HON. JENNIFER B. LINT
District Judge, Dept. 2
Twenty-First Judicial District
Ravalli County Courthouse
205 Bedford, Suite B
Hamilton, Montana 59840
Ph: (406) 802-7198
Fax: (406) 802-7199

MONTANA TWENTY-FIRST JUDICIAL DISTRICT COURT, RAVALLI COUNTY

MONTANA SMOKEFREE ASSOCIATION INC.; FREEDOM VAPES LLC; LIBERTY SMOKE INC; and UBLAZE VAPOR LLC, Petitioners, vs. MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; SHEILA HOGAN, in her capacity as the Director of the Montana Department of Public Health and Human Services and, STEPHEN C BULLOCK, in his official capacity as the Governor of the State of Montana, Respondents.	Cause No. DV-19-388 /32 Department No. 2 **Jennifer B. Lint** **OPINION AND ORDER**

This matter is before the Court on Petitioners' *Application for a Preliminary Injunction* requesting this court enjoin the Respondents from implementing the Department of Public Health and Human Services Temporary Emergency Rules I though IV, dated October 8, 2019 and pertaining to the sale of flavored vapor products, recorded at Montana Administrative Register 37-901; also pending is Petitioners' *Motion in Limine*. The Court took evidence at the hearings on October 30 and November 1, 2019 and the matter is fully briefed and ready for a ruling.

PROCEDURAL HISTORY

On October 8, 2019, Respondent Department of Public Health and Human Services enacted emergency rules through a Notice of Adoption of Temporary Emergency Rules, published at Montana Administrative Register 37-901. The rules mandated an immediate halt to offering for sale, giving or otherwise distributing flavored vape products within the state, and prohibiting the transport of flavored vapor products within the state intended for sale or distribution (hereinafter "the Rule"). *Mont. Admin. Reg.* 37-901. The implementation date was to be October 22, 2019.

Petitioners filed the present action for judicial review of the Rule on October 17, 2019, requesting a Temporary Restraining Order and Preliminary Injunction barring implementation of the Rule (Petitioners' *Petition for Judicial Review of Montana Department of Public of Health and Human Services Temporary Emergency Rules*, Doc. #1, *Motion for a Temporary Restraining Order and Preliminary Injunction*, Doc. #2, and *Brief in Support of Motion for a Temporary Restraining Order and Preliminary Injunction*, Doc. #3). Included in Petitioners' pleadings were affidavits of individual Petitioners documenting their claims for loss of business revenue if the Rule were to go into effect.

The Court issued a *Temporary Restraining Order* on October 18, 2019 (Doc. #4) and set the matter for hearing on October 30, 2019. As a result of this order, the Rule did not go into effect as scheduled on October 22, 2019.

On October 29, 2019, Petitioners filed a *Motion in Limine* (Doc. #14), requesting the Court limit the testimony to be presented at the October 30, 2019 hearing. On the same day, the Respondents filed their *Response Motion for a Temporary Restraining Order and Preliminary Injunction* (Doc. #17) which included 31 exhibits (approximately 3" of documents) including

numerous scientific articles from peer-reviewed journals, Surgeon General Reports, Center for Disease Control (CDC) publications and statistical information regarding youth vaping use.

Respondents filed their *Response to Petitioners' Motion in Limine* (Doc. #19) on October 30, 2019, requesting the Court deny the *Motion in Limine*. In a meeting on the record with counsel prior to commencement of the hearing on October 30, 2019, the Court informed the parties that the *Motion in Limine* would be taken under advisement, but for purposes of the hearing, proposed evidence and testimony would be allowed from all parties.

Hearing on the preliminary injunction commenced on October 30, 2019, and was continued over to November 1, 2019. Petitioners presented their case first with six witnesses and nine exhibits. Respondents presented their case, calling five witnesses to the stand and presenting twenty-one exhibits. Petitioners had no rebuttal witnesses. Counsel for the parties presented closing arguments and the Court took the matter under advisement.

On November 1, 2019, Petitioners filed their *Reply* briefs to the *Motion for a Temporary Restraining Order and Preliminary Injunction* and *Motion in Limine*, Docs. #20 and #21 respectively. Respondents filed the *Affidavit of Nicholas Domitrovich*, Doc. #22, documenting his role in assembling data in support of the Department of Health and Human Service's decision to issue the Rule. The parties then filed supplemental documents, most notably with another update from the CDC. Docs. #23-26.

OPINION

MOTION IN LIMINE

I. PARTIES' ARGUMENTS

Petitioners assert that the language of Montana Code Annotated § 2-4-303 requires the Court's review of the Rule be limited solely to the four corners of the Rule itself and, therefore,

the Respondents should be precluded from presenting any testimony or evidence outside of the text of the Rule.

Respondents counter, asserting that Petitioners have "opened the door" to collateral material in their own pleadings and exhibits, and that the Montana Supreme Court has routinely given district courts latitude in the evidence it receives when considering a preliminary injunction.

II. DISCUSSION

A. Legal Authorities

The Montana Supreme Court has repeatedly held that "the authority to grant or deny a motion in limine rests in the inherent power of the court to admit or exclude evidence and to take such precautions as are necessary to afford a fair trial for all parties." *City of Helena v. Lewis*, 260 Mont. 421, 425-26, 860 P.2d 698, 700 (1993), *citing Feller v. Fox*, 237 Mont. 150, 153, 772 P.2d 842, 844 (1989). In assessing whether to grant a motion in limine, the Court's responsibility is to "prevent the introduction of evidence which is irrelevant, immaterial, or unfairly prejudicial." *Feller*, 237 Mont. at 153; 772 P.2d at 844.

At issue is whether the language of M.C.A. § 2-4-303 precludes the Court considering any evidence outside of the information in the Notice of Adoption of Temporary Emergency Rules. The statute in relevant part states:

> **2-4-303. Emergency or temporary rules.** (1)(a) If 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. The rule may be effective for a period not longer than 120 days, after which a new emergency rule with the same or

substantially the same text may not be adopted, but the adoption of an identical rule under 2-4-302 is not precluded. **Because the exercise of emergency rulemaking power precludes the people's constitutional right to prior notice and participation in the operations of their government, it constitutes the exercise of extraordinary power requiring extraordinary safeguards against abuse. An emergency rule may be adopted only in circumstances that truly and clearly constitute an existing imminent peril to the public health, safety, or welfare that cannot be averted or remedied by any other administrative act**. The sufficiency of the reasons for a finding of imminent peril to the public health, safety, or welfare is subject to judicial review upon petition by any person. The matter must be set for hearing at the earliest possible time and takes precedence over all other matters except older matters of the same character. **The 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**. The dissemination of emergency rules required by 2-4-306 must be strictly observed and liberally accomplished.

M.C.A. § 2-4-303(1) (2019), *emphasis added.*

There are no cases interpreting this statute in Montana; consequently, an investigation into the origins of the statute is warranted. The compiler's comments to § 2-4-303 show that the emergency rule has its origins in the original Model Administrative Procedure Act of 1961, first enacted in Montana in 1971. Changes not relevant to this inquiry were made in 1987 and 1991, and 1997 is where the language at issue first appears. M.C.A. § 45-2-104 commission comments (2019).

The legislative history on the 1997 amendment to § 2-4-303 shows that the original proposed amendment (HB 389, Rep. Bruce Simon, sponsor) was a substantial overhaul of the rulemaking provisions, inserting administrative requirements on agencies to affirmatively identify proposed rules which would have significant impact, and assuring that any person who

expressed interest in the rule and contacted the issuing agency "in any way" be kept apprised of the rule's process. *HB 0389, 1997, as introduced.* The amendments to MCA § 2-4-303(1) are found in section 13 of the original bill and are the underlined and bolded language in MCA § 2-4-303, *supra.*

The sponsor's comments at the March 13, 1997 Senate hearing on the bill state that the basis of the bill was to involve the public in the rulemaking process and assure they are not bypassed. *Minutes of Senate Committee on State Administration*, HB 0398, March 13, 1997, pp. 9, 10. A perusal of the sponsor's comments show that the gravamen of his proposed amendments was to ensure that the public receives functional notification of agency rulemaking. *Id., generally.*

In his closing statement on the March 13, 1997 hearing, the sponsor Rep. Simon noted that as to the amendments to the emergency rulemaking provision, the focus is on the balance between Montana citizens' right to participate in government as guaranteed by the Montana Constitution, and the need for government to be responsive to extraordinary situations requiring immediate action. The minutes from Rep. Simon's closing state:

> [Rep.Simon] indicated that this section [13] is attempting to say that is an extraordinary power for agencies, and they should have a good reason for doing that, and that, once a rule has been adopted, that decision will be subject to immediate judicial review if a citizen requests that.

Id. at 18-19.

On March 14, 1997, the Senate Committee on State Administration met again to discuss HB 389. Senators Gage and Thomas concurred that the language of section 13 of the bill should remain in as a reminder that emergency rulemaking is an extraordinary power. *Minutes of Senate Committee on State Administration*, HB 0398, March 14, 1997. On March 17, 1997, the bill passed out of the Senate Committee markedly changed from the original bill, with essentially

only the amendments to the emergency rulemaking provisions intact. Unfortunately, this is where the substantive legislative history ends, and HB 389 was passed and signed by the Governor containing the language we still see in M.C.A. § 2-4-303(1)[1].

The legislative history record offers little insight into the origin of the language "The 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", and this Court has been unable to find any similar language in any other jurisdiction's administrative procedures. However, the overall purpose of entire amendments put forth by Rep. Simon was to ensure public notice and involvement, and to assure that the purposes of which agencies propose rules are articulated in plain language and accompany the notice of the rule itself. Rep. Simon's amendments were pared down to just the changes to the emergency rule statutes, and other legislators noted the importance of emphasizing the extraordinary act of emergency rule making.

While other jurisdictions have emergency rulemaking provisions, no other jurisdiction has the language specifying that the adoption notice must "stand on its own". There has been litigation in other jurisdictions regarding the sufficiency of adoption notices. The Supreme Judicial Court of Massachusetts in *American Grain Products Processing Institute v. Department of Public Health*, 392 Mass. 309; 467 N.E.2d 455, (Mass. 1984) assessed whether the Department of Public Health's immediate ban of food products containing certain levels of ethylene dibromide (EDB) through emergency rulemaking was proper. One of the issues raised

[1] The Court recognizes the intrepid efforts and encyclopedic knowledge of Rita Gibson at the State Law Library in providing the legislative history which exists, and trying to chase down the Conference and Free Conference committee recordings on HB 389. Despite the minutes of those committee hearings referencing audio tapes, none exist. As this is a 1997 bill, the House side proceedings were audio recorded, whereas the Senate side still had substantive minutes being taken of proceedings. Left with only the Senate side of the proceedings as content, the Court relies on the assumption that the bill sponsor presented similar arguments as to the purpose of the bill in the House, Senate and Conference hearings.

was whether the agency complied with the provisions of Massachusetts' rulemaking states, specifically:

> The agency's finding and a brief statement of the reasons for its finding [that emergency regulation is a necessity] shall be incorporated in the emergency regulation as filed with the state secretary under section five.

Mass. Gen. Laws ch. 30A, § 2

The Massachusetts court found that the issuing agency "fulfilled this requirement" by filing the requisite findings and stating:

> "[t]he Department finds that consumption by the public of foods containing ethylene dibromide (EDB) in a concentration equal to or greater than the action level set forth in 105 CMR 515.005 poses an immediate and lasting threat to health. Further consumption of foods which contain ethylene dibromide in a concentration equal to or greater than the action level must be prevented or reduced to the greatest extent possible as soon as practicable."

Amer. Grain Prod., 392 Mass. at 323; 467 N.E.2d at 467.

The acceptable standard for the Massachusetts court was that the agency's filing contained information articulating the risk to public health and the reason for the emergency. The court did not require the agency's filing to contain all collateral evidence relating to the articulated public health risk and emergency.

At the other end of the spectrum, the State of Washington Court of Appeals, in *Mauzy v. Gibbs*, 44 Wn. App. 625; 723 P.2d 458, (Wash. Ct. App. 1986), found that the issuing agency did not meet its burden to articulate facts constituting emergency when the agency only put forth "mere statements of the motivation for the enactment". *Id.* at 631; 723 P.2d at 462. At issue in *Mauzy* were emergency regulations put into place by the Department of Social and Health Services (DSHS) making significant changes to community work and training programs for

citizens receiving Aid to Families with dependent children. *Id.* at 626; 723 P.2d at 459. Washington's emergency rulemaking authority stated at the time:

> **Emergency rules and amendments.** If the agency finds that immediate adoption or amendment of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observance of the requirements of notice and opportunity to present views on the proposed action would be contrary to the public interest, the agency may dispense with such requirements and adopt the rule or amendment as an emergency rule or amendment. The agency's finding and a concise statement of the reasons for its finding shall be incorporated in the emergency rule or amendment as filed with the office of the code reviser under RCW 34- .04.040 and with the rules review committee.

RCW 30.04.030 (1985)[2].

The Washington Court invalidated the emergency regulations, finding in part that:

> The error of DSHS lies in the fact that its published justification for this "emergency" regulation merely parroted the language of RCW 34.04.030 and utterly failed to articulate any credible ground for believing, as required by the statute, (1) that the emergency procedure was necessary for the preservation of the public health, safety, or general welfare, and (2) that observance of the requirements of notice and opportunity to present views would be contrary to the public interest. The emergency regulation was adopted without substantial compliance with RCW 34.04.030 and was therefore invalid.

The concern for the Massachusetts Court and the Washington Court was that the emergency rule articulated the precise emergency, and its nexus to public safety. The emergency rules in those states require, as does Montana's, that the public can easily determine the purposes for the rule and the rule's necessity.

[2] Washington's emergency rulemaking authority has since been renumbered to RCW 34.05.350; (1)(c) contains nearly the same language as the 1985 version.

Taking into consideration the legislative history which exists, and that actions under emergency rule statutes in other jurisdictions have been upheld when the issuing agency clearly articulates the reason and purpose of the emergency rule, the Court finds that the intent of the legislature in adding the language that the sufficiency of the reasons articulated in the notice of adoption "must stand on their own" is that the Respondents must be specific in its justification for the emergency rule, and that the justification stated in the adoption notice is the jurisdiction the Respondents must defend. To require the Respondents to have included all scientific journals, statistics and other data in support of this rule, and every emergency rule, would be burdensome and unnecessary. The Respondents are bound to the reasons articulated in the rule, but when a rule is challenged, the Respondents are entitled to defend it with collateral, supporting evidence. Furthermore, under the standard for motions in limine provided by *Feller*, the Respondents' offered evidence is neither irrelevant, immaterial, nor unfairly prejudicial. Consequently, it would not be proper to exclude the Respondents' evidence under that standard.

Therefore, Petitioners' Motion in Limine is DENIED, and the Court will consider all testimony and evidence presented at the hearing, as well as all exhibits provided by the parties.

PRELIMINARY INJUNCTION

Petitioners allege Respondents' enaction of the Rule through the emergency rulemaking process is "in excess of constitutional, statutory and administrative authority". In support of the claim for a preliminary injunction, Petitioners allege there is no determinative nexus between the rise of vaping related lung injuries (now referred to as EVALI by medical professionals) and flavored vaping liquids. Petitioners rely on many of the same Center of Disease Control (CDC) reports that Respondent's do, which have yet to pinpoint a cause for EVALI.

Petitioners do not deny the significant rise in under-18 use of vape products, but state they do not sell their products to individuals under the age of 18 and, therefore, are not contributing to the rise of youth use of vaping products. Petitioners assert that since they sell primarily, or in some cases, exclusively, the "open system" vaping devices and liquids, and not the more easily concealed "closed systems" (like Juul), preferred by youth, the Rule improperly targets them as Juul products (devices and the liquid "pods") are not impacted by the Rule.[3]

Petitioners also assert, under M.C.A. § 2-4-303, that the emergencies articulated by the Respondents in support of the Rule could have been remedied by another administrative act. Accordingly, Petitioners contend they will likely succeed on the merits of having the Rule declared null and void.

Petitioners further contend that a ban on flavored vaping liquids will cause irreparable harm as they will be "forced to shut down their business operations entirely or face significant criminal penalties for non-compliance." Petitioners assert that flavored vaping liquid needs to stay in the market to serve the over-18 users who are using vaping as an alternative method of nicotine delivery (as opposed to smoking tobacco and/or chewing tobacco). Petitioners' pleadings cite to numerous sources in support of their assertions that vaping is safer than tobacco based nicotine delivery.[4]

Respondents assert the combination of the meteoric rise in youth use of vaping products and the growth of EVALI are bona fide emergencies requiring the extraordinary act of

[3] The Court takes judicial notice that Juul removed its fruit vape liquids from the U.S. market first from brick and mortar stores in 2018, and in 2019, suspended sales of all fruit/sweet flavored liquids and, therefore, by its own act, is not impacted by this Rule. Juul announced on November 7, 2019, it is discontinuing its mint flavored liquids, citing youth prevention as the purpose.

[4] The Court notes that a substantial number of the sources cited by Petitioners in the footnotes of their opening brief are opinion pieces whose authors have ties to the vape industry.

implementing the Rule. Respondents rely on extensive documentation supporting the rise in use of nicotine vaping products by youth, and the as-yet undetermined cause of EVALI.

Respondents contend no other administrative act could curb the concurrent emergencies, noting the unknown cause of EVALI and that use and possession of nicotine vaping products is prohibited by individuals under the age of 18, and yet use is rising. Respondents assert the primary reason for the increase in youth use is the availability of flavored vaping liquid and its specifically targeted marketing toward youth, and that vaping puts youths (and others) at risk for EVALI. Respondents provided testimony and evidence that the closed vaping systems can be manipulated to make use of vaping liquids, essentially refilling the pods which were not intended to be refillable, and this results in youths using the easily concealable devices such as Juul, refilled with flavored vape liquid. Consequently, Respondents dispute Petitioners' assertion that they will succeed on the merits of their claim – to have the Rule determined null and void.

Lastly, Respondents dispute Petitioners' claim of irreparable harm, citing well established Montana precedent that mere financial harm is not irreparable harm.

The Court has considered the briefs, exhibits, testimony and arguments of counsel and based upon those, makes the following:

FINDINGS OF FACT

1. Nicotine infused liquid can be inhaled via either a "closed" system or an "open" system.

2. A closed system is a product sold with the intent of the vessel holding the nicotine infused liquid (called a pod) to be single use, and is not intended to be refilled or reused; the device into which the pod is inserted is intended for reuse.

3. Closed system vaping devices are smaller; as an example, Juul devices are closed systems and, due to the size, are easily concealed and resemble a USB device.

4. An open system is a product whereby the device and the pod holding nicotine infused liquid are intended to be reused.

5. Petitioners sell almost exclusively open systems, with the purpose that their customers can chose various flavors of nicotine liquid and refill the pods for use in the open system devices.

6. Petitioners do not sell THC infused liquid.

7. Petitioners have safeguards in place to prevent sale of vape devices and vape liquid to minors.

8. Petitioners' unrebutted anecdotal evidence is that their primary customer base is tobacco users attempting to reduce or eliminate nicotine use, or to replace tobacco-based nicotine delivery with vaping.

9. Petitioners unrebutted anecdotal evidence is that their customer base is almost all current or former tobacco users, and customers are not entering the nicotine market using vaping.

10. Petitioners' experts Greg Troutman, a vaping industry consultant, and Dr. Michael Siegel, a professor of Community and Health Sciences at Boston University, testified that delivering nicotine via vaping is safer than tobacco-based delivery, and that vaping nicotine is an effective smoking reduction method; however, they provided no peer-reviewed studies to support these assertions.

11. Both Mr. Troutman and Dr. Siegel have read the CDC reports and note that no specific causation of EVALI has been established, and a minority of patients vaped only nicotine liquid.

12. Mr. Troutman derives some of his income from representing the vaping industry and advocating for legislation which both controls the industry and protects its existence; his basic information about how vaping devices work is credible, but his opinions on the causes of EVALI are without scientific basis at this point and are not credible.

13. Dr. Siegel is an experienced public health researcher and professor and is an advocate for a non-tobacco replacement for delivery of nicotine but there are no present data to establish the safety of vaping. He concurred EVALI is a public health emergency, that vaping potentially has unknown long term consequences and that there is "no question" there is a problem with youth vaping. Dr. Siegel's testimony is credible to the extent it relies on established scientific data (nicotine addiction issues and tobacco damage), but his testimony is less credible when he avers that vaping is definitively a safer delivery mechanism for nicotine, as there are no peer reviewed studies establishing this fact.

14. Vaping nicotine infused liquid is not an FDA approved nicotine or tobacco cessation method, nor has the FDA assessed it as such.

15. Individual Petitioners, all owners of shops which sell vaping devices and liquid, testified and established:

a. They sell flavored nicotine infused vape liquid and agree that manufacturers packaging and the array of flavors makes it attractive to youths.

b. Their sales of flavored nicotine infused vape liquid are estimated at 65% and higher, depending on the stores.

c. Their sales will potentially drop if prevented from selling flavored nicotine infused vape liquid, but no specific evidence such as customer surveys, was presented.

d. They faithfully employ methods to prevent in-shop sales to minors, however, acknowledge they have no control over the product once it leaves the shop.

16. Both parties acknowledge that nicotine is devastating to the development of children and teenagers.

17. Respondent's witness Dr. Lauren Wilson, a pediatrician currently employed as a hospitalist at Community Medical Center in Missoula, testified and established:

a. She is active in the Montana Chapter of the American Academy of Pediatrics (AAP), is on the Executive Committee and will be President of the Chapter in two years.

b. The Montana Chapter is in favor of the emergency rule.

c. She attended a conference on vaping and youth nicotine use at the end of September, which emphasized the urgency to address increased use by youths of nicotine via vaping.

d. Youths who vape are four times more likely to transition to traditional tobacco.

e. Flavors are an effective onramp for youths to try nicotine.

f. Nicotine has long term effects on the brain; it affects executive functioning, makes early users more susceptible to addiction and nicotine addiction is very difficult to treat in children.

g. She read the CDC reports on EVALI and agrees the most recent statistic showed a minority of EVALI injuries were in patients who exclusively vaped nicotine (as opposed to only THC or THC and nicotine).

h. The AAP's concern and her concern is that a new generation of youth is getting addicted to nicotine, and while some negative effects are seen immediately (EVALI), others may not appear for 20 to 30 years.

18. Dr. Wilson is independent of any vaping or tobacco industry, leading the Court to find her testimony credible.

19. Both parties acknowledge the statistical drop in teenage nicotine use via tobacco since 1997, only to have nicotine use skyrocket through vaping to 30% in 2019.

20. Neither party disputes that youth vaping has exploded, that nicotine is harmful to youth's neural development, and that youths are attracted to the flavored liquids.

21. Respondents' witness Dan Kimzey, a school administrator who was most recently principal at Hamilton High School (HHS), testified and established:

a. He first starting seeing vaping increase at HHS in 2013-14, during a time that tobacco use was dropping.

b. The 2015 Youth Risk Behavior Survey (YRBS) for Montana first reported vaping use by youth in the prior 30 days at 30%.

c. For the school year 2017-2018, 33% of students reported vaping in the past 30 days, and for Hamilton Middle School, 13% of students reported vaping in the last 30 days.

d. His personal observances are that youth who have never tasted tobacco or tried a tobacco product are getting addicted to nicotine.

e. Students are sharing and bartering vape devices and the closed system pods, which are refillable.

f. Students are missing school due to discipline as a result of being caught vaping.

g. Students are coordinating meetups to go to the bathroom and vape, and younger students are worried about going to the bathroom for fear they might interrupt a vaping meetup.

h. His anecdotal evidence is that vaping rates are higher than smoking ever was at HHS.

i. He most frequently sees the more concealable devices such as Juul.

22. Mr. Kimzey is an experienced school administrator and the Court finds his testimony credible.

23. Missoula School Resource Officer Jeff Lloyd testified and established:

a. He is frequently citing students for Minor in Possession of vaping devices, accessories and liquid.

b. He confiscates many devices often Juul devices or similar closed systems, along with pods, often numerous pods per device, are confiscated.

c. The pods can be refilled by inserting a hypodermic needle into the pod and refilling it, which allows for flavored vape liquid to be used in the easily-concealable Juul and Juul-type devices.

d. The vaping and tobacco use statistics in the YRBS are reflected in what he sees as a School Resource Officer.

24. Officer Lloyd is a sworn peace officer with experience in schools as a School Resource Officer and, therefore, the Court finds his testimony credible.

25. Both parties acknowledge that EVALI has an undetermined origin, but the commonality is all EVALI sufferers documented by the CDC have vaped some type of liquid.

26. The majority of EVALI patients vaped only THC infused liquid.

27. Dr. Robert Jackler, a faculty member at Stanford in the Otology and Neurotology Division and tobacco advertising researcher, testified and established:

a. Vaping presents two emergencies, immediate (EVALI and the addiction of youth to nicotine) and delayed (long term effects of vaping).

b. EVALI has likely been "hiding in plain sight", and it was a group of dedicated physicians who finally put the pieces together and pointed to vaping some type of liquid as a source of the illness.

c. Vaping has become a gateway drug for youths and the 30% and higher youth use of nicotine is reversing decades of public health gains to reduce nicotine addiction.

d. Aerosolizing products and inhaling them are inherently dangerous; vaping *may be* safer than tobacco use as a nicotine delivery system, but that is a "very low bar".

e. FDA has approved the flavorings in vaping liquid for ingestion into the gastrointestinal tract; however, the lung has a very different toxicity spectrum and the FDA has not reviewed the safety of aerosolizing those liquids and then inhaling them.

f. Toxins are present in vaping smoke; in addition to the aerosolized liquid, there are heavy metals given off by the heating coils.

g. Humans learned the hard way the toxicity of tobacco, and tobacco users take three to four decades to die; vaping could be the same and there are already acute injuries related to vaping.

h. The tobacco industry has a notorious past with respect to targeting youth in order to continue a customer base; one tactic used was flavored tobacco.

i. Juul's advertising, before it was pulled from the market, "faithfully followed" old Marlboro cigarette ads, to the point where Juul was sued by Altria, the owner of Marlboro.

j. Subsequently, Altria invested in Juul, acquiring a 35% stake in the company.

k. Youth have a differential appeal for sweeter flavors and flavored vape liquid is an easy onramp for introduction to nicotine use. This contrasts with adult smokers, who entered their nicotine use via tobacco and are, therefore, accustomed to tobacco flavor.

l. If flavored vaping liquid is not available, these former tobacco users will likely transition back to tobacco flavor as the nicotine need will persist. Dr. Jackler disputes Dr. Siegel's contention that, without flavored vaping liquid, former tobacco users will turn to black market products, stating that Dr. Siegel is outside "the mainstream" on this issue.

m. There is a concern to provide tobacco use cessation products for people who want to quit or reduce their use, but new users must be prevented. Tobacco flavor is bitter and difficult to get accustomed to; youth users avoid that problem by using fruity and sweet flavored nicotine infused liquids.

n. Youths are able to use the combination of the smaller, concealable, closed systems with flavored vaping liquid by refilling closed system pods with flavored liquids.

o. Youth uptake of vaping dramatically rose beginning in 2017, due in large part to Juul's successful marketing and the availability of sweet and flavored liquid.

p. There is a public health emergency in that there is a trend toward creating more nicotine addicts, starting at young ages.

q. There is a public health emergency in that there is something about vaping that causes acute lung injuries.

r. State actions are necessary as the Federal government has not taken action and individual states inform the national conversation; a total ban on flavored (other than tobacco flavor) vaping juice is appropriate.

28. Dr. Jackler's experience in studying and accumulating tobacco and now vaping advertising, combined with this medical expertise and lack of ties to the tobacco or vaping industry, renders his testimony highly credible.

29. Neither party disputes that youth vaping has exploded, that nicotine is harmful to youth's neural development, and that youths are attracted to the flavored liquids.

CONCLUSIONS OF LAW

1. The purpose and goal of a preliminary injunction is not to "resolve the merits of a case, but rather [it is to prevent] further injury or irreparable harm by preserving the status quo of the

subject in controversy pending an adjudication on its merits." *Four Rivers Seed Co. v. Circle K. Farms, Inc.*, 2000 MT 360 ¶12, 303 Mont. 342, 345, 16 P.3d 342, 344.

2. An injunction is an order preserving the status quo, defined by the Montana Supreme Court as "the last actual, peaceable, noncontested condition which preceded the pending controversy." *Sweet Grass Farms, Ltd, v. Board of County Comm'rs,* 2000 MT 147 ¶28, 300 Mont. 66, 72, 2 P.3d 825,829.

3. When assessing whether an injunction should be issued, the Court must balance the potential harm to the applicant against the potential hardship to the enjoined party. *Four Rivers* at, 12, 303 Mont. at 345, 16 P.3d at 344.

4. Montana's statutes governing preliminary injunctions are set forth in Montana Code Annotated § 27-19-201, which forth five circumstances in which preliminary injunctions may be issued. The Montana Supreme Court in *Stark v. Borner,* 226 Mont. 356, 735 P.2d 314 (1987), held that the five subsections are disjunctive, that is that an applicant need only show he is entitled to injunctive relief under one of the subjections. *Borner,* 226 Mont. at 358, 735 P.2d at 317. This case states "an applicant for a preliminary injunction must either establish a prima facie case on the underlying claim **or** show that ... he or she will suffer irreparable injury before an adjudication on the merits." *MH., J.R., MH. and T.H.* v. *Montana High School Ass'n,* 280 Mont. 123, 129, 929 P.2d 239, 243 (1996) (emphasis added).

5. The Montana Supreme Court has consistently held that while alleging financial loss is generally not irreparable injury (*Curran v. Dept' of Highways*, 258 Mont. 105, 109, 852 P.2d 544, 546 (1993); *Dicken v. Shaw*, 255 Mont. 231, 236, 841 P.2d 1126, 1129 (1992)); it can be if the moving party satisfies certain elements.

6. When financial loss is the irreparable injury claimed, the Court adopted a four-part test to assess "whether a preliminary injunction should issue when a party's monetary judgment may be made ineffectual by the actions of the adverse party thereby irreparably injuring the applicant. The moving party has the burden of proving these elements." *Shammel v. Canyon Resources Corp.*, 2003 MT 372 ¶17, 319 Mont. 132, 138, 82 P.3d 912, 917, citing *Van Loan v. Van Loan*, 271 Mont. 176, 182, 895 P.2d 614,617.

7. The elements of the *Van Loan* test, all of which must be met in order for financial loss to be irreparable injury, are as follows:

a. the likelihood that the movant will succeed on the merits of the action;

b. the likelihood that the movant will suffer irreparable injury absent the issuance of a preliminary injunction;

c. the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party (a balancing of the equities); and

d. the injunction, if issued, would not be adverse to the public interest.

Shammel at, ¶ 7, 319 Mont. at 138-38, 82 P.3d at 917 (citation omitted).

Petitioners assert, in their opening brief, that injunctive relief is proper under § 27-19-201 sections (1) – likelihood of success on the merits, and (2) – irreparable harm. In their reply brief, they assert (3) applies as well, arguing that the emergency rule is arbitrary and capricious and thus infringes upon their rights to public participation in the rulemaking process. Noting the findings of fact, as well as the analysis of the purposes of the emergency rule (*infra*), the court will address each basis for an injunction in turn.

I. Likelihood of Success on the Merits

A. Whether the recent outbreak of vaping-related lung injury ("EVALI") in connection with the rise in teen vaping constitutes an imminent peril to public health.

Ballantine's Law Dictionary defines "imminent peril" as "threatened peril" or "danger immediately at hand." (3d ed., LexisNexis 2010). In the past, agencies have deemed subjects such as flooding and medical marijuana as justifications for emergency rulemaking. *See, e.g., Mont. Admin. Reg. Notice 12-519, No. 11*, 6/7/2019; *Mont. Admin. Reg. Notice 37-884, No. 8*, 4/26/2019.

The Rule promulgated by Respondents identifies the imminent peril to be addressed as a "concurrent epidemic of youth e-cigarette or vapor products use (vaping) and the emerging outbreak of lung injury and death associated with vaping." *Mont. Admin. Reg. Notice 37-901, No. 20*, 10/18/2019, 1 (*hereinafter* Notice of Adoption). The Rule states that the rate of vaping among high school students has risen 243% since 2017. *Id.* The Rule also states that, as of its execution, there were two confirmed EVALI cases in Montana.[5] *Id.* at 2.

Evidence at the hearing, in support of the articulated reasons in the Rule, conclusively established, by experts for both Petitioner and Respondent, that the exact cause of EVALI is unknown, but the common nexus is all patients vaped. Both parties' experts agreed there is a health crisis not only with EVALI, but with the exponential growth in youth nicotine use and that nicotine use is developmentally damaging to youths.

The evidence further conclusively established that nicotine use by youths is increasing dramatically with the availability of flavorful vaping liquid – allowing youths an onramp to nicotine addiction without having to suffer through adapting to the harsh taste of tobacco.

[5] Since the writing of the Rules, that number has risen to five EVALI cases, including one confirmed teen death. Montana DPHHS, *E-Cigarette, or Vaping, Related Lung Injury (EVALI)*, MONTANA.GOV, https://dphhs.mt.gov/publichealth/mtupp/vapingpulmonarydisease (accessed Nov. 4, 2019); Montana DPHHS, *Health Officials Identify First Montana Death of Severe Pulmonary Disease Associated With Vaping*, MONTANA.GOV, https://dphhs.mt.gov/aboutus/news/2019/vapingassociateddeath (accessed Nov. 4, 2019).

Marketing by vaping companies, many now financially tied to tobacco companies, has packaging, flavors, and names of liquid which appeal to youths and youths are using them in record numbers.

Uncontroverted testimony by several witnesses established that youths are using the pods in closed systems and refilling them with flavored vape liquids, thus necessitating the existence of the Rule to ban all flavored liquid sales; otherwise youths would still have the ability, as they do today, to secure flavored vape liquids and use them in the easily concealable closed systems. Petitioners' argument that the Rule unfairly targets open system sellers when closed systems are what is preferred by youths fails in light of the information that closed system pods are refillable.

Therefore, the Petitioners' likelihood of success on their claim that the Rule does not address an immediate peril fails.

B. Whether the twofold concern of the EVALI outbreak and rise in teen vaping could have been averted or remedied by any other administrative act.

Under usual MAPA rulemaking procedure, an agency must provide notice to the public with the time, location, and manner by which the public may present their views on the proposed rule. Mont. Code Ann. § 2-4-302(1)(a). The agency must give the public thirty days to respond to the proposed action. *Id.* at § 2-4-302(2)(c). Additional time may also be required. *Id.* at § 2-4-302(3).

Evidence during the hearing showed that minors are obtaining flavored products despite it being illegal for them to do so and despite the responsible efforts of Petitioners to keep minors from accessing their resale products. Until scientific data provides information about what specifically in vapor products is causing EVALI, the danger that minors will be drawn to vaping through flavored products and be exposed to pulmonary illness cannot be alleviated through another administrative act.

Moreover, evidence at the hearing conclusively established, despite Petitioner's assertions in their brief, that flavored vaping liquids are onramps for youth to enter the nicotine market, that they are using nicotine for the first time through flavored liquids and not tobacco, and that substantial public health gains in reducing tobacco use were being decimated by the marked increase in youth nicotine use. Despite statements from officials at the federal level that some regulatory action would be taken to address the youth nicotine crisis, none has occurred. The mere existence of flavored vape liquid in the market creates the immediate peril to youth and no other administrative act could remove it from the hands of youth. Consequently, Petitioners' claim for injunction on the basis that the circumstances addressed by the Rule could be accomplished by another administrative act fails.

II. Irreparable Harm

Whether a preliminary injunction is proper under Mont. Code Ann. § 27-19-201(1)–(2) when the harm to Petitioners is economic.

Montana caselaw establishes that injunctive relief under sections (1) and (2) of the statute is only appropriate when more than economic harm is at stake. *Caldwell v. Sabo*, 2013 MT 240, ¶ 25, 371 Mont. 328, 308 P.3d 81. Under section (1), in relevant part, "final injunctive relief may only be granted if pecuniary compensation would not afford adequate relief" or if "it would be extremely difficult to ascertain the amount of compensation which would afford adequate relief." *American Music Co. v. Higbee*, 1998 MT 150, ¶ 13, 289 Mont. 278, 961 P.2d 109. If monetary damages would provide full relief, injunctive relief is inappropriate. *Id.* An irreparable injury under section (2) is "an injury so significant it could not later be repaired even by means of the litigation." *BAM Ventures, LLC v. Schifferman*, 2019 MT 67, ¶ 15, 395 Mont. 160, 437 P.3d 142. Economic loss alone does not constitute an irreparable harm because "money damages may be recovered in an action at law without resort to equity." *Id.* at ¶ 17 (quoting *Caldwell*, ¶

29). Additionally, a petitioner must offer evidence demonstrating irreparable injury "beyond mere speculation." *Benefis Healthcare*, ¶ 26.

At the hearing, Petitioners estimated flavored sales and related equipment was at least 65% of their sales. Petitioners acknowledge that monetary harm alone does not constitute irreparable harm under Montana caselaw. They point to caselaw from other jurisdictions to support their contention that loss of a business constitutes irreparable harm for the purposes of an injunction. Petitioners' Brief in Support, 22. However, Montana currently follows the approach seen in *American Music Co.* and *Caldwell*. It is well established that only in limited circumstances can injunctions be granted when the claimed irreparable harm is economic. When that claim is made, a further analysis under *Van Loan* is warranted.

As to the four *Van Loan* elements noted above, the Court has already determined that the Petitioners cannot show a likelihood of success on the merits in having the Rule vacated, on either the imminent public threat claim, or the arbitrary and capricious claim addressed below. As to the second element, whether Petitioners will suffer irreparable injury, the Court has determined that the Petitioners' irreparable harm claim is financial and speculative, and not of the extraordinary type so as to rise to irreparable harm. Moreover, because the damage claimed is economic in nature, it appears that monetary damages could be reasonably calculated to compensate Petitioners for loss of revenue or a breach of their contractual obligations if leases, taxes and vendors go unpaid. As in *American Music Co.*, the harm here would be to a business, its economic success, and Petitioners' finances. Other harms raised by Petitioners, such as nicotine-addicted customers returning to combustible cigarettes or harm to customers buying flavored products illegally or mixing them on their own, are both speculative and unspecific to Petitioners.

The third element, the balancing of the equities, does not favor Petitioners. The damage to Petitioners is currently speculative to the extent it is unknown how much business they may lose without the sale of flavored vapor products. Evidence at the hearing did not include customer surveys regarding how many customers would cease using vaping products. Compelling evidence at the hearing from Dr. Jackler noted that current vape users who are former tobacco users are a) already addicted to nicotine and b) accustomed to the flavor of tobacco. Accordingly, he posited that these users would continue to use vaping products, even though the fruity and sweet flavors would no longer be available. The health and lives of people who vape, and especially minors, are currently threatened by the EVALI outbreak and youth's development is threatened by the easy onramp to nicotine addiction provided by flavored vaping liquids. Preventing further harm to the public health is more important than preventing economic harm to vapor product businesses.

Similarly, an assessment of whether an injunction would be against the public interest weighs in favor of the Respondents. Despite Petitioners' genuine, and apparently successful, prevention of youths purchasing vaping products in their stores, uncontroverted evidence shows youths are getting vaping devices and liquids, and that the flavored liquids are appealing and popular. Experts from both Petitioners and Respondents concurred that youths should not use nicotine, that nicotine is harmful to youth's development and nicotine addiction is perilous. Moreover, the acute nature of EVALI's injuries and the still yet undetermined source justifies protecting the public by eliminating the availability of flavor-attractive vape liquid.

Therefore, Petitioners claim for an injunction on the basis of irreparable harm fails as the harm articulated is financial, speculative and if it occurs, calculable.

B. Whether a preliminary injunction is proper under Mont. Code Ann. § 27-19-201(3) when Petitioners allege the Rule infringed their right to participate

and are arbitrary and capricious for banning flavored open-system vaping products.

Mont. Const. art. II, § 8 states: "The public has the right to expect governmental agencies to afford such reasonable opportunity for citizen participation in the operation of the agencies prior to the final decision as may be provided by law." MAPA's emergency rulemaking statute contemplates the preclusion of this right and thus requires emergency rules to stand on their own merits for the purpose of judicial review. Mont. Code Ann. § 2-4-303(1)(a).

Under Montana law, an arbitrary and capricious agency decision is "made without consideration of all relevant factors or based on a clearly erroneous judgment" such that it appears "random, unreasonable, or seemingly unmotivated based on the existing record." *Bitterrooters for Planning, Inc. v. Mont. Dept. of Envtl. Quality*, 388 Mont. 453, 460, 401 P.3d 712, 718 (2017). A court cannot substitute its judgment for that of an agency but may "conduct a searching and careful review of the record" to determine whether the agency made a reasoned decision. *Id.*

Evidence at the hearing supported the reasons set forth in the Rule and established that youths use both open and closed systems – the closed systems for their concealable nature, and the vaping liquid used in open systems to refill the allegedly unrefillable pods used with the closed systems. Regardless of the delivery system, youths are drawn to vaping by flavored products that mimic youth-targeted sweet foods and allow for the delivery of nicotine without the harsh tobacco flavor. Vaping places users at risk for EVALI. As part of tailoring the Rule to the articulated reasons – acute lung injury and youth vaping - the Rule is only a flavor ban rather than a total vapor product ban.

The Rule meets the requirements for rational basis because the flavor ban has a rational relation to decreasing youth vaping and thus decreasing cases of EVALI in minors. This rational

basis is present on the face of the Rule. The agency decision was supported by the evidence at the hearing which established the main impetus for youth vaping is the availability of flavored vaping liquid, and the use of vaping devices exposes persons to the risk of acute lung injury. The Rule therefore appears to be the result of a reasoned decision by the agency for the purpose of decreasing the emergent danger of youth EVALI cases in the state. Consequently, the preclusion of Petitioners' right to participate meets the requirements of Mont. Code Ann. § 2-4-303(1)(a). A preliminary injunction to prevent enforcement of the Rule is improper under the arbitrary and capricious claim.

Therefore, the Court finds the Petitioners have not sustained a claim for a Preliminary Injunction and the Court's Temporary Restraining Order of October 18, 2019 is hereby DISSOLVED.

DATED this 17th day of December, 2019.

HON. JENNIFER B. LINT, District Judge

cc: Counsel of Record

I certify that I forwarded copies of this instrument to counsel of record
by email
on Dec 17, 2019
Paige Trautwein, Clerk
Deputy