

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

VAPOR TECHNOLOGY ASSOCIATION, IAN
DEVINE, DEVINE ENTERPRISE INC.,
CHRISTOPHER AUSTIN, RISING SUN VAPORS
LLC, OHMERICA LLC, ADAM WEBSTER, THE
STEAM CO. LLC,

Plaintiffs,

v.

CHARLIE BAKER, in his official capacity as
GOVERNOR OF THE COMMONWEALTH OF
MASSACHUSETTS, and MONICA BHAREL,
M.D., in her official capacity as DEPARTMENT
OF PUBLIC HEALTH COMMISSIONER,

Defendants.

CIVIL ACTION
NO. 19-cv-12048-IT

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

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INTRODUCTION

Barely two months ago, States throughout the country began to experience an alarming outbreak of severe lung disease associated with the use of e-cigarettes and other vaping products. Within weeks, the incidence of vaping-related lung illnesses skyrocketed. Reflecting the urgent nature of the emerging public health crisis, the federal Centers for Disease Control (“CDC”) activated its “Emergency Operations Center” to dedicate greater resources to its investigation of the cause of the illness because, while all of the reported cases have now been linked to vaping, investigators have yet to identify a single brand or ingredient that is common to all of the reported cases of the illness. The plaintiffs’ assertion here that the CDC has “principally attribute[d]” the outbreak of lung disease to “black-market THC-based vaping products” is both dangerous and wrong. To the contrary, the most recent CDC data reflects that a significant percentage of affected patients vaped nicotine and THC products (41%) or nicotine products alone (16%), and it remains unknown how many cases of the illness are attributable to sales of vaping products in stores. In addition, numerous medical experts have recognized the severe and potentially long-term effects of vaping, although the full extent of the damage is yet to be known.

In the midst of this public health crisis, Governor Baker, acting pursuant to statutory authority, declared a public health emergency in the Commonwealth, and Department of Public Health (“DPH”) Commissioner Bharel, with the approval of the Governor and the Public Health Council, issued an Emergency Order banning the sale or display of all vaping products to consumers in Massachusetts. On October 3, 2019, in response to inquiries about the scope of the Order, the Commissioner issued another order, referred to as an Implementation Order, “to ensure clarity for businesses subject to” the Emergency Order and to ensure its uniform enforcement. The Implementation Order clarified that the original Emergency Order prohibits the sale of vaping products in Massachusetts retail stores, as well as the sale online, by phone, or

by other means for delivery to a consumer in Massachusetts; but the Order does not prohibit a Massachusetts seller from making a sale online, by phone, or by other means of delivery to a consumer located in another State. The Implementation Order also clarified that the Emergency Order “does not apply to the online ‘display’ of vaping products” and “does not limit the advertisement of vaping products.”

The plaintiffs—a trade association of manufacturers and retailers of vaping products, together with retailers from Massachusetts, New Hampshire, and Connecticut—filed this action on October 1, 2019, seeking a temporary restraining order and preliminary injunction prohibiting enforcement of the Emergency Order. The plaintiffs’ request for immediate relief is based on the economic harm that they allege they will suffer if the Order remains in effect. While defendants recognize that the ban on the sale of these dangerous products will cause economic displacement for some, the health of Massachusetts residents must take precedence over plaintiffs’ economic interests. Until state and federal public health officials are able to pinpoint the specific source of the rapidly growing number of vaping-related illnesses, the continued sale of vaping products in Massachusetts will almost certainly lead to more cases of severe illness, and potentially deaths, among our residents. The Emergency Order is intended to prevent that tragic outcome.

BACKGROUND

I. The Emerging Epidemic of Severe Cases of Vaping-Related Lung Injury.

Throughout the summer of 2019, doctors in hospitals across the country treated an influx of patients who arrived gasping for breath and, in many cases, vomiting and experiencing chest pain, fatigue, and fever.¹ Chest x-rays and CT scans of the patients revealed hazy, opaque

¹ N. Martin, *Why the vaping lung illness crisis is exploding now, according to Boston doctors*, BOSTON GLOBE (Sept. 17, 2019) (Kobick Aff. Ex. A); B. Abbott, “*The Bells Started Going Off.*” *How Doctors Uncovered the Vaping Crisis*, WALL STREET J. (Sept. 23, 2019) (Kobick Aff. Ex. B).

blotches in the patients' lungs, but the patients tested negative for pneumonia and other infections.² Many of the patients were admitted to intensive care units for respiratory failure, required intubation or mechanical breathing assistance, and suffered from acute respiratory distress syndrome.³ Some were put into medically induced comas; others have markedly diminished lung capacities and uncertain long-term prognoses. *See* Aff. of Alicia Casey, M.D. (“Casey Aff.”) ¶¶ 2-3.⁴

Doctors in Wisconsin and Illinois, who were treating a cluster of patients, notified CDC officials of this emergent lung illness in August 2019. Officials at the Wisconsin Department of Health Services and the Illinois Department of Public Health initiated a joint public health investigation.⁵ While most of the stricken patients had no relevant medical history, doctors realized that they shared one “common denominator”: all reported a recent history of vaping.⁶

Vaping products were first introduced to the United States market in 2007 as an alternative to traditional cigarettes.⁷ Vaporizers are battery-powered devices that use metal coils to heat oils or liquids into vapor to be inhaled into the lungs.⁸ Users can vaporize fluids containing nicotine, cannabidiol (“CBD”), butane hash oils (known as “dabs”), and tetrahydrocannabinol (“THC”), the psychoactive ingredient in marijuana.⁹ In addition to these

² *See id.*; J. Layden et al., *Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin—Preliminary Report*, NEW ENGLAND J. MEDICINE (Sept. 6, 2019), 10.1056/NEJMe1911614 (Kobick Aff. Ex. C).

³ Layden et al., *supra* note 2, at 11.

⁴ *See also* H. Knowles & L. Sun, *What we know about the mysterious vaping-linked illness and deaths*, WASH. POST (Sept. 27, 2019) (Kobick Aff. Ex. D); J. Bosman, *At School, ‘Everyone Vapes,’ and Adults Are in Crisis Mode*, N.Y. TIMES (Sept. 20, 2019) (Kobick Aff. Ex. E).

⁵ Layden et al., *supra* note 2, at 5.

⁶ Abbott, *supra* note 1; *see* Layden et al., *supra* note 2, at 9.

⁷ Layden et al., *supra* note 2, at 2.

⁸ Martin, *supra* note 1.

⁹ Layden et al., *supra* note 2, at 2.

substances, vaping fluids contain other potentially toxic compounds and heavy metals that can damage lungs.¹⁰

On September 6, 2019, the *New England Journal of Medicine* published the first article that systematically described the presentation of the illness seen in the Wisconsin and Illinois victims.¹¹ The “severity of the illness and the recent increase in the incidence of this clinical syndrome,” the authors explained, “indicates that these cases represent a new or newly recognized and worrisome cluster of pulmonary disease related to vaping.”¹² Victims of the illness included teenagers and adults, urban and rural residents, men and women.¹³ Of those victims who were extensively interviewed, 44% used both nicotine and THC products in the 90 days before symptom onset, 37% used only THC products, and 17% used only nicotine products.¹⁴ Aside from the linkage to vaping, the mechanism of illness was unknown and the illness could not be attributed to any single product or substance.¹⁵ On the same day the *New England Journal of Medicine* published this study, a separate editorial in the journal stressed that “there is clearly an epidemic that begs for an urgent response.”¹⁶

The number of afflicted patients kept climbing through September. By September 18, the CDC, which was conducting its own investigation, had been notified of seven deaths caused by

¹⁰ See D. Christiani, *Vaping-Induced Lung Injury*, NEW ENGLAND J. MEDICINE (Sept. 6, 2019), 10.1056/NEJMe1912032 (Kobick Aff. Ex. F) (listing “carbonyls, volatile organic compounds (such as benzene and toluene), particles, trace metal elements according to flavor, and bacterial endotoxins and fungal glucans”); Abbott, *supra* note 1.

¹¹ Layden et al., *supra* note 2.

¹² *Id.* at 6.

¹³ *Id.* at 9.

¹⁴ *Id.* at 12.

¹⁵ *Id.* at 19.

¹⁶ Christiani, *supra* note 10.

vaping and 530 confirmed or probable cases of vaping-associated lung disease nationwide.¹⁷

Federal health officials urged the public to stop vaping all substances, including nicotine and THC, while they investigated the cause of the disease.¹⁸

On September 24, a congressional subcommittee held a hearing on the vaping crisis. Dr. Anne Schuchat, the Principal Deputy Director of the CDC, testified that “hundreds more” cases of vaping-related illness had been reported to the CDC since September 18.¹⁹ At a different congressional subcommittee hearing the following day, Dr. Norman Sharpless, Acting Commissioner of the Food and Drug Administration (“FDA”), testified that “[i]nvestigating this [vaping] crisis is FDA’s Office of Criminal Investigations’ top priority.”²⁰ Nevertheless, he explained, the “investigation has not identified any specific product or substance or vaping product that is linked to all cases,” and “it is not clear” if the cases “have a common cause, or if they involve different diseases with similar presentations.”²¹ “In retrospect,” Dr. Sharpless acknowledged, “the F.D.A. should have acted sooner.”²²

II. Governor Baker’s Declaration of a Public Health Emergency and Commissioner Bharel’s Order Temporarily Banning the Sale of Vaping Products.

Like States nationwide, Massachusetts is in the midst of the outbreak of vaping-related lung illness. As of September 30, 2019, DPH had received reports of more than 80

¹⁷ Anne Schuchat, M.D., *Written Testimony: House Committee on Oversight & Reform, Subcommittee on Economic and Consumer Policy*, at 1 (Sept. 24, 2019) (Kobick Aff. Ex. G).

¹⁸ See N. Martin, *38 patients now have reported to have mysterious vaping-related lung illness in Mass.*, BOSTON GLOBE (Sept. 16, 2019) (Kobick Aff. Ex. H).

¹⁹ M. Perrone, *US official expects ‘hundreds more’ cases of vaping illness*, BOSTON GLOBE (Sept. 24, 2019) (Kobick Aff. Ex. I).

²⁰ Testimony of Norman E. Sharpless, M.D., *House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations*, at 12 (Sept. 25, 2019) (Kobick Aff. Ex. J).

²¹ *Id.* at 11.

²² S. Kaplan et al., *Juul Replaces Its C.E.O. with a Tobacco Executive*, N.Y. TIMES (Sept. 25, 2019) (Kobick Aff. Ex. K).

Massachusetts residents with lung injuries potentially linked to vaping.²³ Five of the cases were confirmed and five were probable under the criteria for the vaping-related illness established by the CDC; 51 others remained under evaluation.²⁴ Of the 10 confirmed and probable cases – a group that included teenagers and adults – one person had vaped only nicotine products, four had vaped nicotine and THC products, and had five vaped only THC products.²⁵

On September 24, Governor Baker invoked his authority under Mass. Gen. L. c. 17, § 2A to declare that a public health emergency exists that is detrimental to the public health in the Commonwealth of Massachusetts.²⁶ The Governor’s declaration determined that it is “necessary for DPH to take action immediately to address this public health emergency” of “severe lung disease associated with the use of vaping products.”²⁷ Noting the explosion of reported cases nationwide and in Massachusetts, the declaration stressed that “the specific cause of this disease is unknown,” but that all cases “have a history of vaping and have indicated a history of using vaping products containing [THC], nicotine, or a combination of THC and nicotine.”²⁸

Following the Governor’s declaration of a public health emergency, and in accordance

²³ Lindsey Tucker, *Request for Approval of the Public Health Council for the Commissioner to Take Action to Address the Public Health Emergency of Vaping* (Sept. 24, 2019) (Kobick Aff. Ex. L); D. McDonald, *Mass. announces five more cases of vaping-related illness*, BOSTON GLOBE (Sept. 30, 2019) (Kobick Aff. Ex. M).

²⁴ *Id.*

²⁵ *Id.*

²⁶ Charles D. Baker, *Governor’s Declaration of Emergency 2* (Sept. 24, 2019) (Kobick Aff. Ex. N). The statute provides that, upon a declaration by the Governor “that an emergency exists which is detrimental to the public health” the Commissioner of the Department of Public Health “may, with the approval of the governor and the public health council, during such period of emergency, take such action and incur such liabilities as [she] may deem necessary to assure the maintenance of public health and the prevention of disease.” Mass. Gen. L. c. 17, § 2A. Upon the Governor’s declaration that such an emergency has ended, “all powers granted to and exercised by the commissioner under this section shall terminate.” *Id.*

²⁷ *Governor’s Declaration of Emergency*, at 1-2.

²⁸ *Id.* at 1.

with Mass. Gen. L. c. 17, § 2A, the Public Health Council met and unanimously voted to approve Commissioner Bharel's Order temporarily banning the sale of vaping products (hereinafter "Emergency Order").²⁹ The Council heard from five physicians on the front lines of the public health crisis: Dr. Alicia Casey, Pediatric Pulmonologist at Boston Children's Hospital; Dr. Benjamin Raby, Chief of Pulmonary Medicine at Boston Children's Hospital; Dr. Sharon Levy, Director of Adolescent Substance Use and Addiction Program at Boston Children's Hospital; Dr. Sucharita Kher, Adult Pulmonologist and Critical Care Doctor, Director of the Pulmonary Clinic at Tufts Medical Center; and Dr. Maryanne Bombaugh, President of the Massachusetts Medical Society.³⁰ Dr. Casey explained that, in the acute cases she has seen, "the lungs are diffusely damaged and the pattern of injury . . . is compatible with toxic chemical lung damage."³¹ "This acute illness seems quite different from the chronic illnesses that happen after years of smoking," Dr. Kher testified.³² In line with that testimony, Dr. Raby emphasized that it "is simply untrue" to claim that e-cigarettes are "safer" than traditional cigarettes.³³ Commissioner Bharel also explained that, as part of its implementation of the Order, DPH would immediately increase its capacity to field calls to its smoking cessation hotline, 1-800-QUIT-NOW, and would provide eight weeks of free nicotine replacement treatment to anyone who calls that hotline, a commitment that doubled the amount of nicotine replacement treatment previously provided.³⁴

²⁹ Monica Bharel, MD, MPH, *Order of the Commissioner of Public Health Pursuant to the Governor's September 24, 2019 Declaration of a Public Health Emergency* (Sept. 24, 2019) (Kobick Aff. Ex. O).

³⁰ Transcript of Emergency Meeting of the Public Health Council 7:14-22 (Sept. 24, 2019) (Kobick Aff. Ex. P).

³¹ *Id.* at 9:5-7.

³² *Id.* at 20:3-5.

³³ *Id.* at 14:17-24, 15:1-5.

³⁴ *Id.* at 6:1-13.

In substance, the Commissioner’s Emergency Order forbade the “sale or display of all vaping products to consumers in retail establishments, online, and through any other means . . . in the Commonwealth.” It covered THC and nicotine products, flavored and unflavored. The Emergency Order, which was effective immediately, will remain in effect for four months, until January 25, 2020, or until the public health emergency is terminated or the Emergency Order is rescinded by the Commissioner. The same day the Emergency Order was issued, DPH notified retailers of the Order,³⁵ issued guidance to local boards of health on the implementation of the Order,³⁶ and sent a letter to health care providers with resources for treating patients who are addicted to nicotine and other substances.³⁷

On October 3, 2019, the Commissioner issued another Order to “ensure clarity for businesses subject to the Emergency Order and uniformity in enforcement.”³⁸ This Implementation Order explained that the ban on “display” of vaping products “applies only to the *physical* display of vaping products in retail establishments in Massachusetts.”³⁹ Thus, the term “display” in the Emergency Order “does not apply to the online ‘display’ of vaping products,” nor does it “limit the advertisement of vaping products.”⁴⁰ The Implementation Order also made clear that the Emergency Order prohibits retailers in Massachusetts from making in-store sales of vaping products; prohibits sellers anywhere from making sales online, by phone, or

³⁵ See Monica Bharel, MD, MPH, *Order of the Commissioner of Public Health Pursuant to the Governor’s September 24, 2019 Declaration of a Public Health Emergency (Temporary Ban on Sale or Display of Vaping Products)* (Sept. 24, 2019) (Kobick Aff. Ex. Q).

³⁶ See Monica Bharel, MD, MPH, Memorandum to Local Boards of Health re: Implementation of DPH order regarding vaping products (Sept. 24, 2019) (Kobick Aff. Ex. R).

³⁷ See Monica Bharel, MD, MPH, Letter to Providers (Sept. 24, 2019) (Kobick Aff. Ex. S).

³⁸ See Monica Bharel, MD, MPH, *Order of the Commissioner of Public Health Pursuant to the Governor’s September 24, 2019 Declaration of a Public Health Emergency (Oct. 3, 2019) (“Implementation Order”)* (Kobick Aff. Ex. T).

³⁹ *Id.* (emphasis added).

⁴⁰ *Id.*

by other means for delivery of vaping products to a consumer located in Massachusetts; and has no effect on sales online, by phone, or by other means for delivery of vaping products to consumers outside of Massachusetts.⁴¹

III. The Most Recent Data on Deaths and Injuries from Vaping.

Two days after the Governor's Declaration and the Commissioner's Emergency Order, the CDC released updated numbers of vaping-related fatalities and illnesses across the country. As of September 26, twelve people from ten different states had died from vaping-related lung injuries.⁴² Forty-six States had reported 805 vaping-related cases of lung illness to the CDC.⁴³ Consistent with the aforementioned data from Wisconsin and Illinois, 41% of the afflicted patients had vaped nicotine and THC products, 36% had vaped only THC products, and 16% had vaped only nicotine products.⁴⁴ The CDC emphasized that "[t]he specific chemical exposure(s) causing this outbreak is unknown at this time,"⁴⁵ and it continued to recommend that people refrain from using any vaping products.⁴⁶

Two days ago, doctors at the Mayo Clinic published research in the *New England Journal of Medicine* concluding that the lungs of people with acute vaping-related lung illness

⁴¹ *Id.*

⁴² CDC, Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping (Sept. 26, 2019) (hereinafter "CDC Outbreak Sept. 26") (Kobick Aff. Ex. U); D. Grady, *Vaping-Related Illnesses Climb to 805, C.D.C. Says*, N.Y. TIMES (Sept. 26, 2019) (Kobick Aff. Ex. V).

⁴³ CDC Outbreak Sept. 26, *supra* note 42.

⁴⁴ CDC, *Characteristics of a Multistate Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping—United States, 2019*, MORBIDITY AND MORTALITY WEEKLY REPORT, Vol. 68, p. 2 (Sept. 27, 2019) (Kobick Aff. Ex. W).

⁴⁵ *Id.* at 3.

⁴⁶ CDC Outbreak Sept. 26, *supra* note 42.

most closely resembled the lungs of people with “chemical burns.”⁴⁷ As the reporting on this study reiterated,

Medical investigators have been unable to identify exactly what is causing the lung damage, or even how many harmful substances are involved. They do not know whether the source is the liquids being vaped, or a toxin released from the materials used to make vaping devices. It is also unclear whether some devices used in vaping may be defective.⁴⁸

According to an author of the study, the lungs of people with vaping-related illness exhibit “the kind of change you would expect to see in an unfortunate worker in an industrial accident where a big barrel of toxic chemicals spills, and that person is exposed to toxic fumes and there is a chemical burn in the airways.”⁴⁹ “The injuries also look like those seen in people exposed to poisons like mustard gas, a chemical weapon used in World War I,” the doctor added.⁵⁰

ARGUMENT

A preliminary injunction is “an extraordinary and drastic remedy,” *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997), “never awarded as of right.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). “To obtain a preliminary injunction, the plaintiffs bear the burden of demonstrating (1) a substantial likelihood of success on the merits, (2) a significant risk of irreparable harm if the injunction is withheld, (3) a favorable balance of hardships, and (4) a fit (or lack of friction) between the injunction and the public interest.” *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003). The last two factors “merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). The first factor—likelihood of success on the merits—is the “‘sine qua non’ of a preliminary injunction.”

⁴⁷ D. Grady, *Lung Damage from Vaping Resembles Chemical Burns, Report Says*, N.Y. TIMES (Oct. 2, 2019) (Kobick Aff. Ex. X); Y. Butt et al., *Pathology of Vaping-Associated Lung Injury*, NEW ENGLAND J. MEDICINE (Oct. 2, 2019) (Kobick Aff. Ex. Y).

⁴⁸ Grady, *supra* note 48.

⁴⁹ *See id.*

⁵⁰ *Id.*

Arborjet, Inc. v. Rainbow Treecare Sci. Advancements, Inc., 794 F.3d 168, 173 (1st Cir. 2015) (citations omitted). “[T]he movant, by a clear showing, carries the burden of persuasion.” *Mazurek*, 520 U.S. at 972.

Here, the Court should deny the plaintiffs’ motion for a temporary restraining order and preliminary injunction, because plaintiffs fail to establish that they are likely to succeed on any of their claims. The Order does not place an undue burden on interstate commerce and does not violate plaintiffs’ First Amendment rights. In addition, the balance of equities favors upholding the temporary ban, as the financial harm that plaintiffs allegedly will suffer is outweighed by the overwhelming public interest in protecting Massachusetts residents from a rapidly escalating, life-threatening public health emergency. For the same reason, the public interest strongly weighs in favor of keeping the ban in place while state and federal investigators work to determine the source of the illness.

I. PLAINTIFFS FAIL TO ESTABLISH A LIKELIHOOD OF SUCCESS ON THE MERITS OF ANY OF THEIR LEGAL CLAIMS.

A. The Emergency Order Comports with the Dormant Commerce Clause.

The Commerce Clause, which authorizes Congress “[t]o regulate Commerce . . . among the several States,” U.S. Const., Art. I, § 8, cl. 3, also “limits the ability of States and localities to regulate or otherwise burden the flow of interstate commerce.” *Maine v. Taylor*, 477 U.S. 131, 151 (1986). Nevertheless, the “restriction imposed on states by the dormant Commerce Clause is not absolute.” *Pharmaceutical Research & Manufacturers of Am. v. Concannon*, 249 F.3d 66, 79 (1st Cir. 2001), *aff’d* 538 U.S. 644 (2003). Rather, “the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected.” *Maine*, 477 U.S. at 138.

The plaintiffs do not contend that the Emergency Order discriminates against interstate

commerce on its face, and properly so. Instead, they argue that the Emergency Order places an undue burden on interstate commerce under the test articulated in *Pike v. Bruce Church, Inc.*, which applies when a challenged government action “regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental.” 397 U.S. 137, 142 (1970); *see* Pltfs.’ Mem. 11. Under that test, the government action must “be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142. “State laws frequently survive this *Pike* scrutiny,” the Supreme Court has emphasized. *Dept. of Revenue of Ky. v. Davis*, 553 U.S. 328, 339 (2008). Moreover, “[t]he crucial inquiry” in any undue-burden case “must be directed to determining whether [the challenged law] is basically a protectionist measure, or whether it can fairly be viewed as a law directed to legitimate local concerns, with effects upon interstate commerce that are only incidental.” *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978).

The Emergency Order is plainly not a “protectionist measure” designed to bolster in-state industry and burden out-of-state competitors. The Governor and Commissioner, public officials charged with safeguarding the wellbeing of Massachusetts residents, have taken an emergency action to target an imminent threat to the health and safety of Massachusetts residents. They determined that, in light of the severe lung illness afflicting users of vaping products in Massachusetts and nationwide, a temporary ban on vaping products is necessary to prevent deaths and injuries within Massachusetts. *See supra*, at 6-7. Accordingly, the Commissioner prohibited the sale of vaping products for four months or until the public health emergency is terminated or the Order is rescinded. That Order is a legitimate policy decision directed to an urgent matter of local concern. Indeed, because it involves public health and safety, it goes to the core of the Commonwealth’s police powers. *See United Haulers Ass’n v. Oneida-Herkimer*

Solid Waste Mgmt. Auth., 550 U.S. 330, 344 (2007) (courts “should be particularly hesitant to interfere . . . under the guise of the Commerce Clause” where a local government engages in a traditional government function); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (noting “the historic primacy of state regulations of matters of health and safety”).

Nor does the Emergency Order unduly burden interstate commerce or disrupt national uniformity. This Court has emphasized that “[i]t does not contravene the dormant commerce clause for a state merely to regulate the distribution within its borders of a product that travels in interstate commerce.” *Zogenix v. Baker*, 2015 WL 1206354, No. 14-11689-RWZ, at *7 (D. Mass. March 17, 2015) (rejecting a dormant Commerce Clause challenge to regulations promulgated to address public health crisis in opioid abuse). Thus, in *National Kerosene Heater Association v. Commonwealth*, this Court rejected a dormant Commerce Clause challenge to a ban on the sale of certain kerosene space heaters within Massachusetts, a ban that was enacted for the purpose of protecting public health and safety. *See* 653 F. Supp. 1079, 1092-96 (D. Mass. 1987). As the Court explained, a “total ban” of a product “certainly” disrupts national uniformity “to a lesser extent than a regulation which imposes certain manufacturing standards which conflict with manufacturing standards imposed by other states.” *Id.* at 1093. In the former case, a business may continue selling the same product nationwide; it “simply may not sell [the product] in Massachusetts.” *Id.* In the latter case, the manufacturer must accommodate conflicting state-law requirements. *See id.*

The Supreme Court has likewise upheld bans on products against dormant Commerce Clause challenges, and it has done so in cases involving government objectives less urgent than stemming a life-threatening public health crisis. In *Minnesota v. Clover Leaf Creamery Co.*, for example, Minnesota banned the sale of milk sold in plastic, nonreturnable containers in order to

promote conservation. 449 U.S. 456, 458-59 (1981). Even if the ban would burden the out-of-state plastics industry more than the non-plastic bottling industry in Minnesota, the Court reasoned, the burden was “not ‘clearly excessive’ in light of the substantial state interest in promoting conservation of energy and other natural resources.” *Id.* at 473. And in *Exxon Corp. v. Governor of Maryland*, the Court upheld a Maryland law that, in response to a petroleum shortage, banned retail gasoline stations operated by producers and refiners of petroleum products. 437 U.S. 117, 125-30 (1978). Notably, the Court rejected the plaintiffs’ “novel suggestion that because the economic market for petroleum products is nationwide, no State has the power to regulate the retail marketing of gas.” *Id.* at 128. Rather, the Court concluded that the state retained authority to regulate gasoline, and that Maryland’s ban of certain petroleum stations did not place an undue burden on interstate commerce. *Id.* at 127-29.

The plaintiffs have no answer to this binding precedent. They argue that the Emergency Order prohibits the online advertising of vaping products across state lines. *See* Pltfs.’ Mem. 11-12. But the Implementation Order makes clear that the Emergency Order only prohibits the *physical* display of vaping products in Massachusetts stores, and that it “does not limit the advertisement of vaping products.” *See* Implementation Order. The plaintiffs also object that the Emergency Order prevents out-of-state residents from purchasing vaping products in Massachusetts stores and prevents out-of-state businesses from selling vaping products through online or mail-order transactions for delivery to Massachusetts residents. *See* Pltfs.’ Mem. 11. But the plaintiffs have introduced no evidence on the frequency with which out-of-state residents travel to Massachusetts to purchase vaping products. Nor have they introduced evidence on how often Massachusetts residents order vaping products online from out-of-state retailers. And even if these transactions did occur, the modest burden imposed by temporarily barring these

transactions is not “clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142. The plaintiffs’ theory—that a ban on a product within Massachusetts unduly burdens interstate commerce merely because it has incidental effects on online transactions—would threaten the constitutionality of many of the Commonwealth’s essential public safety measures. *See, e.g.*, Mass. Gen. L. c. 140, § 131M (banning the sale of assault weapons and large-capacity magazines in Massachusetts); *see also SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 195 (2d Cir. 2007) (holding that the plaintiff did “not state a valid claim for relief under the dormant Commerce Clause simply because it conduct[ed] business over the Internet,” and noting that there was “no risk that the [challenged law] will control sales . . . to anyone other than [in-state] consumers, whether such sales occur in person or online”).

The plaintiffs contest the strength of the Commonwealth’s interests advanced by the Emergency Order, but their efforts to undercut the rationale for the Order are inaccurate and misleading. The Emergency Order applies to both nicotine and THC products because, as the CDC has explained, “[t]he specific chemical exposure(s) causing this outbreak is unknown” and consumers should therefore refrain from using *any* vaping products.⁵¹ The plaintiffs argue that “most of the reported lung injuries present in patients who self-reported using vaping products containing THC,” Pltfs.’ Mem. at 13, but most of the reported lung injuries also present in patients who self-reported using vaping products containing nicotine. Since early September, the data has shown that 41-44% of victims reported using nicotine *and* THC products; 16-17% of victims reported using *only* nicotine products; and 36-37% of victims reported using *only* THC products. *See supra*, at 4, 9. The Emergency Order applies to nicotine and THC products

⁵¹ CDC Outbreak Sept. 26, *supra* note 42; CDC, *Characteristics of a Multistate Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping—United States, 2019*, MORBIDITY AND MORTALITY WEEKLY REPORT, Vol. 68, p. 2 (Sept. 27, 2019).

because a significant percentage of victims used only nicotine products, and a significant percentage of victims used only THC products. *See supra*, at 4, 9; Casey Aff. ¶ 4. The Order is not overbroad, as the plaintiffs contend; rather, reflecting the best available evidence, it is tailored to scope of the still-unfolding public health crisis. *Cf. Zogenix*, 2015 WL 1206354, at *8 (“[A]ny burden that the [agency] regulations might have on interstate commerce cannot ‘clearly exceed’ the regulations’ putative benefits of promoting public health and safety by combating opioid abuse.”)

The Commonwealth’s temporary ban on vaping products does not impose an undue burden on interstate commerce; if there is any burden at all, it is not “clearly excessive” when balanced against the state’s vital objective of preventing deaths and injuries from an emergent, but still poorly understood, illness caused by vaping products. The plaintiffs have failed to demonstrate any likelihood of success on the merits on their dormant Commerce Clause claim.

B. The Emergency Order Is Wholly Consistent with the First Amendment.

The plaintiffs’ First Amendment challenge to the Emergency Order depends on their contention that the Order would prohibit advertising, “a form of commercial speech protected by the First Amendment.” Pltf. Mem. at 14. More specifically, they contend that advertising of vaping products would constitute protected speech under the factors outlined in *Central Hudson Gas & Electric Corp. v. Public Service Comm’n*, 447 U.S. 557, 566 (1980), the Supreme Court’s leading case governing commercial speech. Pltf. Mem. at 15-16. By way of example, they contend that a New Hampshire retailer would be prevented from advertising its products online or in print, if the advertising were available in Massachusetts, “even if the advertising simply invited Massachusetts residents to purchase vaping products lawfully in New Hampshire.” *Id.*

The plaintiffs cannot succeed on the merits of their First Amendment claim for the simple reason that the claim is premised entirely on their erroneous interpretation of the Order as

prohibiting advertising (whether online or in print). In fact, the Order does not apply to advertising at all. As the Implementation Order explains, the Emergency Order “does not apply to the online ‘display’ of vaping products”: and “does not . . . limit the advertisement of vaping products.” *See* Implementation Order. The original Order’s reference to “display of all vaping products to consumers” thus prohibits *only* “the physical display of vaping products in retail establishments in Massachusetts,” and simply “requires Massachusetts retailers to remove from their shelves usable product that falls within the Emergency Order’s definition of ‘vaping products.’” *Id.*

Moreover, even if plaintiffs expanded their First Amendment claim to encompass a challenge to the Order’s prohibition on “physical display of vaping products in retail establishments in Massachusetts,” such a claim would fail. Regardless of whether an in-store display of a *lawful* product might be found to have an expressive component in certain circumstances,⁵² “the Supreme Court made clear [in *Central Hudson*] that ‘[t]he government may ban . . . commercial speech related to illegal activity.’” *National Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 78 (1st Cir. 2013) (quoting *Central Hudson*, 447 U.S. at 563-64). And more recently, the Court stated that “[o]ffers to engage in illegal transactions are categorically excluded from First Amendment protection.” *United States v. Williams*, 553 U.S. 285, 298 (2008) (upholding conviction based on violation of statute criminalizing offers to provide or requests to obtain child pornography or child obscenity, both

⁵² The First Circuit has explained that, in a case involving regulation of tobacco advertising, the Supreme Court left unresolved the question whether displays of lawful tobacco products in fact had any expressive component. *See National Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 78 (1st Cir. 2013) (stating that while the Supreme Court recognized in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), that self-service displays of tobacco products “may have [had] a communicative component,” the decision in *Lorillard* “did not decide that the displays did in fact have a communicative value”).

of which were constitutionally proscribed). Because the Commissioner's Order lawfully prohibits sales of vaping products in Massachusetts, displays of such products in Massachusetts stores are not protected speech. Moreover, the Commonwealth has a compelling interest in preventing further death and injury from this vaping-related lung illness and, in light of the indeterminate cause of the outbreak, the Emergency Order "is not more extensive than is necessary to serve" that interest. *Central Hudson*, 447 U.S. at 566.

II. ANY HARM THAT PLAINTIFFS EXPERIENCE CANNOT JUSTIFY THE EXTRAORDINARY RELIEF THEY SEEK.

When, as here, "the moving party cannot demonstrate that [they are] likely to succeed [on the merits], the remaining factors become matters of idle curiosity." *Arborjet*, 794 F.3d at 173; *see also Weaver v. Henderson*, 984 F.2d 11, 14 n.5 (1st Cir. 1993) ("[E]ven 'excruciatingly obvious' injury is irrelevant when a plaintiff has not demonstrated likely success on the merits." (citation omitted)). Here, the plaintiffs have failed to establish that they are likely to prevail on any of their claims.

In any event, the harm that the plaintiffs allege is diminished by the temporary nature of the Emergency Order. The plaintiffs assert that the Order will cause significant financial harm to the vaping industry in Massachusetts and to the out-of-State sellers, allegedly resulting in the closure of their stores and causing attendant layoffs of their employees. Pltf. Mem. at 8-10. While defendants are not unmindful of the economic effects of the Order on plaintiffs' businesses, plaintiffs' asserted harm is diminished by the fact that, contrary to their suggestion, the Order does not require them to "discard their now-prohibited stock," *id.* at 8, and, given the one-to-two-year shelf-life of vaping products,⁵³ the inability to sell these products for four

⁵³ *See* S. Papamichael, *E-Liquid Guide: Ingredients, Shelf Life, Nic Strengths and More*, Vaping360.com (Aug. 2, 2018) (Kobick Aff. Ex. Z).

months is not irreparable harm. *See Am. Grain Products Processing Inst. v. Dep't of Public Health*, 392 Mass. 309, 328 (1984) (vacating preliminary injunction against enforcement of emergency regulation banning sale of food products containing certain levels of ethylene dibromide, and holding that plaintiffs had failed to establish irreparable harm where, among other facts, none of the products were perishable “and nearly all of them have a shelf life of one to four years”). Moreover, the Emergency Order does not prohibit Massachusetts retailers from selling vaping products for delivery to consumers outside of Massachusetts. *See Implementation Order*.

III. THE BALANCE OF HARDSHIPS AND THE PUBLIC INTEREST STRONGLY FAVOR UPHOLDING THE EMERGENCY ORDER.

Issuance of an injunction against enforcement of the Emergency Order would put the health and safety of Massachusetts residents in immediate jeopardy. While plaintiffs have alleged significant disruption to their business interests, the strong public interest in preventing the incidence of additional vaping-related lung illnesses among Massachusetts residents, with attendant hospitalizations and potential deaths, is paramount. Particularly given the “severity of the illness,” *see Layden, supra* note 2, at 6, and the rapidly escalating nature of the epidemic, the balance of equities and public interest weigh strongly in favor of keeping the Emergency Order in place while medical and public health professionals work to determine the cause of the illness. As a federal court in Michigan stated just three days ago, vaping is “at the center of public concern about serious illness, and event death, that has been linked to vaping. The linkage is, as yet, poorly understood and disputed. But the reality of people becoming seriously ill, and in some cases dying, after using certain vaping products, underscores the serious risks at stake while medical professionals unravel the mysteries.” *See Order in Mister E-Liquid LLC v. Governor Gretchen Whitmer* (W.D. Mich. No. 19-cv-00786) (Sept. 30, 2019) (Kobick Aff. Ex.

AA) (denying temporary restraining order against Michigan’s ban on flavored e-cigarette products).

In such circumstances, economic harm must yield to protection of public health. As the Department of Public Health aptly noted during another public health emergency—the 1972 “red tide” in Massachusetts waters that was linked to 26 cases of paralytic shellfish poisoning among residents—the disruption to the shellfish industry resulting from a temporary ban on shellfish products was an “unavoidable cost.” “In an unanticipated and acute public health emergency . . . it is impossible to protect the industry and the consumer simultaneously. The first concern has to be the life and health of the consumer.”⁵⁴

⁵⁴ W. Bicknell & D. Walsh, Massachusetts Dept. of Public Health, *The First ‘Red Tide’ in Recorded Massachusetts History: Managing an Acute and Unexpected Public Health Emergency*, in PROCEEDINGS OF THE FIRST INTERNATIONAL CONFERENCE ON TOXIC DINOFLAGELLATE BLOOMS 456 (V. LoCicero, ed. 1974) (Kobick Aff. Ex. BB). As a law review article summarizing this exercise of the Governor’s and DPH’s powers under Mass. Gen. L. c. 17, § 2A explained, “in September 1972, after the discovery of about 100 dead seabirds in the Merrimack River estuary, a toxic algal bloom south of Plum Island was identified. The [DPH] concluded that the particular toxic algae posed a very real threat of paralytic shellfish poisoning. Then-Governor Dukakis declared a public health emergency which gave the Commissioner of Public Health sweeping powers for any action related to the defined emergency. The Commissioner of Public Health obtained this within two hours of request, and instituted a total embargo on the harvesting, sale, import and export of all fresh and frozen shellfish at wholesale and retail levels. The major lesson of this incident for the present discussion is that a declaration of a public health emergency by the governor gave the DPH sweeping and fluidly defined powers to deal with an unfolding and unpredictable emergency.” Warren Kaplan, *Massachusetts Disease Control Law in the 21st Century: Running in Place?*, 87 MASS. L. REV. 84, 89 (2002).

CONCLUSION

For all the reasons set forth above, the Court should deny plaintiffs' motion for a temporary restraining order and preliminary injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the above memorandum of law, which I filed electronically through the Court's electronic case filing system on October 3, 2019, will be sent electronically to all parties registered on the Court's electronic filing system.

/s/ Amy Spector

Amy Spector, BBO #557611