COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT CIVIL NO. 2019-3102-D

VAPOR TECHNOLOGY ASSOCIATION, IAN DEVINE And DEVINE ENTERPRISE, INC., Plaintiffs,

VS.

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.

MEMORANDUM OF DECISION AND ORDER ON PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

On October 4, 2019, the plaintiffs Vapor Technology Association ("Association"), Ian Devine ("Devine") and Devine Enterprise, Inc. ("Company") (collectively, "plaintiffs") filed their complaint against defendants, Charlie Baker, in his official capacity as Governor of the Commonwealth of Massachusetts ("Governor"), and Monica Bharel, M.D., in her official capacity as Department of Public Health Commissioner ("Commissioner") (collectively, "defendants"). They challenge an emergency order prohibiting the sale or display of all vaping products to consumers until January 25, 2020. See the "Order of the Commissioner of Public Health Pursuant to the Governor's September 24, 2019 Declaration of a Public Health Emergency" ("Order"). The Complaint alleges that the Order reflects executive over-reach, which violates state constitutional separation-of-powers principles, and is arbitrary and capricious. It seeks injunctive relief to invalidate the Order.

Accompanying the complaint was the "Plaintiff's Motion for a Preliminary Injunction" ("Motion"). The court heard argument on October 8, 2019 and took evidence from three live witnesses on October 9 and 18, 2019. The parties supplemented their original filings with

written filings on October 16 (defendants) and October 17 (plaintiffs). After hearing, the Motion is **ALLOWED IN PART AND DENIED IN PART**.

PRELIMINARY FACTUAL FINDINGS

Solely for purposes of the Motion, and without in any way affecting the parties' rights to litigate the factual issues later in this case, the court finds, on the limited record available at the preliminary injunction stage, that the parties are likely to prove following facts:

The Vaping Industry

Vaping devices (also known as "e-cigarettes") are handheld electronic devices that aerosolize a liquid mixture containing nicotine, cannabis-derived products or other ingredients. The Governor's Declaration of Emergency dated September 24, 2019 ("Declaration of Emergency") lists a number of components that vaping products may contain, including THC, flavorings, propylene glycol, vegetable glycerin and, sometimes, toxic chemicals or metal particles. A user inhales the aerosolized vapor into the lungs. Unlike traditional combustible cigarettes, vaping devices do not produce flame or ash. Some professionals and officials view e-cigarettes as a safer alternative to smoking combustible cigarettes. Others disagree.

Nicotine e-liquids were subjected to regulation by the U.S. Food and Drug Administration ("FDA") as of August 8, 2016 and have been on the market in their current form since mid-2017.

The vaping-products industry employs approximately 166,000 people nationwide, including approximately 2,530 in Massachusetts. In Massachusetts, employers include 8 nicotine-vapor products manufacturers, 1 nicotine-liquid-mixture manufacturer and 221 retail vape shops. Massachusetts vapor-products companies and sellers and their employees contribute

nearly \$19 million in state taxes. Sales taxes on vaping products in Massachusetts generate about \$10.7 million annually. The plaintiffs assert that the Order will force a permanent shut down of stores, including Devine's.

The Order

The Order's operative paragraph reads:

The sale or display of all vaping products to consumers in retail establishments, online and through any other means, including all non-flavored and flavored vaping products, including mint and menthol, including tetrahydrocannabinol (THC) and any other cannabinoid, is prohibited in the Commonwealth.

The Order then defines the term "vaping products" and exempts "any product that has been approved by the federal Food and Drug Administration either as a tobacco use cessation product or for other medical purposes and which is being marketed and sold or prescribed solely for the approved purpose." The Order "takes effect immediately and shall remain in effect, unless extended with the approval of the Governor and the Public Health Council, through January 25, 2020, or until the declared public health emergency is terminated, or the Order is otherwise rescinded by me, whichever happens first."

The Order also provides for enforcement by fines and other means:

Pursuant to the authority granted by G.L. c. 17, § 2A, this Order may be enforced in the manner of a regulation adopted pursuant to G.L. c. 111, § 31, and by injunction through proceedings initiated in the Superior Court. A person or entity found in violation of this Order may also be subject **to the maximum fine** provided in G.L. c. 111, § 31; provided that violations shall be calculated on a per item and per transaction basis and may be punished cumulatively. [Emphasis added].

On October 4, 2019, apparently in response to federal litigation, the Commissioner made certain clarifications or changes not relevant here, in an "Implementation Order, Order of the Commissioner of Public Health Pursuant to the Governor's September 24, 2019 Declaration of a

The Science

The parties appear to agree on certain points. Since August, 2019, a serious, multistate outbreak of vaping-associated pulmonary disease has come to the attention of the medical and public health professions, as well as regulators. The parties *to this case* agree that vaping THC products and products obtained on the black market cause such disease. They disagree whether nicotine vaping products also have caused this disease.

The most authoritative and objective discussion of the lung injury outbreak caused by vaping appears in the publications of the Centers for Disease Control and Prevention ("CDC") and the FDA. As of October 17, 2019, the CDC has published the following information, among other things, on its website (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html) (last visited October 18, 2019):

What We Know

- As of October 15, 2019, 1,479* lung injury cases associated with the use of e-cigarette, or vaping, products have been reported to CDC from 49 states (all except Alaska), the District of Columbia, and 1 U.S. territory.
- Thirty-three deaths have been confirmed in 24 states.
- All patients have reported a history of using e-cigarette, or vaping, products.
- We do know that THC is present in most of the samples tested by FDA to date, and most patients report a history of using THC-containing products.
- The latest national and state findings suggest products containing THC, particularly those obtained off the street or from other informal sources (e.g. friends, family members, illicit dealers), are linked to most of the cases and play a major role in the outbreak.
- As such, we recommend that you should not use e-cigarette, or vaping, products that contain THC.
- Since the specific causes or causes of lung injury are not yet known, the only way to assure that you are not at risk while the investigation continues is to

consider refraining from use of all e-cigarette, or vaping, products

• The use of e-cigarettes, or vaping, products is unsafe for all ages, including youth and young adults. Nicotine is highly addictive and can harm adolescent brain development, which continues into the early to mid-20s.

What We Don't Know

- At this time, FDA and CDC have not identified the cause or causes of the lung injuries in these cases, and the only commonality among all cases is that patients report the use of e-cigarette, or vaping, products.
- No one compound or ingredient has emerged as the cause of these illnesses to
 date; and it may be that there is more than one cause of this outbreak. Many
 different substances and product sources are still under investigation. The specific
 chemical exposure(s) causing lung injuries associated with e-cigarette
 product use, or vaping, remains unknown at this time.

What CDC Recommends

- CDC recommends that people **should not**:
 - o Use e-cigarette, or vaping, products that contain THC.
 - o Buy any type of e-cigarette, or vaping, products, particularly those containing THC, off the street.
 - Modify or add any substances to e-cigarette, or vaping, products that are not intended by the manufacturer, including products purchased through retail establishments.
- At present, CDC continues to recommend that people **consider refraining from** using e-cigarette, or vaping, products that contain nicotine.
- If you are an adult using e-cigarette, or vaping, products to quit cigarette smoking, do not return to smoking cigarettes. Use evidence-based treatments, including healthcare provider counseling and FDA approved medications. [icon omitted]
- If you have recently used an e-cigarette or vaping product, see a healthcare provider immediately if you develop symptoms like those reported in this outbreak.
- Irrespective of the ongoing investigation:
 - E-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant.
 - Adults who do not currently use tobacco products should not start using ecigarette, or vaping, products.
 - THC use has been associated with a wide range of health effects, particularly with prolonged heavy use. The best way to avoid potentially harmful effects is to not use THC, including through e-cigarette, or vaping, products. Persons with marijuana use disorder should seek

- evidence-based treatment by a health care provider.
- There is no safe tobacco product. All tobacco products, including ecigarettes, carry a risk.
- o CDC will continue to update guidance, as appropriate, as new data emerges from this complex outbreak.

Latest Outbreak Information

- As of October 15, 2019, 1,479* lung injury cases associated with e-cigarette use, or vaping, have been reported to CDC from the District of Columbia, 1 U.S. territory (USVI) and all 49 states (all except Alaska).
- Thirty-three deaths have been confirmed in 24 states: Alabama, California (3), Connecticut, Delaware, Florida, Georgia (2), Illinois, Indiana (3), Kansas (2), Massachusetts, Michigan, Minnesota (3), Mississippi, Missouri, Montana, Nebraska, New Jersey, New York, Oregon (2), Pennsylvania, Tennessee, Texas, Utah and Virginia. More deaths are under investigation.
 - The median age of deceased patients was 44 years and ranged from 17 to 75 years.
- Among 1,358 patients with data on age and sex:
 - o 70% of patients are male.
 - O The median age of patients is 23 years and ages range from 13 to 75 years.
 - o 79% of patients are under 35 years old.
 - o By age group category:
 - 15% of patients are under 18 years old;
 - 21% of patients are 18 to 20 years old;
 - 18% of patients are 21 to 24 years old;
 - 25% of patients are 25 to 34 years old; and
 - 21% of patients are 35 years or older.
- To date, national and state data suggest that products containing THC, particularly those obtained off the street or from other informal sources (e.g., friends, family members, or illicit dealers), are linked to most of the cases and play a major role in the outbreak.
- All patients have a reported history of e-cigarette product use, or vaping, and no consistent evidence of an infectious cause has been discovered. Therefore, the suspected cause is exposure to a chemical or chemicals.
- The specific chemical exposure(s) causing lung injuries associated with ecigarette use, or vaping, remains unknown at this time.
- Among 849 patients with information on substances used in e-cigarette, or vaping, products in the 3 months prior to symptom onset**:
 - O About 78% reported using THC-containing products; 31% reported exclusive use of THC-containing products.
 - O About 58% reported using nicotine-containing products; 10% reported exclusive use of nicotine-containing products.

• This complex investigation spans almost all states, involves over a thousand patients, and involves a wide variety of brands and substances and e-cigarette, or vaping, products. Case counts continue to increase and new cases are being reported, which makes it more difficult to determine the cause or causes of this outbreak.

(Emphasis added). The court notes the CDC's different recommendations for THC, black-market and modified products ("should not use") and for nicotine products ("CDC continues to recommend that people **consider** refraining from using e-cigarette, or vaping, products that contain nicotine") (Emphasis added). CDC also has stated: "the predominant use of prefilled THC-containing cartridges among patients with lung injury associated with e-cigarette use suggests that they play an important role." CDC does not address the specific issues raised by medical use of marijuana. Nor does the court in this case at this time.

The FDA's recommendations are similar, though focused even more directly upon THC, black market and modified vaping products. See https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping (last visited October 18, 2019). Its latest update bears the title: "Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street/ FDA strengthens warning to public to stop using THC-containing vaping products and any vaping products obtained off the street."

Recommendations for the Public:

FDA recommends:

- Do not use vaping products that contain THC.
- Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources.
- Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments.
- No vaping product has been approved by the FDA for therapeutic uses or

authorized for marketing by the FDA. The agency recommends contacting your health care provider for more information about the use of THC to treat medical conditions.

- No youth or pregnant women should be using any vaping product, regardless of the substance. Adults who do not currently use tobacco products should not start using these products. If you are an adult who uses e-cigarettes instead of cigarette smoking, do not return to smoking cigarettes.
- If you choose to use these products, monitor yourself for symptoms (e.g., cough, shortness of breath, chest pain) and promptly seek medical attention if you have concerns about your health. . . . [Emphasis supplied].

There is a complete disagreement as to other aspects of the science, particularly on whether any scientific basis exists to ban the sale of nicotine vaping products to adults. On these points, the court treads lightly, recognizing that even experts cannot resolve some aspects of the dispute and that the court is not a medical, epidemiological or scientific expert. To the extent that findings are necessary to facilitate an appeal, the court adopts the CDC's assessment (above) as preliminary facts.

Each side has presented experts, attacked by the other side as not credible. A credibility attack borders on futile, given the split in the public health community over whether a total ban on retail nicotine vaping products will do more harm than good. The fact that the experts disagree does not lead the court to adopt the analysis of one or the other expert. That just reflects the existing disagreement in the public health community. The experts have the necessary credentials, have reviewed the data and literature thoroughly, and have applied their expertise appropriately to the scientific evidence. Without hesitation, the court finds each testifying expert credible.

The record elaborates on why nicotine-vaping products cannot be ruled in or out as a cause of the outbreak. While 10% (previously 13% or 17%) of vaping lung injury patients report using nicotine vaping products only, there are reasons why patients might not report using THC.

As CDC stated in an article dated September 27, 2019: "patients might not always know what substances they use or might be hesitant to reveal use of substances that are not legal in their state." In a study of patients from Illinois and Wisconsin (where the outbreak was first publicized), the CDC stated: "In Wisconsin, eight patients initially denied using THC-containing products in interviews, but five (63%) were later found to have used THC through review of medical charts, re-interview, or cross-referencing with friends who were also interviewed as patients."

The record in this case reinforces CDC's concerns about the reliability of the self-reported data. Even as this court held hearings on the Motion, the CDC's published data reflected declining percentages of patients who "reported exclusive use of nicotine-containing products." The CDC reported that percentage as 17% as of October 3, 2019 (Comm. Ex. U), 13% as of the October 9 hearing and 10% as of the October 18 hearing (Hearing Exhibit 8). This steep and rapid decline almost certainly reflects improved questioning and verification by investigators. It now appears that at least a major portion of the data previously cited by the Commonwealth is an artifact of the self-reporting process. The record includes no verified or confirmed data about exclusive nicotine use. At a minimum, the credibility of the self-reports on that issue is seriously in question and may be unreliable for purposes of banning an entire industry. Indeed, the CDC's latest update eliminates the statement that previously appeared in its October 11 update to the effect that: "Therefore, the possibility that nicotine-containing products play a role in this outbreak cannot be excluded." The Order predated, and therefore does not reflect any consideration of, these recent developments. Nor does the record show that

any comprehensive follow-up and verification has occurred (or is even possible at this point) to determine the accuracy of the reports of exclusive nicotine use by 10% of the patients.

It is true that nicotine-vaping products have been in use for several years, while the THC recreational vaping products are far more recent. The plaintiffs' expert considers that fact, along with demographic data, as supporting the conclusion that something other than nicotine-vaping products must be causing the outbreak, which came to light only in summer 2019. There is substantial force to this argument. However, although the current outbreak may be a new phenomenon, it may also reflect a recent recognition of a problem that has been ongoing for several years. Only recently have public health professionals been asking the right questions to determine, for instance, exposure to THC or black market products. It may also be that ingredients, such as specific flavorings, have changed recently.

Neither the CDC nor the FDA recommend governmental action to van all nicotine-vaping products. No state other than Massachusetts has enacted such a broad ban. The record identified only one other governmental body (San Francisco) with such a ban. Some states have opted for narrower bans on, for instance, flavored products or THC vaping products. Sales to minors and on school busses or grounds are already illegal. G.L. c. 71, § 2A; c. 270, § 6. So are black market products.

DISCUSSION

To obtain preliminary relief, plaintiffs must prove a likelihood of success on the merits of the case and a balance of harm in their favor when considered in light of its likelihood of success. Packaging Indus. Group, Inc. v. Cheney, 380 Mass. 609, 616-617 (1980). "One ... is not

¹ The alternative explanation – that nicotine-vaping products are causing proportionately fewer and fewer injuries –

entitled to seek [injunctive] relief unless the apprehended danger is so near as at least to be reasonably imminent." Shaw v. Harding, 306 Mass. 441, 449-50 (1940). A party seeking to enjoin governmental action must also ordinarily show that "the relief sought will [not] adversely affect the public." Tri-Nel Mgt. v. Bd. of Health of Barnstable, 433 Mass. 217, 219 (2001), citing Commonwealth v. Mass CRINC, 392 Mass. 79, 89 (1984).

I.

Without a public hearing, notice and comment, or any explicit statement of fiscal or small business impacts under G.L. c. 30A, the executive branch has prohibited the sale or display of all vaping products to consumers until January 25, 2020. The plaintiffs argue that this violates article 30 of the Declaration of Rights of the Massachusetts Constitution. Article 30 mandates a separation of governmental powers in order to provide structural protections for the liberty of our citizens and preserve the rule of law. It reads:

In the government of this commonwealth, the legislative department shall never exercise the executive and judicial powers, or either of them: **the executive shall never exercise the legislative** and judicial **powers**, or either of them: the judicial shall never exercise the legislative and executive powers, or either of them: **to the end it may be a government of laws and not of men**. (Emphasis Added).

A.

"The power to regulate is a delegated legislative function that lies at the heart of the executive responsibility to enforce the law." "Rulemaking by Administrative Agencies Under the APA," in Massachusetts Administrative Law and Practice, § 2.01, p. 2-2 (Lexis Nexis 2015 ed.). "An administrative body does not have any inherent authority to issue regulations." Telles v. Commissioner of Ins., 410 Mass. 560, 563 (1991). The plaintiffs here assert that the

defendants have acted without any valid delegation of legislative authority. That argument requires close examination of the statute under which the defendants acted. Indeed, in their recently-filed Reply in Support of Motion for Preliminary Injunction, the plaintiffs do just that.²

As the defendants see it, G.L. c. 17, § 2A ("§ 2A") gives the executive branch all the legislative authority and direction that it needed to promulgate the Order. That section reads, in its entirety:

Upon declaration by the governor that an emergency exists which is detrimental to the public health, the commissioner [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 he may deem necessary to assure the maintenance of public health and the prevention of disease.

The commissioner, with the approval of the public health council, may establish procedures to be followed during such emergency to insure the continuation of essential public health services and the enforcement of the same.

Upon declaration by the governor that such emergency has terminated, all powers granted to and exercised by the commissioner under this section shall terminate. [Emphasis added].

It may be an open question whether this statute authorizes broad relief in the nature of a regulation affecting (and, indeed, stopping) an entire industry. In the leading case addressing public health regulations of an entire industry, the Department of Public Health proceeded by emergency regulation under G.L. c. 30A, § 2, rather than under c. 17, § 2A. American Grain Products Processing Institute v. Department of Public Health, 392 Mass. 309 (1984). Rejecting an argument that the Department must proceed under § 2A instead of c. 30A, the court stated:

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² In a sense, any Article 30 challenge alleging that an executive official exercised legislative power includes the question whether any statute, properly construed, delegates authority for the executive branch to act. In this case, it is the defendants who have asserted authority under § 2A, thus requiring the court to construe that section before passing on any constitutional question, regardless of the breadth of the plaintiffs' constitutional argument. Cf. Commonwealth v. Paasche, 391 Mass. 18, 21 (1984). If the defendants were suggesting during the first hearing that the plaintiffs did not make any such argument, the court still had the duty to construe § 2A even then. In any event,

The only reported instance of the exercise of G.L. c. 17, § 2A, is the Commissioner's takeover in 1976 of the operation of Woodland Nursing Home in Methuen and his payment of its employees and suppliers. See <u>Davidson v. Commonwealth</u>, 8 Mass. App. Ct. 541, 543–544 (1979). We believe that it was this sort of expenditure and administrative action which § 2A was designed to allow.

<u>Id.</u> at 321 (Emphasis added).³ The Supreme Judicial Court concluded:

Accordingly, in the absence of any indication of legislative intent to the contrary, [footnote omitted] we construe G.L. c. 17, § 2A, to have conferred on the Commissioner, in a declared emergency, powers which neither he nor the department previously possessed. We do not construe it to have transferred the power to adopt emergency regulations from the department to the Commissioner.

<u>Id.</u>, 392 Mass. at 322 (Emphasis added).⁴ This may mean that, while the Commissioner obtained powers under § 2A, she lacks the power to adopt emergency regulations. Yet, that is exactly what she did in issuing the Order.⁵ Under binding precedent, therefore, the Commissioner may lack the power she asserts here, which may reside solely in the Department, acting as such, in compliance with G.L. c. 30A, § 2.

Recognizing that the above-quoted passages from <u>American Grain</u> do not squarely hold that regulations exceed the scope of the phrase "take . . . action" in § 2A, even as <u>dicta</u>, they are binding upon this court. The <u>dicta</u> certainly suggest that the plaintiffs have a significant

the plaintiffs' supplemental memorandum, filed on October 17, clearly argues the limited scope of § 2A and the import of American Grain Products Processing Institute v. Department of Public Health, 392 Mass. 309 (1984).

³ In addition to <u>American Grain</u> and <u>Davidson</u>, the only other reported case citing G.L. c. 17, § 2A is <u>Bleeker v. Dukakis</u>, 665 F.2d 401 (1st Cir. 1981). <u>Bleeker</u> is of no relevance here as it involved a claim brought under 42 U.S.C. § 1983 by the administrator of the same nursing home at issue in <u>Davidson</u> concerning his termination, and that court merely cited the statute as the basis under which the Commonwealth took control of the nursing home's operations. See <u>Bleeker</u>, 665 F.2d at 402, n. 1.

⁴ The defendants repeatedly cite the first sentence of this quote out of context, i.e. without addressing the second sentence. This leaves the court without any argument from the defendants on the meaning of the text in bold.

⁵ In addition to the Order's own reference to enforcement of its terms as though a regulation, the discussion below shows that the Order meets the controlling definition of regulation in G.L. c. 30A, § 1(5). Of course, actions such as increased availability of nicotine cessation products or public dissemination of information and warnings does not fall within the questionable category and, appropriately, are not even challenged in this case.

likelihood of success in arguing that the Order exceeds any authority delegated by the Legislature in § 2A. That is, they may well succeed in showing that the defendants exceeded their statutory authority.

The defendants object that the Order is not a "regulation." But the Order itself provides that it "may be enforced in the manner of a regulation" More basically, the Executive Branch has no authority to disregard the Legislature's broad definition of the term "regulation," which reads:

(5) "Regulation" includes the whole or any part of every rule, regulation, standard or other requirement of general application and future effect, including the amendment or repeal thereof, adopted by an agency to implement or interpret the law enforced or administered by it, but does not include (a) advisory rulings issued under section eight; or (b) regulations concerning only the internal management or discipline of the adopting agency or any other agency, and not substantially affecting the rights of or the procedures available to the public or that portion of the public affected by the agency's activities; or (d) regulations relating to the use of the public works, including streets and highways, when the substance of such regulations is indicated to the public by means of signs or signals; or (e) decisions issued in adjudicatory proceedings.

G.L. c. 30A, § 1(5). The Order is plainly a "requirement of general application and future effect." The term "agency" includes any "official of the state government, authorized by law to make regulations." G.L. c. 30A, §1(2). None of the exceptions applies here. Although invited by the court to explain why the Order is not a "regulation," the defendants have provided no logical theory why the Order falls outside this definition. By the statute's clear language, the Legislature has bound the executive and judicial branches to consider the Order a "regulation."

Any entity with power to enact regulations such as the Order must comply with G.L. c. 30A, §§ 2, 3 in doing so. Agency compliance with G.L. c. 30A, §§ 2, 3 when adopting

regulations is not optional. Those provisions use mandatory language ("shall" and "is required"). Again, the defendants do not challenge the mandatory nature of that plain language.

In response to the court's questions about G.L. c. 30A, §§ 2, 3, the defendants respond that § 2A gives the Commissioner independent authority to act, while the Department of Public Health has the power to enact emergency regulations. See Defendants' Supplemental Memorandum in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 4. This is a non-sequitur. The defendants must show two things: (1) that the Commissioner has the power to adopt an Order that meets the definition of "regulation," and (2) that she may do so without complying with G.L. c. 30A, §§ 2, 3. These two components are black-letter administrative law. Farnting that § 2A provides independent authority to take "action" and even assuming (contrary to the above discussion) that "action" includes the Order, nothing in its language provides explicit or implicit authority to adopt a regulation without complying with G.L. c. 30A, §§ 2, 3. Nor does it purport to authorize the defendants to legislate a new exception to the definition of "regulation" in G.L. c. 30A, § 1(5). Appropriately, the defendants expressly disclaim any argument that § 2A implicitly repeals any part of c. 30A. It is obviously possible to

The focus of this chapter – i.e., what constitutes proper regulatory promulgation – is of foundational importance. There are two primary components. The promulgating agency (1) must have pertinent regulatory authority, and (2) must follow the process set forth in its enabling statute or the state Administrative Procedure Act, G.L. c. 30A.

The reference to an agency –specific regulatory process applies where the agency's enabling statute is inconsistent with c. 30A. See <u>id</u>. n. 10, citing <u>New England Milk Dealers Ass'n</u>, supra. See also FN 8, infra. No one does, or could, claim that anything in § 2A is inconsistent with c. 30A compliance. Section 2A merely identifies the governmental bodies and officials who must approve the action – the Governor, Commissioner and Public Health Council. If § 2A even authorizes a regulation such as the Order, section 2A dictates the bodies that must approve it,

⁶ An argument that the Commissioner lacks authority to make regulations would, of course, defeat any construction of § 2A that would authorize the Commissioner to adopt a "requirement of general application and future effect." ⁷ See, e.g., Rulemaking by Administrative Agencies Under the APA," in Massachusetts Administrative Law and Practice, § 2.01, p. 2-3 (Lexis Nexis 2015 ed.):

comply with the mandates of both § 2A and c. 30A, §§ 2-3. Cf. American Grain, 392 at 322 (statutes should be construed "to have consistent directives so that both may be given effect"). 8 The plaintiffs are likely to show that the defendants lack executive power to violate the plain language of c. 30A.

To succeed on their separation of powers claim, the plaintiffs do not actually need to show a full-blown constitutional violation. They need only show that § 2A must be construed narrowly to avoid an unconstitutional result. Cf. Pineo v. Executive Council, 412 Mass. 31 (1991) (construing statute not to apply where it would violate separation of powers). At a minimum, American Grain identifies potential limits upon the use of § 2A to promulgate regulations. Where the Order meets the definition of a "regulation" in G.L. c. 30A, § 1(5), nothing in § 2A obviates the duty to comply with G.L. c. 30A, § 2 and 3 in implementing regulations. The claim of executive authority to adopt the Order, in the face of these limits, creates, at best, great uncertainty in a matter affecting the constitutional separation of powers. That triggers the rule that "a statute is to be construed where fairly possible so as to avoid constitutional questions." Commonwealth v. Jones, 471 Mass. 138, 143 (2016), quoting United States v. X-Citement Video, Inc., 513 U.S. 64, 69 (1994). See also O'Brien v. Borowski, 461 Mass. 415, 422 (2012) ("we have not hesitated to construe statutory language narrowly to avoid constitutional overbreadth"); Demetropolos v. Commonwealth, 342 Mass. 658, 660 (1961)

but not the process by which those bodies enact it. A contrary holding would vitiate c. 30A, §§ 2, 3, because virtually every enabling statute identifies the body or official who must authorize a regulation.

⁸ The defendants' view that c. 30A and § 2A are separate and irreconcilable seem to follow the reasoning of the dissent in <u>American Grain</u>, 392 Mass. at n. 2 (Lynch, J. et al, dissenting). This court must, of course, follow the majority's reasoning. It also bears note that the dissent's ultimate position actually required even more process and stricter review of alleged emergency declarations than the majority and therefore could not support the Order even if the dissent's view had prevailed in the Supreme Judicial Court.

("where a statute may be construed as either constitutional or unconstitutional, a construction will be adopted which avoids an unconstitutional interpretation").

Reading § 2A to apply only to the type of administrative action identified in <u>American</u>

<u>Grain</u> would avoid a constitutional question here, and would favor the plaintiffs' position. The court therefore evaluates whether the constitutional issue is substantial.

В.

Even if "action" under § 2A includes something as broad as the Order, the question remains whether such a construction is constitutional. Except to identify serious constitutional questions that preclude an expansive interpretation of § 2A, it is not necessary to resolve the constitutional question at this time.

Because it is the Legislature's job to "set forth the fundamental policy decisions of the state," the Supreme Judicial Court has set forth the following test to determine whether a delegation of legislative authority is valid:

In determining whether such a legislative delegation of authority is proper, we consider three questions: "(1) Did the Legislature delegate the making of fundamental policy decisions, rather than just the implementation of legislatively determined policy; (2) does the act provide adequate direction for implementation, either in the form of statutory standards or, if the local authority is to develop the standards, sufficient guidance to enable it to do so; and (3) does the act provide safeguards such that abuses of discretion can be controlled?"

Powers v. Sec'y of Administration, 412 Mass. 119, 127-28 (1992), quoting Chelmsford Trailer Park, Inc. v. Chelmsford, 393 Mass. 186, 190 (1984).

The plaintiffs have some likelihood of success in establishing the defendants' failure to meet the first <u>Powers</u> factor. When a well-established public health emergency exists but is arguably limited to discrete segments of an industry – as evidenced, for instance, by the CDC's

focus upon THC and black market products – choosing to shut down an entire industry immediately may well be a "fundamental policy decision[]" rather than simply "the implementation of legislatively determined policy." Faced with that specific choice earlier this year, the Massachusetts Legislature has declined to ban all vaping products. See Sen. Bill 1279 (2019); House Bill 1902 (2019). Moreover, as noted above, American Grain suggested (if not held) that there are limits to the type of "action" included within § 2A, making it hard to discern a "legislatively determined policy" that might justify action as broad as a regulation. When the court cannot even say that adoption of a regulation is an "action" within the scope of § 2A, how can it discern legislative policies to be implemented by such a regulation? If construed broadly enough to encompass the Order, § 2A may well cross the line set forth in the first Powers factor.

At this point, it appears that, on its face, § 2A meets the second Powers factor. It establishes standards for evaluation of the executive action, namely the existence of an "emergency... which is detrimental to the public health." Executive authority under § 2A extends only to "action[s]" found "necessary to assure the maintenance of public health and the prevention of disease." (emphasis added). It is precisely that limitation, however, that calls into question the use of § 2A to impose a ban so wide that it reaches parts of the industry (retail nicotine products, for example) in ways that might prove unnecessary upon deeper consideration after input from the public and affected businesses, such as that required by G.L. c. 30A, §§ 2, 3. The defendants' appropriate concession at the October 18 hearing that the ongoing youth vaping epidemic is not an "emergency" illustrates how § 2A, as applied here, may not meet the second Powers factor here. That is, if an "emergency" can be construed to include ongoing epidemics

(as the Emergency Declaration appears to do, in part), then § 2A may well lack the necessary discernable standards limiting the scope of executive action.

The constitutional questions deepen upon consideration of the third <u>Powers</u> factor, namely whether § 2A "provide[s] safeguards such that abuses of discretion can be controlled." Section 2A – particularly as applied here – lacks the most basic safeguards that the Legislature has provided for agency rulemaking. The lack of safeguards supports an inference that the Legislature did not intend for executive "action" under § 2A to include full-blown regulations, as <u>American Grain</u> seems to suggest. Even if one interprets the statute broadly, however, the absence of safeguards against abuse of discretion is striking.

A contrast with safeguards provided in other contexts is instructive. Input from affected industries and members of the public is a potent safeguard against executive abuse of discretion. Under G.L. c. 30A, §§ 2 and 3 the promulgation of a regulation requires notice and comment, even for an emergency regulation (though the regulation may become effective prior to notice and comment if the agency files an emergency declaration). Including the public and affected persons or businesses allows them to help the agency determine how best to regulate, while minimizing collateral damage. Where, as here, the Order purports to be enforceable by fines, G.L. c. 30A, § 2, actually requires a public hearing, because the Legislature has determined that these additional, public processes are necessary to control abuses of discretion when enacting these types of regulations. The Legislature has also limited the duration of any emergency regulation to three months, in the absence of notice and comment. G.L. c. 30A, §§ 2 and 3. 10

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⁹ Of course, the Legislature likely had additional purposes in mind when it required notice and comment. Among other things, including the public and affected persons and industries in the regulatory process promotes the actual and apparent fairness of the process. It also holds the prospect of a more effective, less intrusive and generally

The Legislature has also required the filing of a fiscal impact statement and small business impact statement, so that no agency can regulate without considering the economic impact of the regulation upon the regulated community, other affected individuals, the taxpayers and the public in general. See G.L. c. 30A, § 5, as amended through St.1980, c. 329, § 28. This section provides:

No rule or regulation so filed with the state secretary shall become effective until an estimate of its fiscal effect including that on the public and private sector, for its first and second year, and a projection over the first five-year period, or a statement of no fiscal effect has been filed with said state secretary.

Moreover, c. 30A, §§ 2 and 5 provide, in part:

A small business impact statement shall be filed with the state secretary on the same day that the notice is filed and shall accompany the notice. Notwithstanding section 6, the state secretary shall include the full text of said small business impact statement on the electronic website of the state secretary; provided, however, that the full text of the small business impact statement may also be inspected and copied in the office of the state secretary during business hours.

That small business impact statement shall include, but not be limited to, the following:

- (1) an estimate of the number of small businesses subject to the proposed regulation;
- (2) projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation;
- (3) the appropriateness of performance standards versus design standards;

better regulation, informed by the input of those who are affected and who often tend to be the most knowledgeable about certain aspects of a given problem. The Order provides none of that.

¹⁰ It is true that the Legislature has, on rare occasions, provided for unique processes to enact regulations, outside c. 30A. See New England Milk Dealers Ass'n v. Department of Food & Agric., 33 Mass. App. Ct. 935, 936 (1992), discussing G.L. c. 94A, §§ 11, 16-19. In that case however, the Legislature provided for more process, not less, and required a full evidentiary hearing on the record. The same is true of industry-wide ratemaking, which is sometimes viewed as regulatory or legislative in nature, but nevertheless requires a full evidentiary hearing. See, e.g., G.L. c. 25, § 5; G.L. c. 175, § 113B. None of the exceptions to c. 30A known to the court suggest the validity of any process that provides fewer safeguards against abuse of discretion than c. 30A, §§ 2 and 3.

- (4) an identification of regulations of the promulgating agency, or of another agency or department of the commonwealth, which may duplicate or conflict with the proposed regulation; and
- (5) an analysis of whether the proposed regulation is likely to deter or encourage the formation of new businesses in the commonwealth:

These requirements guard against the very concern raised by the plaintiffs here; there is no suggestion in the record that the defendants considered the fiscal impact upon, for instance, businesses who sell legal nicotine products to adults. It is easy for an agency to brush such concerns aside unless a law like c. 30A, § 5 requires transparency about fiscal impact. Because of all these safeguards, our courts have tolerated the executive exercise of authority that would otherwise be exclusively legislative.

The defendants construe § 2A not to require such notice and comment (let alone a public hearing) and, indeed, have provided none. The Legislature did not authorize promulgation of regulations without that input. If the executive branch avoids such input and safeguards it unwittingly creates an echo chamber in which government officials' own viewpoints reinforce each other, potentially causing unnecessary harm and ill-informed decisions, despite the best of intentions. In this case, the Order also violates the three-month limit on emergency regulations by imposing a ban upon vaping products for four months, and perhaps more. It imposes fiscal impacts without transparent consideration by the agency, if the agency even considered those impacts relevant.

The defendants argue correctly that the need for prompt action in an emergency often supports executive action. See Comm. Mem. at 14, citing <u>Youngstown Sheet & Tube Co. v.</u>

Sawyer, 343 U.S. 579, 636 (1952) (Jackson, J. concurring in the judgment). That principle does

not excuse non-compliance with c. 30A – such as notice and comment, filing of a fiscal impact statement and a three month duration – because c. 30A allows for emergency regulations to take effect immediately upon filing with the Secretary of State, with other requirements to be satisfied later. The need to immediate action might excuse taking these steps before the Executive acts, but it provides no rationale for indefinite non-compliance. While the constitution does not necessarily require all of the safeguards in G.L. c. 30A, § 2, the absence of any of those safeguards cuts strongly in favor of the plaintiffs' position. The plaintiffs argue, in part, that the lack of safeguards have led Massachusetts to adopt an over-inclusive ban that no other state has found necessary or appropriate. On this record, the court cannot disagree. The third <u>Powers</u> factor therefore weighs against the validity of § 2A, if construed to authorize the Order.

Considering all three <u>Powers</u> factors, the plaintiffs are likely to succeed in proving that the defendants' construction of § 2A would, at a minimum, raise serious constitutional questions under article 30 that require rejection of that broad view of executive power under the statute.

C.

Alternatively, the plaintiffs argue that the Order is arbitrary and capricious. It is not clear what vehicle exists for review of action under § 2A like the Order. See generally Frawley v. City of Cambridge, 473 Mass. 716 (2015). If no route for meaningful judicial review exists under § 2A, the absence of that safeguard against arbitrary action would be yet another reason to find that the legislature has not lawfully delegated power to adopt the Order. Although § 2A contains no judicial review provision, the parties appear to agree that the court should review the Order under the arbitrary and capricious test. For purposes of the Motion, the court follows the parties' lead.

The plaintiffs are likely to succeed on this argument. Most simply, the Order is arbitrary and capricious because it violates the law for all the reasons stated in parts IA and B, above. That is, the defendants likely overreached the scope of their statutory authority in promulgating the Order without duly adopting a regulation under G.L. c. 30A, § 2.

The plaintiffs also challenge the substantive basis for the Order. Assuming that the court should review the Order's rational basis under the arbitrary and capricious test, the standard of rule in the usual case is well-settled. "Duly promulgated regulations of an administrative agency are presumptively valid and 'must be accorded all the deference due to a statute." Craft Beer Distributors, Inc. v. Alcoholic Beverages Control Commission, 481 Mass. 506, 520 (2018) (Emphasis added), quoting Pepin v. Division of Fisheries & Wildlife, 467 Mass. 210, 221 (2014), quoting Massachusetts Fed'n of Teachers, AFT, AFL-CIO v. Board of Educ., 436 Mass. 763, 771 (2002). The problem here is that the Order was not "duly promulgated" as a regulation.

The premise of deference is that the agency has fully considered a regulation that it has "duly promulgated." As the plaintiffs argued orally, the court should not defer to a regulation that does not reflect the input and consideration that must precede lawful action. The parties have not cited a case addressing substantive review of a regulation that was not duly promulgated. That is not surprising, because any such regulation has no legal validity and would be declared void without ever having to examine substantive issues. That is true here, as well.

Moreover, under the arbitrary and capricious test "[t]he process by which the information is gathered, identified, and applied to the statutory standards under [governing law] must be logical, and not arbitrary or capricious." <u>Allen v. Boston Housing Authority</u>, 450 Mass. 242, 254 (2009), quoting <u>Sierra Club v. Commissioner of the Dep't of Envtl. Mgt.</u>, 439 Mass. 738, 749

(2003); Receiver of the Boston Hous. Auth. v. Commissioner of Labor & Indus., 396 Mass. 50, 58 (1985); <u>Long v. Comm'r of Pub. Safety</u>, 26 Mass. App. Ct. 61, 65 (1988) (citation omitted) (an unreasoned decision willfully made "without consideration and in disregard of facts and circumstances."). "[A]n abuse of discretion" exists where the decisionmaker "made 'a clear error of judgment in weighing' the factors relevant to the decision, (citation omitted), such that the decision falls outside the range of reasonable alternatives." L. L. v. Commonwealth, 470 Mass. 169, 185 n. 27 (2014). See Frawley v. Cambridge, 473 Mass. 716, 720 (2016) ("lacks any rational explanation that reasonable persons might support ") Here, the process by which the information was "gathered, identified, and applied to the statutory standards" was arbitrary and capricious because it ignored statutory criteria (e.g., fiscal and small business impact), included a declaration of emergency based in part on a non-emergency (ongoing youth vaping epidemic) and failed to provide numerous mandatory safeguards. See G.L. c. 30A, § 2. The Order was made without consideration and in disregard of facts and circumstances from the public and affected persons and entities that the Commissioner should have entertained in a public hearing (or even a notice and comment process).

It follows that (1) the defendants are not entitled to defend on the ground that the court must give the same degree of deference it would accord a duly promulgated regulation (2) the process and substance of the decision-making likely was arbitrary and capricious and (3) the plaintiffs are likely to succeed on their alternative argument that the Order is arbitrary and capricious.

The balance of harms, including consideration of the public interest, favors the defendants in some, but not all respects.

It is true that the plaintiffs have shown great irreparable harm, because the Order puts many companies out of business for four months. As the plaintiffs' affidavits show, there is a strong likelihood of irreparable harm to these businesses, many of which are small and may even go out of business. Their injury, though economic, amounts to irreparable harm because this "loss threatens the very existence of the movant's business." See <u>Hull Mun. Lighting Plant v.</u>

Mass. Mun. Wholesale Elec. Co., 399 Mass. 640, 643 (1987). In this case, shutting down small businesses for four months is indeed likely to threaten the existence of the plaintiffs' businesses and those of members of the Association.

On the other side of the equation, the evidence indisputably demonstrates numerous vaping injuries and deaths. With respect to THC vaping products and black market vaping products, the public health effects are clear and devastating. The plaintiffs do not urge the court to enjoin implementation of the Order as to such products, and the court does not do so, leaving that issue for future litigation (and noting that those who use THC vaping for medical reasons potentially may be able to show much greater harm to their own health than can the present plaintiffs).

The CDC's assessment of retail nicotine-vaping products sold to adults is less dire.

Fairly stated, the strongest possible statement is that nicotine-vaping products cannot be ruled out

– but the CDC's latest update on October 17 drops even that relatively mild statement, which

appeared in the October 10 update. The CDC and FDA recommend informational campaigns

urging individuals to choose not to vape until the cause of the outbreak is known. They leave it to individuals to decide how to address their addiction, if they cannot stop ingesting nicotine altogether. Other states have followed that lead, banning something less than all nicotine vaping products. That approach avoids one public harm that the Order may be inflicting: removing the nicotine-vaping alternative may push individuals to the clearly-dangerous black market or to other less beneficial nicotine alternatives.

The court also notes that the record does not establish a consensus among the CDC, FDA or other state public health authorities for government action completely banning all retail nicotine-vaping products. Massachusetts' claim of irreparable harm is somewhat undermined by the fact that no other state has enacted such a ban (and apparently only San Francisco has followed suit among municipalities).

Still, there is serious potential harm to individuals and the public if it does turn out that lawful nicotine-vaping is a factor in causing the current outbreak. If the court were considering an immediate preliminary injunction against implementing the Order in its entirety as to nicotine-vaping products, the balancing of public interest in this case would therefore be as complex as diagnosing the vaping injury outbreak itself. Instead, in such a complex regulatory context, the defendants must be the ones to assess these countervailing considerations after receiving full input in a public hearing, articulating the fiscal and small business impact, and otherwise complying with c. 30A. When the defendants fully comply with their obligations and consider updated information that became available after September 24, the result could be no order, a more limited order (as in other states), or reassertion of the same Order.

There is no harm to the public interest and no legally cognizable harm to the defendants if the court's order gives the opportunity to enact the Order as an emergency regulation. The provisions of G.L. c. 30A, § 2 do not harm the executive branch's authority to take necessary immediate action in the event of a true emergency, because an emergency regulation can be adopted as quickly and easily. Complying with G.L. c. 30A, § 2 allows public input within a limited time in a way that causes no harm whatsoever to the defendants or to the public interest. In that regard, the avoidance of public scrutiny or expense of public process is not a cognizable harm for purposes of preliminary injunction analysis, or separation of powers principles. The public interest is served when the executive branch complies with the obligations placed upon it by the Legislature and Constitution, particularly when considering a measure as broad as the Order. It is also served when the executive branch explicitly considers the fiscal impact and small business impact of the Order, as required by G.L. c. 30A, §§ 2, 3 and 5.

In sum, the plaintiffs have certainly suffered, and will suffer, very great and irreparable financial impact, which should not be imposed prior to compliance with those sections according to the public interest as declared by the legislature in adopting c. 30A. It is not at all clear why the defendants have chosen not to provide the protections of c. 30A, which they could do even if they contest their applicability. It is particularly hard to understand why they did not initiate such proceedings once the issue arose in this case. Because the plaintiffs are suffering significant harm and are likely to show that the Order is unlawful as presently promulgated, the balance of harms weighs in favor of the limited relief granted below, which gives the defendants the option to avoid any harm to the public interest by adopting, amending or rescinding the Order as an emergency regulation.

Preliminary Injunctive Relief

Key to the court's choice of relief is the fact that the defendants could cure the deficiencies identified in this Memorandum by proceeding under G.L. c. 30A, § 2.

There has been no notice and comment or public hearing, but the executive branch has authority to adopt emergency regulations in a true emergency:

If the agency finds that immediate adoption, amendment or repeal of a regulation is necessary for the preservation of the public health, safety or general welfare, and that observance of the requirements of notice and a public hearing would be contrary to the public interest, the agency may dispense with such requirements and adopt, amend or repeal the regulation as an emergency regulation. The agency's finding and a brief statement of the reasons for its finding shall be incorporated in the emergency regulation as filed with the state secretary under section five.

G.L. c. 30A, § 2. The Governor has already declared an emergency under § 2A, but the long-standing and ongoing youth vaping epidemic figured prominently in that declaration. It remains to be seen whether the executive branch can or will declare an emergency with respect to adult use of nicotine-vaping products. See Slis v. State of Michigan, No. 19-0152-MZ (Michigan Court of Claims) (Opinion and Order dated October 15, 2019) (Preliminarily enjoining an emergency ban on flavored nicotine products based upon the plaintiff's likelihood of success in challenging the agency's emergency determination under the state APA).

The Order has not been filed as a regulation with the Secretary of State, although that could be done easily within a week. The court also recognizes that the Commissioner may not be the appropriate entity to adopt a regulation, but the proper regulatory body could adopt the Order if it sees fit.

There is no fiscal impact statement or small business impact statement, or equivalent, in the record before the court. The Declaration of Emergency, Order, transcript of the Public Health Council meeting of September 24, 2019 and the testimony at the hearing reflect no executive branch discussion of these impacts. Under G.L. c. 30A, §§ 2, 3 and 5, the executive branch must safeguard fiscal and small business interests by expressly incorporating these impacts into the decision-making process. No reason appears why the defendants cannot comply with this requirement. Without judicial relief, the plaintiffs will have no assurance that the executive branch has explicitly determined the fiscal and small business impacts, which, of course, are the plaintiffs' prime concerns. Of course, explicit consideration of those impacts may also produce a different outcome at the agency level.

Curing these defects is no small or technical matter. Complying with the mandatory safeguards of c. 30A in adopting a regulation may well serve as a check upon abuse of discretion here. At a minimum, it is for the agency to decide whether to re-enact the Order or revise it after considering input from the public and affected parties and taking account of information received since September 24. Consideration of fiscal impact and small business impact likewise ensure that the breadth of the Order takes account of all factors mandated by the Legislature.

Compliance with c. 30A respects the legislature's authority under Article 30, including observance of statutory requirements. It also enables the judiciary to perform its proper role, by making sure that the agency has done its statutory duty and has made its decisions in a judicially-reviewable regulation.

Given the availability of a cure to the defects identified above, great uncertainty and confusion would result if the court invalidated the Order immediately, only to see the Order

lawfully adopted quickly after such invalidation. In curing the existing violations, to avoid separation of powers issues and to avoid irreparable harm to the plaintiffs for more than the three-month statutory period (G.L. c. 30A, §§ 2, 3), the executive branch would need to adopt an emergency regulation effective as of September 24 or with a termination date on or before December 24, 2019.¹¹

The best course is to give the executive branch time to bring itself into compliance with the Legislature's mandates. If that does not occur, the court has a duty to see that the article 30 violation does not persist so long that the safeguards imposed in c. 30A will fail to achieve their intended effect.

The court is aware that major substantive issues may remain even if the executive branch complies with c. 30A. As noted above, the defendants have either not yet addressed those issues (e.g., fiscal and small business impact) or have done so in a way that ignores important distinctions, including whether there is any true "emergency" at this time concerning adult use of nicotine-vaping products alone. Because the executive branch may choose to adopt a more limited ban, or no ban at all – and will have the chance to consider new input and more recent data, it is not appropriate for the court to rule more broadly on the issues in this case at this time. If any further litigation is needed, the court will expedite proceedings, to avoid the ongoing harm to the plaintiffs.

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¹¹ Given that, at the October 8 hearing, the court's inquiries placed the defendants on notice of the possible need for an emergency regulation, and the speed with which an emergency regulation can be filed, there should be plenty of time to act within one week, i.e. October 28, 2019.

ORDER

While the plaintiffs have shown a likelihood of success, the balance of harms weigh in defendants' favor in some respects, and an immediate injunction against the entire Order would contravene the public interest. The court therefore allows the defendants an opportunity to cure the defects identified above. Accordingly, the Plaintiffs' Motion for Preliminary Injunction is **ALLOWED in part AND DENIED in part as follows:**

- The Commissioner is preliminarily enjoined from implementing and enforcing the Order from and after October 28, 2019 as to nicotine-vaping products unless and until the executive branch promulgates the Order in compliance with G.L. c. 30A, §
 The October 28 date shall be extended automatically until further order of the court if the executive branch chooses to enact an emergency regulation by that date.
- 2. The Commissioner is preliminarily enjoined from implementing and enforcing the Order from and after December 24 as to nicotine-vaping products, unless during that time the agency gives notice and holds a public hearing as required in G.L. c. 30A, § 2, and files notice of compliance with the state secretary.
- 3. Notwithstanding paragraphs 1 and 2 above, nothing in this Memorandum and Order shall affect the validity of the defendants' Order as applied to products containing tetrahydrocannabinol (THC) and any other cannabinoid or to black market products. Nor does it preclude substituting compliance with G.L. c. 30A, § 3 in lieu of § 2, if the executive branch adopts a substitute or amended order or regulation that does not trigger G.L. c. 30A, § 2. This Memorandum and Order is without prejudice to a challenge to any emergency regulations that may be promulgated, any challenge

to any future declaration of emergency or any future action regarding the Order.

4. The Motion for Preliminary Injunction is otherwise DENIED.

5. Given the effective dates of the above orders and the possibility that the

defendants may choose to comply with c. 30A rather than file an appeal, the oral

request for a Stay is DENIED, as unnecessary at this time.

Dated: October 21, 2019 Douglas H. Wilkins

Associate Justice, Superior Court