, 2020 compliance deadline was judicially-established in *American Academy of Pediatrics v Food and Drug Admin*, No. 8:18-cv-00883-PWG (D. Md. 2019). Therein, the Maryland District Court, *J. Grimm*, ruled the FDA violated the Administrative Procedures Act in August 2017 when it adjusted the compliance deadlines applicable to ENDS products by way of guidance documents instead of a public and formal comment process. Further, an additional challenge to the manner in which the FDA has promulgated guidance and regulations for implementation of the pre-market tobacco applications for ENDS products are presently at issue in *Vapor Technology Association vs. Food and Drug Admin*, No. 5:19-cv-00330-KKC (E.D. Ky. 2019).

²⁹ 21 USC § 387g(a)(1)(A).

³⁰ 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/newsevents/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-useplan-clear-market-unauthorized-non>> (accessed October 10, 2019).

marketing restrictions under Section 5 of the Federal Trade Commission Act.³¹

MONTANA STATE REGULATION OF ENDS PRODUCTS

60. The regulation of ENDS products in Montana is governed by § 16-11 Part 3, MCA. Differing from the federal classification, the Montana Legislature has classified ENDS products distinctly from traditional combustible tobacco products. For instance, § 16-11-302(6)(a), MCA defines the term “tobacco product” as being “a substance intended for human consumption that contains tobacco.” In turn, § 16-11-303(7)(a), MCA separately defines “vapor product” as being:

“a noncombustible product that may contain nicotine and that uses a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from a solution or other substance.”

An ENDS product would be considered a “vapor product” based upon the definition found in § 16-11-303(7)(a), MCA.

61. § 16-11-303, MCA requires that all ENDS product retailers obtain a license from the Montana Department of Revenue.

62. § 16-11-305 prohibits ENDS retailers from selling ENDS products to person under 18 years of age.

63. § 16-11-304 mandates that ENDS product retailers must conspicuously a sign which states: “Montana law prohibits the sale of tobacco products, alternative nicotine products, and vapor products to persons under 18 years of age.”

64. In recent years, the Montana Legislature has undertaken a robust debate in considering several proposed bills to impose additional prohibitions on the sale of ENDS products,

³¹ 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/newsevents/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-useplan-clear-market-unauthorized-non>> (accessed October 10, 2019).

but none of those bills have become law and a number of never advanced beyond a committee hearing.³² Thus, the Montana Legislature, in its collective wisdom, elected to endorse the controls embodied in existing laws thereby allowing continued sales of flavored e-liquid ENDS products to customers over the such age with proper identification.

ENDS DISTRIBUTION AND RETAIL CHANNELS

65. Closed system ENDS products, which presently occupy approximately fifty-eight percent (58%) of the total United States market, are typically distributed and sold through established general retail channels where consumers tend to buy cigarettes and other combustible tobacco products, like gas stations, convenience stores, groceries and pharmacies.

66. Accordingly, closed system ENDS product manufacturers generally either utilize direct distribution to national chain retailers or through existing tobacco distributors.

67. On the other hand, the advent of the open system ENDS products led to the establishment of wholesale distribution businesses and independently owned brick-and-mortar retail stores, such as Freedom Vapes, Liberty Vapor and Ublaze Vapor, colloquially known as “vape shops”. This is the case because those consumers using the early versions of open system ENDS products saw the existence of new business opportunities as the open system segment grew and expanded.

68. Open system ENDS product wholesale distributors have contractual relationships with manufacturers and typically supply ENDS products to multiple vape shops either regionally or nationally. This enables open system ENDS product manufacturers to have ready access to a wide number of retail customers throughout the United States or the world.

69. In turn, vape shops serve as a social hub where ENDS product consumers not only

³² 2017 Senate Bill 147; 2019 Senate Bill 122 and 2019 House Bill 653.

purchase open system ENDS devices and e-liquids, but also seek advice and guidance on using this emerging technology. It is common that employees of vape shops are themselves ENDS product consumers who are well-versed in the many facets of the technology.

70. It is verily believed that presently more than 10,000 brick-and-mortar vape shops operate across the United States,³³ with at least 20 of these retail stores operating in Montana. These domestic vape shops are predominately owned by Montana residents, employ Montana residents and serve Montana consumers.

71. Montana ENDS product consumers have benefited from the growth of the vaping industry, as scientific studies indicate that ENDS products do not pose the same health risks as traditional cigarettes and are substantially less harmful.

72. As such, scientific studies show that ENDS products can serve the purpose as tobacco harm reduction products that help consumers avoid the significant health hazards associated with combustible tobacco products. Indeed, recent survey results show that smokers largely turn to ENDS products to improve their health, with the primary goal by reducing or ultimately ceasing their smoking habit.

ENDS RETAIL CUSTOMERS

73. It is estimated that approximately 10 million American adults presently use ENDS products,³⁴ and this number has continued to grow as annual smoking rates among American adults has fallen. To this point, approximately 3.8 million Americans have stopped the use of all tobacco because of ENDS products.

³³ See The Value of Vapor, Guerilla Economics, available at <<http://vta.guerrillaeconomics.net/>> (accessed October 10, 2019).

³⁴ See Mirbolouk, *et al*, *Prevalence and Distribution of E-Cigarette Use Among US 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 October 10, 2019).

74. It is further estimated that approximately 75,000 Montanans presently use ENDS products, with many having stopped the use of all tobacco because of ENDS products.

75. Many ENDS product consumers have previously made multiple unsuccessful attempts to stop smoking, including attempts utilizing FDA-approved smoking cessation drugs and other smoking cessation programs. For many smokers, ENDS products have proven to be their last option and the only means of attaining a successful smoking cessation experience.

ROLE OF FLAVORED ENDS PRODUCTS

76. Numerous published studies highlight the important role which flavored ENDS products play in the success of tobacco harm reduction. An extensive online survey of 20,836 American adults who use ENDS products found that cigarette smokers who, switch to ENDS products are doing so increasingly with a variety of fruit and other non-tobacco flavors.³⁵ These results were buttressed by another more expansive survey of more than 69,000 adult ENDS consumers, which similarly found that the vast majority (more than 85%) preferred fruit and dessert flavored ENDS products compared to tobacco and menthol.³⁶

77. The flavors available in e-liquid ENDS products are therefore crucial to helping adult smokers eschew combustible tobacco products.³⁷ The ability of adult consumers to use non-

³⁵ 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 October 10, 2019).

³⁶ See Konstantinos Farsalinos, *Submitting to the FDA the Findings of the Largest Ever Survey on E-Cigarette Flavors Use by US Vapers*, E-Cigarette Research: Blog (August 11, 2018), <<http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav>> (accessed October 10, 2019).

³⁷ 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-ecigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/#95fb8a48fc1e>> (accessed October 10, 2019).

tobacco flavors is what drove the development of these many flavored ENDS products by early industry entrepreneurs. ENDS products were in fact invented by adult smokers for adult smokers who were looking for less harmful products that did not smell or taste like traditional combustible tobacco products.³⁸ Adult ENDS product consumers overwhelmingly report that non-tobacco flavored ENDS products and flavor variability in ENDS products matter to them and help keep them off combustible tobacco products.³⁹

78. Non-tobacco flavors have been shown to help adult smokers disassociate their habit and nicotine addiction with the tobacco and smoke flavors associated with combustible tobacco products. While some adult smokers may initially try an accustomed to tobacco flavored ENDS product to mimic combustible tobacco, the availability of multiple flavored e-liquid product choices is the factor that keeps them from reverting back to using combustible tobacco products, particularly as their taste and olfactory senses return after years of smoking.⁴⁰ If *only* tobacco flavored e-liquid products were permitted, adult 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.

79. In 2018, researchers studying the impact of ENDS products use on preventing

³⁸ See SFATA Letter to FDA CTP Director, Mitch Zeller, dated February 11, 2009, available at <https://www.khlaw.com/Files/38993_SFATA%20Response%20to%20January%202023,%202019%20CTP%20Meeting.pdf> (accessed October 10, 2019).

³⁹ 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 October 10, 2019).

⁴⁰ 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 October 10, 2019).

smoking relapse interviewed dozens of adult ENDS product users 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 ENDS products in an attempt to quit smoking.⁴¹ These researchers found that ENDS 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 ENDS products, were an important and pleasurable aspect.

80. Moreover, the availability of flavored e-liquid ENDS products may not be the predominant factor underlying the recent increase in youth experimentation. The sudden surge in past-30-day use in minors observed in 2018 and continuing into 2019 did not coincide with the introduction of flavored ENDS products into the marketplace,⁴² but instead with the introduction

⁴¹ 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 October 10, 2019).

⁴² 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 October 10, 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 one 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-smoking-20190921.html?outputType=amp&_twitter_impression=true> (accessed October 10, 2019).

of high-concentration nicotine-salt based “pod-system” ENDS products (like the Juul)⁴³ which gained access to the convenience store distribution network normally reserved for legacy tobacco products.⁴⁴ Data in Montana verifies this as only 7% of the students surveyed for the 2019 Montana Youth Risk Behavior Survey cited flavors as their reason for using ENDS products.⁴⁵

81. The FDA has itself suggested that “open-tank” (*i.e.* open system) ENDS products are *not* the source of rising underage use.⁴⁶ Open system products are primarily sold in independent adult-only vape shops, rather than in the non-adult-only convenience stores, pharmacies and gas stations where closed system ENDS products are traditionally marketed and sold. It is therefore not surprising that these closed system ENDS product retailers represent the majority of the FDA retailer warning letters, civil monetary fines and No Tobacco Sale Orders for illegal sales to minors.⁴⁷

⁴³ While Juul is available in a handful of non-tobacco and non-menthol flavored pods, what is unique about three-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/juulnicotine-hit-may-be-worst-for-kids-best-for-smokers/27293019?fbclid=IwAR0xF2TgLNHUB2DZDIY30gJ0whezaREGoRMXjWg4cJ9vwpoPHpT4uwVV4k>> (accessed October 10, 2019).

⁴⁴ 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.

⁴⁵ https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/2019_MT_YRBS_FullReport.pdf?ver=2019-08-23-083248-820

⁴⁶ U.S. Food and Drug Administration, Statement from FDA Commissioner Scott Gotlieb, MD., on new steps to address epidemic of youth e-cigarette use, (September 12, 2018) <<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>> (accessed October 10, 2019).

⁴⁷ 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 October 10, 2019).

82. The FDA's suggestion is supported by data from its national compliance checks of tobacco product retailers since inception of the Deeming Rule in August 2016. In Montana, for example, the FDA data since August 2016 evidences the agency has issued 47 total citations for the sale of ENDS products to minors. Of these total violations, 44 were issued to non-vape stores (93.6%), a vast majority of which were convenience stores or general merchandise retailers. Of these violations, 37 related to the sale of closed system ENDS products (78.7%).

POPULATION BENEFITS AND YOUTH CONCERNS

83. The national adult smoking rate was approximately 19.8% at the time ENDS products were first marketed in the United States more than a decade ago. Since then, the national adult smoking rate has continued to fall dramatically to an all-time low of 14% by 2018.⁴⁸ The recent 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 ENDS products.⁴⁹

84. The World Health Organization has estimated that 1 billion people will die worldwide from tobacco-related illnesses in the 21st Century.⁵⁰

85. A Georgetown University study determined that switching from traditional cigarettes to ENDS products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the United States alone.⁵¹ Thus, lives have been saved, and are being saved, both

⁴⁸ See Smoking rate in US 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 October 10, 2019).

⁴⁹ 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 October 10, 2019).

⁵⁰ *World Health Organization -Tobacco Fact Sheet*. World Health Organization. June 2016. Retrieved August 4, 2016.

⁵¹ 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 October 10, 2019).

around the world over the past decade as well as in Montana as a result of cigarette smokers switching to ENDS products.

86. Montana currently has a smoking rate (18%) higher than the national average as approximately 149,900 adult Montanans still smoke cigarettes⁵² resulting in approximately 1,600 annual deaths.⁵³ Thus, it is cigarette smoking-not flavored vapor products-that poses a public health crisis in Montana.

HEALTH PROBLEMS ERRONEOUSLY ATTRIBUTED TO ENDS PRODUCTS

87. Prior to the summer of 2019, ENDS products had been available to United States consumers for approximately a decade. During the time, the Petitioners verily assert there had not been a single death in the United States attributable to adverse health problems resulting from the use of ENDS products.

88. Beginning in the summer of 2019, numerous media reports began circulating that individuals across the United States who vaped were suffering from severe pulmonary issues, colloquially termed as “vaping related” illnesses.

89. While federal and state health officials initially cast blame upon ENDS products, subsequent investigation and testing of the suspected products used by these individuals revealed that most likely the result of the severe pulmonary issues was the illicit addition of delta-9

⁵² Campaign for Tobacco Free Kids, The Toll of Tobacco in Montana <<https://www.tobaccofreekids.org/problem/toll-us/montana>> (accessed October 10, 2019).

⁵³ *Id.*

tetrahydrocannabinol (THC) and/or marijuana.⁵⁴

90. Neither THC and/or marijuana are included as ingredients of any ENDS product permitted for retail sale in the United State under federal law, and are not included as ingredients in any products sold by the Petitioners. Nevertheless, it is believed that some consumers add their own aftermarket oils to ENDS products, including THC and/or marijuana.⁵⁵

91. The illegal vapor cartridges that contain THC and/or marijuana 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.⁵⁶ It is further believed by the Petitioners that the manufacturers of the illegal vapor cartridges do not process the THC oils after extraction from the marijuana plant in order to remove any impurities. Accordingly, the THC oils used in these illegal vapor cartridges may contain certain residual amounts of toxic pesticides, fungicides and/or other substances sprayed upon the marijuana plants from which they are derived.⁵⁷ Perhaps this explains why illegal THC cartridges are sold at a price point significantly less than the THC cartridges sold legally in dispensaries in the states which have legalized medicinal and/or recreational use.

92. The manufacture and sale of these aftermarket THC and/or marijuana oils are

⁵⁴ 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 27, 2019).

⁵⁵ 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 October 10, 2019).

⁵⁶ 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 October 10, 2019).

⁵⁷ CBS News investigates the THC vaping industry's booming black market. <https://www.cbsnews.com/news/vaping-inside-booming-black-market-cbs-news-investigates-2019-10-09/> (accessed October 10, 2019).

illegal under federal law as well as the laws of many states. As such, consumers are purchasing them on the black market and are not available for sale at regulated vapor shops.⁵⁸

93. In most cases of reported pulmonary illnesses, health authorities have found vitamin E acetate residue in the patients' lungs. As recently as several weeks ago, scientific thinking was that the vitamin E acetate and other oils contained in these illegal products might not completely transform into vapor when heated, and instead travel into the user's lungs thus causing pulmonary disorders.⁵⁹

THE EMERGENCY RULES

94. The DPHHS, upon the initiative of Governor Bullock, adopted the Emergency Rules on October 8, 2019. By their terms, the Emergency Rules became effective upon filing with the Montana Secretary of State. The DPHHS, however, has intimated its intention to delay enforcement of the Emergency Rules until October 22, 2019.

95. The DPHHS predicates the Emergency Rules upon "the concurrent epidemic of youth e-cigarette or vapor products use ("vaping") and the emerging outbreak of lung injury and death associated with vaping." With respect to youth use of ENDS products, the DPHHS notes that it seeks to ban "the flavored, youth-targeted products that have been identified as a primary draw to vaping" but points to no studies or research which validate the proposition that flavored ENDS products in general are "youth-targeted" or that any of the specific open system flavored e-liquid ENDS products sold by the Petitioners are "youth targeted". As to the outbreak of lung

⁵⁸ 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-blackmarket-thc-no-regulation/2209009001/>> (accessed October 10, 2019).

⁵⁹ *Id.*

injuries, the DPHHS, however, does not corollate in the Emergency Rules how, or if, flavored e-liquid ENDS products in general or open system flavored e-liquid ENDS products specifically contribute to the perpetuation of such lung injuries.

96. In Emergency Rule 1, DPHHS sets forth the definition of “flavored vapor product” as being a:

“vapor product that imparts a taste or smell other than the taste or smell of tobacco or marijuana. This includes but is not limited to menthol, mint, wintergreen, fruit, chocolate, cocoa, vanilla, honey, or the taste or smell of any candy, dessert, alcoholic beverage, herb, or spice. A vapor product shall be presumed to be a flavored vapor product if a retailer, manufacturer, or a manufacturer's agent or employee has made a statement or claim directed to consumers or the public, whether expressed or implied, that the product or device has a distinguishable taste or aroma other than the taste or aroma of tobacco or marijuana.”

Emergency Rule 1 provides that such definition applies to all ENDS products, regardless of whether they do or do not contain nicotine or THC.

97. In Emergency Rule 2, DPHHS sets forth the operative prohibitions of the Emergency Rules in providing that:

(1) A person shall not sell, offer for sale, give, or otherwise distribute flavored vapor products to persons within Montana.

(2) A person shall not transport within Montana flavored vapor products intended for sale or distribution within Montana by any person.

By its terms, Emergency Rule 2 applies regardless of whether a retailer or reseller is physically located in Montana or utilizes online or other remote sale methods that are intended to deliver flavored vapor products to Montana.

98. DPHHS has intimated that it intends to enforce the Emergency Rules by the

imposition of penalties which include charging a person in violation with a misdemeanor punishable by a term of imprisonment not to exceed 90 days and a fine of up to \$500. DPHHS has further intimated that it intends to treat each day in violation of the Emergency Rules as a separate offense.

99. The Emergency Rules become effective on October 22, 2019 and continue in effect for a period of 120 days pursuant to § 2-4-402, MCA.

FIRST CAUSE OF ACTION
(Declaratory Judgment that Respondents Have Violated the Montana Administrative Procedure Act)

100. Petitioners repeat and reallege by reference each and every allegation set forth above with the same force and effect as if set forth fully herein.

101. As state agencies and actors, Respondents are subject to the requirements of the Montana Administrative Procedure Act (“MAPA”), including the notice and comment requirements imposed by § 2-4-302, MCA. Pursuant thereto, the Respondents must fulfill minimum notice-and-comment requirements, including publishing the proposed rules sufficiently in advance to allow interested parties to comment on the proposed rulemaking.

102. An exception exists, however, “[i]f an agency finds that an imminent peril to the public health, safety, or welfare requires adoption of a rule upon fewer than 30 days’ notice and states in writing its reasons for that finding, it may proceed upon special notice filed with the committee, without prior notice or hearing or upon any abbreviated notice and hearing that it finds practicable, to adopt an emergency rule.” § 2-4-303, MCA.

103. The provisions of § 2-4-303, MCA, however, embody certain safeguards, including the requirement that any declaration of an emergency must be based upon circumstances which truly and clearly constitute an existing imminent peril to the public health, safety, or welfare

and that such imminent peril cannot be averted or remedied by any other administrative act. Further, “[t]he sufficiency of the reasons justifying a finding of imminent peril and the necessity for emergency rulemaking must be compelling and, as written in the rule adoption notice, must stand on their own merits for purposes of judicial review.” § 2-4-303, MCA.

104. The DPHHS and Director purported to promulgate the Emergency Rules pursuant to § 2-4-303, MCA, under the pretense that an emergency existed based upon a “concurrent epidemic of youth e-cigarette or vapor products use” and “the emerging outbreak of lung injury and death associated with vaping.”

105. Respondents fail to satisfy the requirements for promulgation of a temporary or emergency rule under § 2-4-303, MCA in that: (a) the circumstances articulated by the Respondents as a justification for the Emergency Rules do not constitute an “existing imminent peril” with respect to open system flavored e-liquid ENDS products and (b) the Respondents failed to consider and implement other less restrictive and onerous administrative acts, of which there were several viable options, as a means of averting or remedying the alleged existing imminent peril.

106. Based upon the facts set forth above, an actionable controversy of a justiciable nature exists between Petitioners and Respondents regarding whether Respondents’ adoption and intended implementation of the Emergency Rules constitutes a violation of the MAPA, in particular § 2-4-303, MCA, and, if so, the proper remedy therefor.

107. Respondents’ conduct is ongoing and immediate. As a result of Respondents’ actions in contravention to the statutory requirements of § 2-4-303, MCA, Petitioners will suffer immediate and irreparable harm upon enforcement of the Emergency Rules as compliance will cause them to face the Hobson’s choice of criminal penalties or significant financial losses and

business closures.

108. Petitioners have no adequate remedy at law.

SECOND CAUSE OF ACTION
(Declaratory Judgment that the Emergency Rules Are Arbitrary and Capricious As Applied to Open System Flavored E-liquid Products)

109. Petitioners repeat and reallege by reference each and every allegation set forth above with the same force and effect as if set forth fully herein.

110. An administrative regulation will be upheld under Montana law if it has a rational basis and is not unreasonable, arbitrary or capricious. Under Montana law, “[a]n agency decision is arbitrary and capricious if made without consideration of all relevant factors or based on a clearly erroneous judgment” such that the agency’s decision “must appear to be random, unreasonable or seemingly unmotivated based on the existing record.” *Bitterrooters for Planning, Inc. v. Montana Department of Environmental Quality*, 388 Mont. 453, 460, 401 P.3d 712, 718 (Mont. 2017).

111. The Emergency Rules are invalid because they do not have a rational basis, and are unreasonable, arbitrary or capricious as applied to the Petitioners and other Montana retailers of open system flavored e-liquid ENDS Products.

112. Among other things, the Emergency Rules are unlawfully arbitrary and capricious as applied to the retailers of open system flavored e-liquid ENDS products because they allow for the continued sale of combustible tobacco cigarettes, including flavored cigarettes—which are also illegally used by, and enticing to, youth—while banning a significant swath of substantially less harmful flavored e-liquid ENDS products.

113. The National Academies of Science, Engineering, and Medicine have found that “across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes,” and that there is “conclusive evidence that completely

substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.”⁶⁰ Nevertheless, the Emergency Rules do not purport to ban the manufacture, possession, or sale of combustible cigarettes, including flavored cigarettes.

114. In this instance, the Emergency Rules are also unlawfully arbitrary and capricious as applied to the Petitioners and other Montana retailers of open system flavored e-liquid ENDS products because the Respondents cannot establish: (1) that any youth access and use problems relating to flavored e-liquid ENDS products are attributable to the open system flavored e-liquid ENDS products sold by the Petitioners and other Montana open system ENDS product retailers and (2) that any reported incidents of pulmonary illnesses are attributable to the open system flavored e-liquid ENDS products in general or specifically the flavored e-liquid ENDS products sold by the Petitioners.

115. The Emergency Rules are unlawfully arbitrary and capricious as applied to the Petitioners and other Montana retailers of open system flavored e-liquid ENDS products because the Respondents cannot not establish a rational basis which corollate any youth access and use problems relating to flavored e-liquid ENDS products to open system ENDS products which are sold in adult-only retail establishments in Montana, or that such youth access and use problems are attributable to flavored e-liquid ENDS products as opposed to the high nicotine content of closed system ENDS products which empirical data demonstrates are the substantial choice of youth.

116. The Emergency Rules are also unlawfully arbitrary and capricious because the

⁶⁰ 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 October 10, 2019).

Respondents further have failed to consider the effect a ban on open system flavored e-liquid ENDS products will have on adults who rely upon such products for smoking cessation. As noted by the extensive scientific evidence cited above, many adult ex-smokers rely heavily on flavored e-liquid ENDS products to break their dependence from combustible cigarettes and run a significant risk of returning to smoking when those flavors are removed from the market, thereby causing a significant detrimental impact to public health.

117. Respondents' conduct is ongoing and immediate. As a result of Respondents' *ultra vires* actions in contravention to the established separation of powers under the Montana Constitution, Petitioners will suffer immediate and irreparable harm upon enforcement of the Emergency Rules as compliance will cause them to face the Hobson's choice of criminal penalties or significant financial losses and business closures.

118. Petitioners have no adequate remedy at law.

THIRD CAUSE OF ACTION
**(Temporary, Preliminary, and Permanent Injunction Against
Enforcing the Emergency Rule)**

119. Petitioners repeat and reallege by reference each and every allegation set forth above with the same force and effect as if set forth fully herein.

120. The Court is empowered by § 27-19-315, MCA to grant a temporary restraining order if: (1) it clearly appears from specific facts shown by affidavit or by the verified complaint that a delay would cause immediate and irreparable injury to the applicant before the adverse party or the party's attorney could be heard in opposition; and (2) the applicant or the applicant's attorney certifies to the court in writing the efforts, if any, that have been made to give notice and the reasons supporting the applicant's claim that notice should not be required.

121. Further, the Court is empowered by § 27-19-201, MCA to grant a preliminary

injunction where either: “it appears that the applicant is entitled to the relief demanded and the relief or any part of the relief consists in restraining the commission or continuance of the act complained of, either for a limited period or perpetually” or “it appears that the commission or continuance of some act during the litigation would produce a great or irreparable injury to the applicant.”

122. A temporary restraining order and preliminary injunction should be granted upon a showing that: (1) the likelihood that the movant will succeed on the merits of the action; (2) the likelihood that the movant will suffer irreparable injury absent the issuance of a preliminary injunction; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party (a balancing of the equities); and (4) the injunction, if issued, would not be adverse to the public interest. *See, e.g., Van Loan v. Van Loan*, 271 Mont. 176, 895 P.2d 614 (Mont. 1995).

123. For all the reasons set forth above, and in further detail in the accompanying Memorandum of Law and supporting Affidavits, Petitioners respectfully submit that they have a strong likelihood of success on the merits of the action, will be irreparably injured absent injunctive relief, the balance of equities weigh in their favor and the public interest will not be adversely affected by the grant of injunctive relief.

124. Petitioners have no adequate remedy at law.

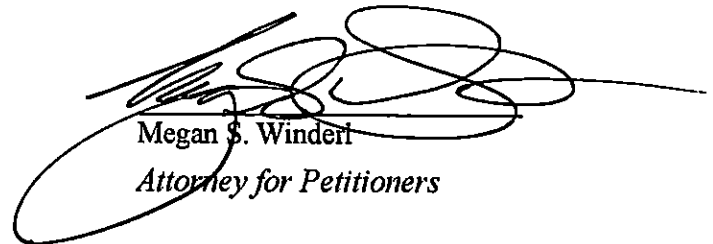
WHEREFORE, Petitioners demand the following:

- A. A declaratory judgment which determines that the Emergency Rules are:
 - a. in violation of MAPA and in particular § 2-4-303, MCA in that there does not exist a circumstance of “existing imminent peril” and the Respondents failed to consider and implement other less restrictive and onerous administrative acts; and
 - b. arbitrary and capricious as applied to the Petitioners and other Montana

retailers of open system flavored e-liquid products.

- B. Temporarily restraining Respondents from enforcing the Emergency Rules;
- C. Preliminarily and permanently enjoining Respondents from enforcing the Emergency Rules;
- D. Awarding Petitioners their costs and expenses;
- E. Awarding Petitioners their reasonable attorneys' fees as allowed by law; and
- F. Granting such further and other relief as is necessary and appropriate

DATED this 17th day of October 2019.


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MONTANA TWENTY-FIRST JUDICIAL DISTRICT COURT, RAVALLI COUNTY

<p>MONTANA SMOKEFREE ASSOCIATION, INC.; FREEDOM VAPES, LLC., LIBERTY SMOKE, INC.; AND UBLAZE VAPOR, LLC</p> <p style="text-align: center;">Plaintiffs,</p> <p>vs.</p> <p>MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; Sheila Hogan, in her official capacity as the Director of the Montana Department of Public Health and Human Services</p> <p style="text-align: center;">Respondents.</p>	<p>Cause No.</p> <p>Dept. No.</p> <p style="text-align: center;">AFFIDAVIT OF RON MARSHALL</p>
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RON MARSHALL, being duly sworn, hereby deposes and states under penalty of perjury as follows:

1. I am over the age of 18 years and have personal knowledge of the facts set forth below such that I would be competent to testify as to the same if called.

2. I am the Vice-President of the Montana Smoke Free Association ("MSFA"), the state trade association for the Montana open system Electronic Nicotine Delivery System ("ENDS") product retailers. MSFA is a Montana not-for-profit corporation whose members throughout the State of Montana are dedicated to developing and selling high quality open system

EXHIBIT 1

ENDS products that provide adult consumers with a safer alternative to traditional combustible cigarettes. MSFA's members include open system ENDS product manufacturers and brick-and-mortar retailers. MSFA and its members are committed to the concept of tobacco harm reduction through the use of ENDS products by adult consumers while seeking to ensure that ENDS products are marketed towards adults only and are not accessible to minors.

3. I am also the co-owner and the president of Freedom Vapes, LLC. ("Freedom Vapes"), a Montana limited liability company headquartered at 840 South 1st Street, Hamilton, Montana. Freedom Vapes owns and operates three ENDS product retail businesses (vape shops) located in Hamilton, Montana, Bozeman, Montana and Belgrade, Montana.

4. I am submitting this affidavit in support of Freedom Vapes' Petition for a temporary restraining order and preliminary injunction against the Temporary Emergency Rules ("Emergency Rules") adopted on October 8, 2019 by the Montana Department of Health and Human Services ("DPHHS") which impose a state-wide emergency ban on the sale of flavored e-liquids ENDS products.

5. I first smoked a cigarette when I was 16 years old and from that point proceeded to smoke two packs a day for 31 years. Like so many smokers, I was hooked on cigarettes and unable to kick the habit no matter how hard I tried despite making numerous attempts. I was blessed to be able to stop smoking cigarettes in September 2013 through the use of an ENDS product, using a peppermint menthol flavored e-liquid.

6. After my wife and I were both able to successfully stop smoking cigarettes with an ENDS product, we became highly motivated to want to help people transition to ENDS products as a less harmful alternatives to cigarettes. To further this mission, my wife and I founded Freedom Vapes in February 2014 upon the opening of the Hamilton, Montana store. Since then, we have

expanded Freedom Vapes to Bozeman and Belgrade. Presently, Freedom Vapes employs 12 Montana residents between its three stores.

7. Of the e-liquid products sold by Freedom Vapes, approximately 95% are flavored products. Presently, Freedom Vapes offers 450 flavored ENDS products for use in open system ENDS devices.

8. Freedom Vapes is an adults-only business establishment. The median age of Freedom Vapes' customers ranges from 35 to 40 depending on the store location. This is likely due to the fact that Freedom Vapes targets its marketing efforts toward long-term adult cigarette smokers. In this regard, Freedom Vapes strictly enforces an age-identification protocol at its three stores. Customers are asked to produce a government issued photo identification upon entering the store and then again at the time a purchase is made. The purpose of these protocols is to ensure that Freedom Vapes' products are not seen by children and to prevent its products, including flavored e-liquids, from falling into the hands of youth.

9. MSFA has the distinction that none of its member retail stores, including Freedom Vapes, has ever been cited by the FDA for either selling ENDS products to minors or failing to age-identify customers.

10. Freedom Vapes' customer base is composed of adults who are current and former combustible cigarette smokers. I am proud to say that every single repeat customer who has come into our store has reduced dramatically or eliminated entirely his or her nicotine consumption over time.


11. This presents a unique business model - - the business operates in a way that is designed to eventually put itself out of business by offering consumers a wide range of products with a variety of nicotine "step-down" options so that not only will those consumers not only stop

smoking combustible cigarettes, but ultimately stop using vapor products as well. To date, approximately 25% to 30% of Freedom Vapes' customers have been able to completely ween themselves off both cigarettes and ENDS products.

12. Freedom Vapes sells approximately 500 bottles of e-liquid per week. For each flavor, we offer various nicotine strengths, including zero nicotine e-liquids, so that our customers who can are able to step down and ultimately end their use of nicotine altogether. For example, the average Freedom Vapes customer uses either a flavored e-liquid containing nicotine levels of either 3 mg/ml or 6 mg/ml.

13. Freedom Vapes is very careful to ensure that the e-liquid products it sells do not include those chemical constituents, including diacetyl, which have been argued by healthcare advocates as potentially posing health risks to consumers.

14. If the flavor ban enacted by the Montana Department of Health and Human Services is not enjoined and is allowed to be enforced, Freedom Vapes will be forced to immediately close all three of its stores and lay off all its employees. In such event, my wife and I will become personally liable for the balance owed for the remaining terms of the three store leases.

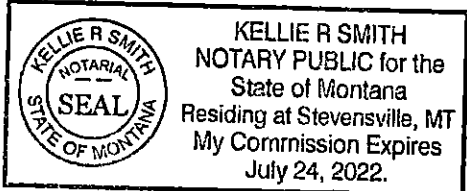

AFFIANT

Printed Name: RONALD MARSHALL

Subscribed and sworn to before me this 16th day of October 2019.



NOTARY PUBLIC



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MONTANA TWENTY-FIRST JUDICIAL DISTRICT COURT, RAVALLI COUNTY

<p>MONTANA SMOKEFREE ASSOCIATION, INC.; FREEDOM VAPES, LLC., LIBERTY SMOKE, INC.; AND UBLAZE VAPOR, LLC</p> <p style="text-align: center;">Plaintiffs,</p> <p>vs.</p> <p>MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; Sheila Hogan, in her official capacity as the Director of the Montana Department of Public Health and Human Services</p> <p style="text-align: center;">Respondents.</p>	<p>Cause No.</p> <p>Dept. No.</p> <p>AFFIDAVIT OF TOMMIE DOBBS</p>
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TOMMIE DOBBS, being duly sworn, hereby deposes and states under penalty of perjury as follows:

1. I am over the age of 18 years and have personal knowledge of the fact set forth below such that I would be competent to testify as to the same if called.

2. I am the owner and the president of Liberty Smoke, Inc., d/b/a Liberty Vapor ("Liberty Vapor"), a Montana corporation headquartered at 1609 South Avenue West, Missoula, Montana. Liberty Vapor owns and operates an ENDS product retail business (vape shop) located in Missoula, Montana.

AFFIDAVIT OF TOMMIE DOBBS

EXHIBIT 2

1

3. I am submitting this affidavit in support of Liberty Vapor's Petition for a temporary restraining order and preliminary injunction against the Temporary Emergency Rules ("Emergency Rules") adopted on October 8, 2019 by the Montana Department of Health and Human Services ("DPHHS") which impose a state-wide emergency ban on the sale of flavored e-liquids ENDS products.

4. I first smoked a cigarette when I was 15 years old and smoked one pack a day for 16 years. Like so many smokers, I was hooked on cigarettes and unable to kick the habit no matter how hard I tried.

5. I was blessed to be able to stop smoking cigarettes in 2012 through the use of an ENDS product, using a Gummy Bear flavored e-liquid.

6. After being able to successfully stop smoking with an ENDS product, I became highly motivated to want to help people transition to ENDS products as less harmful alternatives to cigarettes. To further this mission, my husband and I founded Liberty Vapor in September 2012 upon the opening of the Missoula, Montana store. Presently, Liberty Vapor employees eight Montana residents.

7. Of the e-liquid products sold by Liberty Vapor, approximately 90% are flavored products.

8. The age of Liberty Vapor's customers ranges from 25 to 75. This is likely due to the fact that Liberty Vapor targets its marketing efforts toward long-term cigarette smokers. In this regard, Liberty Vapor strictly enforces an age-identification protocol at its store. Customers are asked to produce a government issued photo identification upon entering the store and then again at the time a purchase is made. The purpose of these protocols is to ensure that Liberty Vapor's products are not seen by children and to prevent its products, including flavored e-

liquids, from falling into the hands of youth.

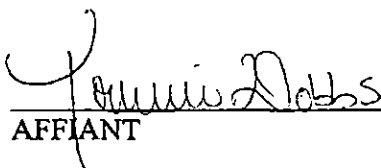
9. Liberty Vapor has the distinction of not ever having a member shop be cited by the FDA for either selling ENDS products to minors or failing to age-identify customers.

10. Liberty Vapor's customer base is composed of current and former combustible cigarette smokers. I am proud to say that every single repeat customer who has come into our store has reduced dramatically or eliminated entirely his or her nicotine consumption over time. To date, approximately 25% to 35% of Liberty Vapor's customers have been able to completely ween themselves off both cigarettes and ENDS products.

11. Liberty Vapor sells approximately 275 bottles of e-liquid per week. For each flavor, we offer various nicotine strengths, including zero nicotine e-liquids, so that our customers who can are able to step down and ultimately end their use of nicotine altogether. For example, the average Liberty Vapor customer uses a flavored e-liquid containing nicotine levels of 6 mg/ml.

12. Liberty Vapor is very careful to ensure that the e-liquid products it sells do not include those chemical constituents, including diacetyl, which have been argues by healthcare advocates as potentially posing health risks to consumers.

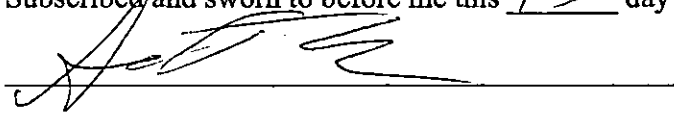
13. If the flavor ban enacted by the Montana Department of Health and Human Services is not enjoined and is allowed to be enforced, Liberty Vapor would more than likely be forced to immediately close its store and lay off all its employees. In such event, I would become personally liable for the balance owed for the remaining term of the store lease.



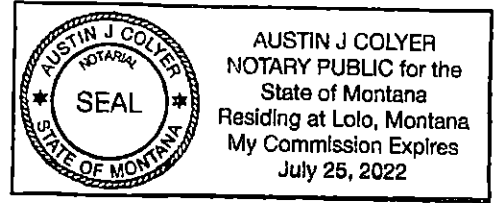
AFFIANT

Printed Name: Tammie Dobbs

Subscribed and sworn to before me this 15 day of October 2019.



NOTARY PUBLIC



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MONTANA TWENTY-FIRST JUDICIAL DISTRICT COURT, RAVALLI COUNTY

<p>MONTANA SMOKEFREE ASSOCIATION, INC.; FREEDOM VAPES, LLC., LIBERTY SMOKE, INC.; AND UBLAZE VAPOR, LLC</p> <p>Plaintiffs,</p> <p>vs.</p> <p>MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; Sheila Hogan, in her official capacity as the Director of the Montana Department of Public Health and Human Services</p> <p>Respondents.</p>	<p>Cause No.</p> <p>Dept. No.</p> <p>AFFIDAVIT OF LUCAS ANDERSON</p>
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LUCAS ANDERSON, being duly sworn, hereby deposes and states under penalty of perjury as follows:

1. I am over the age of 18 years and have personal knowledge of the fact set forth below such that I would be competent to testify as to the same if called.
2. I am the President of the Montana Smoke Free Association ("MSFA"), the state trade association for the Montana open system Electronic Nicotine Delivery System ("ENDS") product retailers. MSFA is a Montana not-for-profit corporation whose members throughout the State of Montana are dedicated to developing and selling high quality open system ENDS products

AFFIDAVIT OF LUCAS ANDERSON

EXHIBIT 3

1

that provide adult consumers with a safer alternative to traditional combustible cigarettes. MSFA's members include open system ENDS product manufacturers and brick-and-mortar retailers. MSFA and its members are committed to the concept of tobacco harm reduction through the use of ENDS products by adult consumers while seeking to ensure that ENDS products are marketed towards adults only and are not accessible to minors.

3. I am also the owner and the CEO of Ublaze Vapor, LLC. ("Ublaze Vapes"), a Wyoming limited liability company headquartered at 111 S 24th Street West, Suite 10, Billings, Montana.

4. I am submitting this affidavit in support of MSFA's and Ublaze Vapors' Petition for a temporary restraining order and preliminary injunction against the Temporary Emergency Rules ("Emergency Rules") adopted on October 8, 2019 by the Montana Department of Health and Human Services ("DPHHS") which impose a state-wide emergency ban on the sale of flavored e-liquids ENDS products.

5. ENDS devices, also known as "electronic cigarettes," "e-cigarettes," are electronic devices that are used to aerosolize a liquid mixture that typically contains nicotine (not cannabis, THC, CBD, or any other active ingredient) by heating it ("e-liquid"). Once the e-liquid is aerosolized, the user of the ENDS device inhales the aerosolized "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without the fire, flame, tar, carbon monoxide, ash, stub, or smell associated with traditional cigarettes.

6. ENDS devices are handheld technologies that typically consist of a battery, software, electronics, an atomizer (or heating element), and a fluid-filled cartridge, pod, or empty reservoir tank. In a so-called "closed system," either the device itself or interchangeable pods or cartridges intended for use with that device come pre-filled with a particular type of e-liquid. In a

so-called “open system,” the device will not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device’s e-liquid reservoir, or “tank,” with the e-liquid and nicotine level of his or her choice.

7. E-liquids are typically made with a mixture of propylene glycol and/or vegetable glycerin, flavorings, and pharmaceutical grade nicotine. E-liquids are sold to consumers in a range of nicotine concentrations and flavor combinations for both open and closed systems and in a variety of bottle sizes for use with open systems. Because e-liquids are sold in varying levels of nicotine concentrations, including zero nicotine products, users have the option to reduce their nicotine intake and/or wean themselves from nicotine entirely.

8. Today’s ENDS products and e-liquids markets contain a wide array of offerings to meet the tastes of adult consumers, the overwhelming majority of which, in my experience, are current or former cigarette smokers.

9. I first tried chewing tobacco at 13 years old and first smoked a cigarette when I was 16 years old. I used deadly traditional tobacco products most of my adult life. Like so many traditional tobacco users I was hooked.

10. I was blessed to be able to stop using traditional tobacco products in 2013 through the use of an ENDS product, using fruit flavored e-liquid.

11. After being able to successfully stop using traditional tobacco products with an ENDS product, I became highly motivated to want to help people transition to vapor products as less harmful alternative to cigarettes. To further this mission, I founded Ublaze Vapor Billings, Montana in 2014. Presently, Ublaze Vapor employs five Montana residents.

12. Of the e-liquid products sold by Ublaze Vapor, approximately 95% are flavored products.

13. The median age Ublaze Vapor's customers ranges from 35 to 45 years old. This is likely due to the fact that Ublaze Vapor targets its marketing efforts toward long-term cigarette smokers. In this regard, Ublaze Vapor strictly enforces an age-identification protocol at its store. Customers are asked to produce a government issued photo identification upon entering the store and then again at the time a purchase is made. The purpose of these protocols is to ensure that Ublaze Vapor's products are not seen by children and to prevent its products, including flavored e-liquids, from falling into the hands of youth.

14. Ublaze Vapor's customer base is composed of current and former combustible cigarette smokers. I am proud to say that every single repeat customer who has come into our store has reduced dramatically or eliminated entirely his or her nicotine consumption over time. To date, approximately 10% to 15% of Ublaze Vapor's customers have been able to completely wean themselves off both cigarettes and ENDS products.

15. Ublaze Vapor Billings location sells approximately 895 bottles of e-liquid per week. For each flavor, we offer various nicotine strengths, including zero nicotine e-liquids, so that our customers who can are able to step down and ultimately end their use of nicotine altogether. For example, the average Ublaze Vapor customer uses either a flavored e-liquid containing nicotine levels of 3 mg/ml to 24 mg/ml.

16. Ublaze Vapor is very careful to ensure that the e-liquid products it sells do not include those chemical constituents, including diacetyl, which have been argued by healthcare advocates as potentially posing health risks to consumers.

17. If the flavor ban enacted by the Montana Department of Health and Human Services is not enjoined and is allowed to be enforced, Ublaze Vapor will be forced to immediately close its store and lay off all its employees. In such event, I will become personally liable for the balance owed for the

remaining term of the store lease.

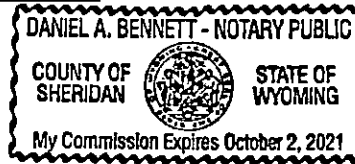
Lucas Anderson
AFFIANT

Printed Name: Lucas Anderson

Subscribed and sworn to before me this 15 day of October 2019.

Daniel A. Bennett

NOTARY PUBLIC



BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of)
Temporary Emergency Rules I)
through IV pertaining to prohibiting)
sale of flavored vapor products to)
reduce youth risk of vaping-)
associated lung injury or death)

NOTICE OF ADOPTION OF
TEMPORARY EMERGENCY RULES

TO: All Concerned Persons

1. The Montana Department of Public Health and Human Services (department) is adopting the following emergency rules in response to the concurrent epidemic of youth e-cigarette or vapor products use ("vaping") and the emerging outbreak of lung injury and death associated with vaping. The rules prohibit the sale of flavored vaping products, regardless of whether they contain nicotine or tetrahydrocannabinol (THC).

According to the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and the National Youth Tobacco Survey, national youth vaping rates increased 78 percent from 2017 to 2018. FDA, *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey> (last updated May 29, 2018). In late 2018, then FDA Commissioner Scott Gottlieb, M.D., issued a statement that was unequivocal: "I now have good reason to believe that it's reached nothing short of an epidemic proportion of growth." FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use> (last updated Sept. 12, 2018). The United States Surgeon General, Jerome Adams, M.D., repeated this alarm in December officially declaring youth vaping an epidemic and warning that action must be promptly taken to protect the health of young people. Office of the Surgeon General, *Surgeon General's Advisory on E-cigarette Use Among Youth*, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf> (last accessed Oct. 2, 2019).

Montana historically has ranked above the national average in youth vaping rates. In 2019, 58 percent of high school-aged youth reported ever trying vaping, 30 percent reported vaping in the past month, and 13 percent report frequent use (at least 20 days in the prior 30-day period). Legislative efforts such as adding vapor products to the Youth Access to Tobacco Products Control Act (Mont. Code Ann. § 16-11-301 et seq) seem to have failed to check youth vaping growth in the state. For example, the rate of high school students reporting frequent vaping has grown 243 percent since 2017. MT Office of Public Instruction, *2019 Youth Risk Behavior*

Montana Administrative Register 37-901



Survey.

[https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/2019 MT YRBS FullReport.pdf?ver=2019-08-23-083248-820](https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/2019%20MT%20YRBS%20FullReport.pdf?ver=2019-08-23-083248-820) (last accessed Oct. 2, 2019).

Research indicates that nicotine exposure occurring as a result of vaping may induce epigenetic changes that sensitize the brain to other drugs and prime it for future substance abuse. Menglu Yuan, Sarah J Cross, Sandra E Loughlin, Frances M Leslie, *Nicotine and the Adolescent Brain*, 593.16 *J Physiology*, 3397–3412 (2015). This concern is compounded by the popularity with youth of product called JUUL. Teens between 15 and 17 years old have 16 times greater odds of using JUUL than 25- to 34-year-olds. Truth Initiative, *Behind the explosive growth of JUUL*, <https://truthinitiative.org/research-resources/emerging-tobacco-products/behind-explosive-growth-juul> (posted Jan. 3, 2019). JUUL is unique in that it has one of the highest levels of nicotine of any vapor product on the market and uses nicotine salts—a chemical formulation that greatly increases the rate and amount of nicotine delivered into the blood. *Id.*

A metanalysis of 21 prior studies also recently revealed that young people who vaped were also 3.5 times more likely to use marijuana. Reuters, *Teen vaping tied to marijuana use*, <https://www.reuters.com/article/us-health-kids-smoking/teen-vaping-tied-to-marijuana-use-idUSKCN1V324S> (posted Aug. 19, 2019). Likewise, studies of the impact of THC—the psychoactive component in marijuana—on the young brain consistently show evidence of both structural brain abnormalities and altered neural activity. American Psychological Association, *Marijuana and the developing brain*, <https://www.apa.org/monitor/2015/11/marijuana-brain> (posted Nov. 2015).

Vaping products contain a liquid that may contain nicotine, THC and other cannabinoid oils, flavoring, propylene glycol, vegetable glycerin, and other ingredients. Vaping liquids may also contain chemicals such as diacetyl, formaldehyde, acrolein, acrylonitrile, propylene oxide, crotonaldehyde and acetaldehyde; as well as metals such as nickel, lead, and chromium.

The federal Centers for Disease Control and Prevention, the federal Food and Drug Administration, and state and local health departments nationally are investigating a multistate outbreak of lung injury and death associated with vaping. As of October 3, 2019, the CDC had confirmed 1080 cases across 48 states and U.S. territories, including 21 fatalities in 15 different states. The department has confirmed two cases in Montana and is tracking several potential cases.

The only commonality in all cases is a history of vaping, but victims otherwise report mixed histories of using vapor products containing THC, nicotine, or a combination of both. Cases show diverse symptoms and signs of injury, including cough, chest pain, shortness of breath, low levels of blood oxygen, abnormal chest X-rays or CT scans, and pathologic evidence of severe damage to the lungs. People suffering from the condition have experienced grievous harms to their health

with some requiring admission to intensive care units and mechanical ventilation. Several other states have already taken steps to protect the public from this harm.

Promulgation of these emergency rules is necessary because no other administrative act can be taken to avert this imminent peril to public health, safety, and welfare of Montana youth who vape or may be considering trying vapor products. The explosive growth of youth use of vapor products in the state has been concerning, but the present outbreak of lung injury and death associated with vaping gives rise to an immediate and alarming condition of public health importance. For the foregoing reasons, the department enacts these emergency rules. These rules will remain in effect no longer than 120 days after the date of enactment.

2. EMERGENCY RULE 1 provides definitions that apply to this rulemaking. These definitions are necessary to clarify that a flavor includes any substance, including mint or menthol, that imparts a taste or smell to a vapor product other than the natural taste or smell that comes from the psychoactive plant component of a nicotine or THC-containing product. These definitions clarify that the emergency rules apply to all individual and corporate entities that sell vapor products in the normal course of business. The definitions further clarify that the rules are intended to apply to all electronic smoking products that produce a vapor or aerosol, regardless of whether they do or do not contain nicotine or THC.

3. EMERGENCY RULE 2 is necessary to curtail the sale or distribution of flavored vapor products within the state of Montana by any means, including by remote or online methods. Emergency Rule 2 protects Montana youth who vape or may be considering trying vapor products by temporarily removing from intrastate commerce the flavored, youth-targeted products that have been identified as a primary draw to vaping—a practice that is presently inflicting grievous injury and illness on people throughout the country, including Montana.

4. EMERGENCY RULE 3 is part of a comprehensive, national effort to expand outbreak reporting to capture information related to lung injury and death associated with vaping. The inclusion of this rule allows public health officials and medical practitioners to better respond to individual cases, but also allows for the gathering of critical information to identify a root cause of the present outbreak and recommend appropriate control measures to stop its spread. Under the rule, cases of unexplained vaping-associated lung injury will be immediately reportable to the department in order to conduct surveillance activities necessary for the investigation, monitoring, control and prevention of this condition.

5. EMERGENCY RULE 4 is necessary to prevent the impairment of functioning of the remaining emergency rules package should a single provision or portion of any provision be invalidated by a court of competent jurisdiction.

6. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice. If you require an accommodation, contact Gwen

Knight at the Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

7. The emergency rules are effective October 22, 2019. This fourteen-day delay in effectiveness will allow for all impacted parties sufficient opportunity to receive notice and come into compliance.

8. The text of the emergency rules provides as follows:

EMERGENCY RULE I DEFINITIONS As used in these emergency rules, the following definitions apply:

(1) "Flavored vapor product" means a vapor product that imparts a taste or smell other than the taste or smell of tobacco or marijuana. This includes but is not limited to menthol, mint, wintergreen, fruit, chocolate, cocoa, vanilla, honey, or the taste or smell of any candy, dessert, alcoholic beverage, herb, or spice. A vapor product shall be presumed to be a flavored vapor product if a retailer, manufacturer, or a manufacturer's agent or employee has made a statement or claim directed to consumers or the public, whether expressed or implied, that the product or device has a distinguishable taste or aroma other than the taste or aroma of tobacco or marijuana.

(2) "Person" means a natural person, company, corporation, firm, partnership, organization, or other legal entity.

(3) "Vapor product" means a noncombustible product, regardless of nicotine or Tetrahydrocannabinol (THC) content, that uses a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from a solution or other substance. The term includes an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device and a vapor cartridge or other container that may contain nicotine or THC in a solution or other form that is intended to be used with or in an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device. The term does not include a product regulated as a drug or device by the United States food and drug administration under Chapter V of the Federal Food, Drug, and Cosmetic Act.

AUTH: 50-1-202, 2-4-303, MCA

IMP: 50-1-202, MCA

EMERGENCY RULE II DISTRIBUTION OF FLAVORED VAPOR PRODUCTS PROHIBITED (1) A person shall not sell, offer for sale, give, or otherwise distribute flavored vapor products to persons within this state.

(2) A person shall not transport within this state flavored vapor products intended for sale or distribution within this state by any person.

(3) These rules apply with equal force regardless of whether a retailer or reseller is physically located in this state or utilizes online or other remote sale methods that are intended to deliver flavored vapor products to this state.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, MCA

EMERGENCY RULE III REPORTING REQUIREMENTS (1) Cases of pulmonary illness associated with the use of vaping products are a reportable disease and condition under ARM 37.114.203 and are subject to the reporting requirements set forth under ARM Title 37, Chapter 114, Subchapter 2.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, 50-2-118, MCA

EMERGENCY RULE IV SEVERABILITY (1) If any rule or subsection of these emergency 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.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, MCA

9. The rationale for the temporary emergency rule is as set forth in paragraphs 1 through 4.

10. It is presently unknown whether a standard rulemaking procedure will be undertaken prior to the expiration of this temporary emergency rule. The necessity and efficacy of these emergency rules will be continuously evaluated as the investigation into the outbreak of vaping-associated pulmonary injury develops.

11. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in paragraph 6 above or may be made by completing a request form at any rules hearing held by the department.

12. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

/s/ Nicholas Domitrovich
Nicholas Domitrovich
Rule Reviewer

/s/ Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State October 8, 2019.