IN THE COURT OF APPEALS OF THE STATE OF OREGON

VAPOR TECHNOLOGY ASSOCIATION; VAPE CRUSADERS PREMIUM E-LIQUID, LLC; and SMOKELESS SOLUTIONS, LLC, Petitioners, v. OREGON HEALTH AUTHORITY, Respondent.	Rule Challenge Appellate Court No. A172417 (Control)
NO MOKE DADDY, LLC, dba Division Vapor, an Oregon limited liability company; and PAUL BATES, an individual, Petitioners, v. OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon and as Chief Executive of the Oregon Health Authority; and PATRICK ALLEN, in his official capacity as Director of the Oregon Health Authority, Respondents.	Rule Challenge Appellate Court No. A172419 RESPONDENT'S RESPONSE TO STAY

Petitioners have moved to stay the implementation of a temporary rule adopted by the Oregon Health Authority (OHA) that bans the sale of certain flavored e-cigarettes. This court should deny that motion. The challenged temporary rule was adopted pursuant to an Executive Order that the governor issued to respond immediately to an ongoing, nation-wide outbreak of potentially fatal lung injuries associated with e-cigarettes or "vaping." While

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public health professionals are working diligently to understand the cause of the outbreak, at this point that information is unknown. Staying the challenged temporary rule during the pendency of this proceeding could jeopardize the health and welfare of Oregonians, including vulnerable youth to whom flavored vape products are attractive, and cannot be justified. This court should deny petitioners' motion.

A. Background

In recent months, a rapidly increasing number of people across the country who have used vaping products have fallen ill and several have died.[1] At this point nobody knows why this outbreak is happening or how to stop it, but we do know that the injuries being caused are severe. Doctors at the Mayo Clinic who published a study in the New England Journal of Medicine described the lungs of those inflicted as exhibiting serious lung damage akin to "chemical burns" that one might expect to see from a serious industrial accident or exposure to chemical weapons.[2] It was unclear whether the source of the

[1] See Center for Disease Control, Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping (October 18, 2019) Available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

[2] D. Grady, *Lung Damage from Vaping Resembles Chemical Burns, Report Says*, N.Y. Times (Oct 2 2019). Available at https://www.nytimes.com/2019/10/02/health/vaping-illnesses.html

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problem is in the liquid that are being "vaped" or a "toxin in the materials used to making the vaping device" or whether the devices are defective.[3] As of this writing, the CDC is reporting 1479 cases of people with lung injuries associated with vaping, and that 33 people have died.[4] Although the majority of the cases appear to involve products containing THC, the cause of the illness is still not understood and the CDC is warning that the only way to assure one is not at risk is to refrain from the use of any vaping products.[5]

To address this potential health crisis and protect the public health, states across the country have taken swift action.[6] Here in Oregon, the governor issued

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[3] *Id.*

[4] Center for Disease Control, Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping (October 18, 2019) Available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

[5] *Id.*

[6] Eight states have implemented or are planning to implement bans on flavored vaping products: Michigan, Massachusetts, New York, Rhode Island, Washington, Utah, Oregon, and Montana. ahttps://www.publichealthlawcenter.org/blogs/2019-09-24/states-and-tribes-stepping-protect-youth-dangers-e-cigarettes-actions-and-options In Massa chusetts, the governed declared a pulic health emergency temporarily banning sale of all vaping products for four months "so that we can work with our medical experts to identify what is making people sick." (Cite) In New York, the governor issued an order banning most flavored e-cigarettes for 90 days effective October 4. (cite) Legal challenges attempting to immediately enjoin the orders in both Massachusetts and New York have been rejected by courts there. (cite) Similar bans by executive order are planning in Rhode Island and

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an executive order calling on her agencies to temporarily stop the sale of flavored vaping products containing THC, and to stop the sale of "flavored" tobacco vaping products. Flavored vaping products are of particular concern because they are attractive to a vulnerable population, namely children.[7] Pursuant to that order and consistent with its own statutory authority, OHA

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Washington. In Michigan, the governor issue emergency rules banning flavored vaping products. A court initially denied a TRO but later granted a preliminary injunction. https://www.reuters.com/article/us-health-vaping-michigan/michigan-judge-blocks-flavored-vape-ban-as-juul-faces-wrongful-death-lawsuit-idUSKBN1WU2PB The Wall Street Journal reports that the Army, Air Force, Navy, and coast Guard have banned the sale of all e-cigarettes from stores on military bases as of October 1. J. Maloney, US Army is Treating Two Soldiers for Vaping-Related Lung Illness, Wall Street Journal (Oct 9, 2019) Available at, https://www.wsj.com/articles/u-s-army-is-treating-two-soldiers-for-vaping-related-lung-illness-11570624268

[7] E-cigarettes come in in a variety of flavors like fruit, candy, or even cookies, that readily appeal to children. *See* CDC "Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults" which can be viewed at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html. Those flavors include, for example, "the rich flavor of a freshly baked sugar cookie and layer in a toasty blend of pralines, macadamia nuts and hazelnuts, topped with a hint of white chocolate." https://velvetcloud.com/products/nutty-cookie. Between 2017 and 2018, vaping jumped dramatically among high school students, rising to nearly 21% of high schoolers. IDS, particularly the non-tobacco flavored variety, are heavily marketed and as a result are now the most commonly used tobacco product among youth, surpassing conventional cigarettes.

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adopted temporary rule OAR 333-015-1000.[8] The rule bans the sale of non-tobacco flavored e-cigarettes.

B. This court should deny petitioner's request for a stay

Petitioners, who sell non-tobacco flavored vaping products, have brought this challenge to OAR 333-015-1000 pursuant to ORS 183.400, asserting that OHA lacked authority to issue it. They have asked this court to stay OHA's temporary rule during the pendency of this proceeding, asserting that the temporary ban will have significant financial consequences and that they have at least a "colorable' challenge to the rules validity.

But as discussed in more detail below, their argument invokes the wrong standard for a stay, and as a result focuses only on financial consequences while completely ignoring the threat to public health. Yet this court must take the threat to public health into consideration in assessing whether to grant a stay. The balance of harms and the public interest tilts sharply against a stay. Further, petitioners fail to carry their burden of showing their likelihood of prevailing on the merits: In the context of a rule challenge like this one, it is not merely whether petitioners have raised a "colorable" claim but whether they can

[8] Pursuant to the Governor's Executive Order, OHA also adopted a temporary rule banning the sale of Cannabinoid Flavored Vaping Product, 333-008-4000. That rule is not here at issue.

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show a likelihood of success. For the reasons also explained below, they fail to make that showing.

1. The standard for a stay in a rule challenge under ORS 183.400

As an initial matter, petitioners misstate the standard for a stay in this circumstance. Petitioners assert that the standard for a stay is whether they can show "irreparable harm" and a colorable claim of error. But that standard applies to the challenge of an agency order in a contested case under 183.482. That is not what this proceeding is.

This is a rule challenge under ORS 183.400, in which petitioners are challenging the facial validity of rule. ORS 183.400 contains no express provision for staying the operation of agency rules. However, OHA accepts that this court has inherent authority, under the judicial power granted to it by the Oregon Constitution, to stay rules under equitable principles. *Northwest Title Loans, LLC v. Div. of Fin. & Corp. Sec., Div. of Dep't of Consumer & Bus. Servs.*, 180 Or App 1, 13, 42 P3d 313, 319 (2002). But the legal standard that applies in a challenge to an order in a contested case is not applicable.

The only authority that petitioners cite for their proposed standard is *Northwest Title*, but that case does not support their proposal. In *Northwest Title* this court explained that to obtain a stay of a challenged rule a party must *at least* show irreparable harm. But it then held that the petitioner in that case had

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failed to make that requisite showing, so it did not consider whether there were other factors that the court needed to consider. *Id.* at 13. It noted, in a footnote, that "arguably" the court could apply the stay standard that applied under ORS 183.482, but then pointed out that it did not need to decide whether that was the applicable standard because petitioner had failed even to show irreparable harm. *Id.* at 13 n 7. In short, *Northwest Title* left open what standard applies in considering the stay of rule.

In the state's view, at least two sources of law are instructive as to the standard for deciding whether to grant the stay: ORS 19.350, which applies to discretionary stays on appeal, and the standards for provisional relief under ORCP 79.

ORS 19.350 allows an appellate court to stay a trial court judgment after considering a number of factors:

- The likelihood that the moving party will prevail on appeal;
- Whether the appeal is taken in good faith and not for the purpose of delay;
- Whether there is any support in fact or in law for the appeal;
- The likely harm to the moving party, to other parties, to third parties, and the public at large from the grant or denial of a stay.

ORS 19.350(3)(a – d).

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ORCP 79 allows the issuance of an injunction based on similar factors. First, "clear and convincing proof" on the merits is required. *Jewett*, 281 Or at 473. Second, there must be a showing that "irreparable harm" will occur and that "there is no adequate legal remedy." *Gildow v. Smith*, 153 Or App 648, 653 (1998); *Josephine Cty. v. Garnier*, 163 Or App 333, 336–37 (1999) ("proof of irreparable harm is a prerequisite of injunctive relief generally"). Third, courts consider the "relative hardship likely to result to the defendant if the injunction is granted and to the plaintiff if it is denied." *York v. Stallings*, 217 Or 13, 23-25 (1959). Finally, courts consider the public interest. *Bennett v. City of Salem*, 192 Or 531, 546 (1951) ("there are situations where the public interest would be so seriously affected by the issuance of an injunction that the court will deny an application therefor."). In addition, the courts have been clear that "[t]o qualify for injunctive relief, it must be shown that the conduct to be enjoined is 'probable or threatened* * * An injunction may not be granted merely to allay the fears and apprehensions of an individual." *Howe v. Greenleaf*, 260 Or App 692, 712 (2014) (citations omitted).

Even where the basic requirements of ORCP 79 are satisfied, the use of the phrase "may be allowed" demonstrates that injunctions do not issue as a matter of right. Instead, "issuance of a preliminary injunction is a matter

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committed to the discretion of the trial court." *State ex rel. Keisling v. Norblad*, 317 Or 615, 616 (1993) (abrogated on other grounds). Indeed, Oregon courts recognize that injunctive relief generally is an "extraordinary remedy" that should be granted sparingly. *Jewett v. Deerhorn Enters. Inc*., 281 Or 469, 473, 575 P2d 164 (1978). "[E]xtraordinary relief by injunction . . . is a remedy which should be exercised sparingly and cautiously and should be awarded only in clear cases reasonably free from doubt." *Wilson v. Parent*, 228 Or354, 369, 365 P2d 72 (1961).

The equitable principles to be gleaned from the statutes, rules of procedure, and case law are clear: in considering whether to grant a stay in the context of a rule challenge, this court must consider not merely whether petitioners have shown irreparable harm, but whether they have shown that the *balance* of harms, including the *public interest*—tilts in their favor. In addition, this court does not consider merely whether petitioners have a "colorable claim of error" but whether they have shown a likelihood of success on the merits. As explained below, petitioners have made neither showing.

2. The balance of hardships and the public interest weigh against a stay.

Balancing the harms in this case weighs decisively against a stay of the rule.

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In requesting a stay, petitioners focus exclusively on the financial harms that will result from not being able to sell flavored vaping products. The state does not dispute that the rule in this case could have significant financial implications for those who sell non-tobacco flavored vaping products.[9] That loss of income is regrettable and the state does not mean to minimize it, but that loss is not fairly attributable to the rule. Rather, it is attributable to the fact that the product that petitioners are selling could be lethal. Given the seriousness of the illness and the speed with which the outbreak has escalated the balance of hardships and the public interest nevertheless weighs in favor of allowing the rule to remain in place. As noted, at this point nearly 1500 cases of the illness have been reported, and 33 people have died. Two of those deaths happened in Oregon. The fact that petitioners will lose money from the sale of devices does not outweigh the public interest in safety if in fact the devices are causing

[9] Yet it should be noted that petitioner's assessment of the financial impact of the ban—they characterize it as an "extinction level event"--assumes that they could not or would not be able to take steps to mitigate the loss of sales associated with flavored vaping products by selling other products. Also mitigating the financial impact of the rule is that it is temporary . Also potentially relevant in considering the balance of hardships of this rule is shifting regulatory context. The US FDA has proposed a rule that would effectively ban the sale of non-tobacco-flavored e-cigarettes by prohibiting their sale without pre-market authorization. If non-tobacco flavored e-cigarettes are eventually banned, then the rule would obviously have no further financial consequences and it would no longer be needed.

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serious injury. Public health professionals across the country are working to determine the cause of the outbreak and how to stop it. In the meantime, this court should not stay the temporary rule.

3. Likelihood of success.

Petitioners also cannot show a likelihood of success on the merits. Petitioners' position at root is that that the governor and her executive agencies lack authority to take rapid response to stop the sale of products that are making people sick sometimes fatally. But the power to take rapid steps to protect the public from an unforeseen threat like an acute threat to public health is one of the quintessential functions of the executive branch. The legislature expressly anticipated that the governor and OHA would respond to such threats and it expressly provided them authority to do so.

a. The Executive Order provides authority for the temporary rule.

In this case, OHA adopted the temporary rule pursuant to (among other authority) the governor's Executive Order that expressly mandated that it do so. *That order is, standing alone, a sufficient source of authority*. Petitioners do not address the Executive Order, other than in a footnote suggesting that an Executive Order cannot provide authority to promulgate a rule because it is not a statute. That is incorrect. Where—as here—the legislature has expressly

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delegated power to the governor and her agencies to address a public threat, the governor may exercise that power by ordering the agency to take action, including adopting a temporary rule, to that end. And that is what happened here.

As a general matter, the legislature has empowered to governor to respond to public health threats and other emergencies. The governor may, for example, declare a public health emergency, or a state of emergency, in dire circumstances. See ORS 443.441; ORS Chapter 401. But even when the threat to public health is not so dire, the legislature has given the governor and her agencies the power to quickly respond and address threats to public health.

Under ORS 431A.015, even if the Governor has not declared a public health emergency, she is authorized to permit the Public Health Director to take certain "Public Health Actions" if the director has determined that "a condition of public health importance is reported in Oregon and is an issue of significant regional or national concern or is an issue for which there is significant involvement from federal authorities requiring state-federal coordination." Among the "Public Health Actions" that the director can take is to "coordinate the public health response across jurisdictions," and to "prescribe measures for the "control of the * * * disease outbreak, epidemic, or other condition of public health importance." *Id.* A "condition of public health importance" is defined as

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"a disease, syndrome, symptom, injury or other threat to public health that is identifiable on an individual or community level." ORS 431A.005(3).

As those provisions show, the legislature has empowered the Governor to work with the OHA to take the measures necessary to control disease outbreaks and similar threats to public health. The Executive Order that the governor issued in this case, and the rule that the agency then adopted, is within the scope of that authority.[10]

b. Other statutes cited by OHA also provide authority.

Even if the Executive Order were not a source of authority for the temporary rule, the other rules cited by the agency are themselves sufficient. ORS 431.110 describes the powers that the legislature has given to OHA, including "direct supervision of all matters relating to the preservation of life and health of the people of this state." Included in that supervisory authority is the authority to temporarily ban the sale of a product linked to an outbreak of a potentially fatal illness. Petitioners contend that the power cannot possibly be so broad as to include the adoption of rules like the one here, because it would mean that the OHA had vast and unfettered authority to adopt rules of any kind

[10] The temporary order does not cite ORS 431A.015, but that is not fatal because the order does cite the Governor's Executive order. So long as the Executive Order is lawful, the rule is too.

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in the interest of public health. But this court does not need to read ORS 431.110 that broadly to conclude that it gives the OHA the authority to enact a temporary rule of the sort it adopted here.

In general, a "supervisory" power may not include the power to adopt regulations in the interest of promoting public health. But where the state is threatened by an unanticipated and acute public health crisis and fast action is required, "supervisory authority of all matters relating to the preservation of life and health" *does* include the power to take necessary actions like the one OHA took here. Notably, the same statute explicitly gives the OHA "full power in control of communicable diseases." This case does not involve the outbreak of a *communicable* disease, as such, and that provision is not directly applicable. But it is useful context for understanding the intended scope of the OHA's supervisory authority and the meaning of that term. While the OHA is not dealing with an outbreak of *communicable* disease, it is struggling to deal with an outbreak of disease nonetheless, and one that threatens public health and requires a rapid response. The supervisory power of the OHA to preserve life and health of Oregonians includes the power to adopt the challenged regulation.[11]

[11] In addition, OHA cited ORS 431A.010 and ORS 431.141 as sources of its authority to adopt the challenged rule. The former statute empowers OHA to

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CONCLUSION

Given the threat to public safety, the balance of harms and the public interest weighs strongly in the state's favor. In addition, petitioners have failed to show that they are likely to succeed on the merits of their rule challenge. This court should not stop rule from going into effect, and it should deny petitioners' request for a stay.

Respectfully submitted,

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enforce all public health laws. The latter statute requires OHA to establish "foundational programs" including a program for "prevention of injury and disease" which includes "prevention and control of tobacco use." While those statutes do not independently provide authority for the adopting the rule at issue here, they provide further context for understanding the intended scope of the OHA's supervisory power. Those statutes further support the conclusion that the supervisory power includes the power to temporarily restrict the sale of tobacco vaping products in the fact of public health emergency.

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NOTICE OF FILING AND PROOF OF SERVICE

I certify that on October 18, 2019, I directed the original Respondent's Response to Stay to be electronically filed with the Appellate Court Administrator, Appellate Records Section, and electronically served upon David H. Angeli, attorney for petitioners Smokeless Solutions LLC, Vape Crusaders Premium E-Liquid LLC and Vapor Technology Association, and J. Ryan Adams, attorney for petitioners No Moke Daddy LLC and Paul Bates, using the court's electronic filing system.

I further certify that on October 18, 2019, I directed I directed the Respondent's Response to Stay to be served upon Kristen Lynn Tranetzki and Tyler Francis, attorneys for petitioners Smokeless Solutions LLC, Vape Crusaders Premium E-Liquid LLC and Vapor Technology Association, by mailing a copy, with postage prepaid, in an envelope addressed to:

Kristen Lynn Tranetzki
Tyler Francis
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121 SW Morrison St., Suite 400
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/s/ Michael A. Casper

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