SUPREME COURT OF THE STATE OF NEW YORK
ALBANY COUNTY

In the Matter of the Application of

VAPOR TECHNOLOGY ASSOCIATION, BENEVOLENT ELIQUIDS INC., and PERFECTION VAPES, INC.,

Petitioners,

Index No. 906514-19

For a Judgment Pursuant to Article 78 of the Civil Practice Laws and Rules.

-against-

ANDREW M. CUOMO, Governor of the state of New York, THE NEW YORK DEPARTMENT OF HEALTH, HOWARD ZUCKER, M.D., Commissioner of the New York Department of Health, THE PUBLIC HEALTH AND HEALTH PLANNING COUNCIL, and NEW YORK STATE POLICE,

Respondents.

MEMORANDUM OF LAW
IN OPPOSITION TO PETITIONERS'
MOTION FOR A PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

There is an epidemic of "vaping" among adolescents in New York State. Between 2014 and 2018, the use of addictive electronic cigarettes (e-cigarettes) by high school students dramatically increased by 160%. An overwhelming 36.7 percent of New York twelfth graders report current e-cigarette use. The availability of flavored electronic liquids (e-liquids), such as gummy bear, root beer float and banana split, is the principal reason that adolescents initiate and maintain e-cigarette use. In an effort to address this alarming epidemic, the Public Health and Health Planning Council, with the approval of the Commissioner of Health, promulgated an emergency rule that bans flavored e-liquids (the "Emergency Rule"). Petitioners now challenge the Emergency Rule.

On September 25, 2019, Petitioners moved for a temporary restraining order enjoining the enforcement of the Emergency Rule (a copy of which is attached as Exhibit "A" to the accompanying Affidavit of Department of Health Deputy Commissioner Brad Hutton [hereafter, "Hutton Aff."]), which was originally scheduled to be enforced beginning on October 4, 2019. Supreme Court, Albany County (Connolly, J.) denied the motion after oral argument on September 27, 2019.

On September 30, 2019, Petitioners filed an Emergency Application in the Third Department, seeking permission to appeal Judge Connolly's order and the entry of a temporary restraining order and preliminary injunction. On October 3, 2019, the Third Department issued a Decision and Order stating that said motion for permission to appeal would be treated as a motion to review an order pursuant to CPLR 5704(a), and granted said motion for a temporary restraining order, enjoining Respondents from enforcing the Emergency Rule, "pending the determination by

Supreme Court, Albany County of petitioners' motion for a preliminary injunction". (Dkt. 35, p. 4).

ARGUMENT

It is well settled that a preliminary injunction is a "drastic remedy" that should be issued "sparingly." *Kuttner v. Cuomo*, 147 A.D.2d 215, 218 (3d Dep't 1989). To prevail on a motion for a preliminary injunction, the moving party must establish: "(1) the likelihood of success on the merits; (2) irreparable injury absent granting the preliminary injunction; **and** (3) a balancing of the equities." (Emphasis added). *Id.*

Each of these requirements must be satisfied by "clear and convincing evidence." *County of Suffolk v. Givens*, 106 A.D.3d 943, 944 (2d Dep't 2013). Further, the burden is on the party seeking the injunctive relief to prove that they are entitled to it. *Pine Hill-Kingston Bus Corp. v. Davis*, 225 A.D. 182, 183 (3d Dep't. 1929).

"Plaintiffs who seek preliminary relief providing all the relief sought as final judgment bear an even heavier burden in demonstrating their entitlement to such relief. 'It is well settled that temporary injunctions which in effect give the same relief which is expected to be obtained by final judgment, if granted at all, are granted with great caution and only when required by urgent situations or grave necessity, and then only on the clearest of evidence. It is the policy of this court not to grant such relief when the plaintiff's ultimate right involved is in doubt.'" *Grumet v. Cuomo*, 162 Misc. 2d 913, 929 - 930 (Sup. Ct. Albany County 1994), *quoting*, *Russian Church of Our Lady of Kazan v. Dunkel*, 34 A.D.2d 799, 801 (2d Dep't. 1970).

"To warrant preliminary injunctive relief, the irreparable harm alleged **must be** immediate, specific, **nonspeculative** and **nonconclusory**." (Emphasis added). *Grumet v. Cuomo*,

162 Misc. 2d 913, 929 - 930 (Sup. Ct. Albany County 1994), *citing, Matter of New York State Inspection, Sec. & Law Enforcement Employees v. Cuomo*, 64 NY2d 233 (1984).

Here, Petitioners fail to carry their heavy burden to demonstrate, by "clear and convincing evidence", their entitlement to a preliminary injunction in that: (1) their claims of irreparable injury are speculative and conclusory; (2) Petitioners fail to demonstrate by clear and convincing evidence the likelihood of their success on the merits; and (3) the balance of equities does not lie in plaintiffs' favor and does not outweigh the public interest.

POINT I

PETITIONERS' CLAIMS OF IRREPARABLE HARM ARE SPECULATIVE AND CONCLUSORY

Petitioners cannot satisfy the irreparable harm element because, as decided by Justice Connolly, any harm alleged is purely speculative. As noted above, the alleged irreparable harm claimed by a party seeking a preliminary injuntion must be immediate, specific, nonspeculative, and nonconclusory. *Matter of New York State Inspection, Sec. & Law Enforcement Empls. v. Cuomo*, 64 N.Y.2d 233, 240 (1984). To prevail, petitioners must establish not a mere possibility that they will be irreparably harmed, but that they are likely to suffer irreparable harm if equitable relief is denied. *Bank of Am., N.A. v. PSW NYC LLC*, 918 N.Y.S.2d 396 (Sup. Ct. N.Y. County 2010).

Here, Petitioners claim that their businesses will close unless Respondents are enjoined from enforcing the Emergency Rule. This is wholly speculative. First, several individuals claim that they expect that they will close their businesses because of the Emergency Rule. (*See, e.g.*, Michelle Troyer Affidavit dated September 30, 2019, ¶ 7, attached hereto as **Appendix 1**; Jeffrey Barry Affidavit dated September 30, 2019. ¶ 4, attached hereto as **Appendix 2**; Michael

Bowers Affidavit dated September 30, 2019, ¶ 4, attached hereto as **Appendix 3**.[1]). They also state that they have laid off employees, sold their inventory at steep discounts, and scaled back their supply orders in anticipation of the Emergency Rule's enforcement. (*Id*.). But their claimed fear of losing their businesses is purely speculative, since at this point, it is impossible to know how the Emergency Rule will impact their sales. (*See, e.g.*, **Appendix 2** Bowers Aff. ¶ 4, stating "*I anticipate*" that business will close [emphasis added]; September 23, 2019 Jonathan Glauser Affidavit ¶ 9, Dkt. 17 stating "*[I]t is my opinion*" that businesses will close [emphasis added]). Similarly, any decisions to lay off employees, discount prices, or cut back on supply are based on conclusory assertions about speculative future events.

Indeed, Petitioners simply ignore the highly addictive nature of their product and the fact that the Emergency Rule only bans the flavored e-liquids favored by adolescents who cannot lawfully purchase their products, anyway, while both tobacco-flavored and non-flavored e-liquids remain legal. Petitioners fail to provide any non-speculative evidence that adult customers lawfully purchasing their addictive products will quit using said addictive products *en masse* because some flavor they might prefer is no longer available. Indeed, given the addictive nature of their products it is unreasonable to believe that would be the case, when Petitioners' adult customers lawfully purchasing their addictive products, who might *prefer* a certain flavor, can simply switch to tobacco-flavored or non-flavored e-liquids once other flavors are no longer available. Petitioners' attempt to counter this argument through their most recent series of affidavits is entirely speculative and unpersuasive. Relying purely on anecdotes, the affiants state in conclusory fashion that they "do not see any possibility of increased" tobacco flavor

[1] The Petitioners submitted these affidavits to the Third Department in connection with their appeal. Respondents attach them here because they have not been submitted to the Supreme Court.

demand (ignoring the continued availability of *non*-flavored e-liquids) because that flavor is "typically" used by cigarette smokers as their first flavor before they move onto other products. (**Appendix 2** Barry Aff. ¶ 9. *See also* **Appendix 1** Troyer Aff. ¶ 13 ["*In my mind*," consumers will not switch to tobacco flavor (emphasis added)]). Petitioners' argument also defies belief. It is unreasonable to suggest that consumers will forgo tobacco-flavored or non-flavored vaping products in favor of combustible cigarettes—cigarettes which are more expensive and, according to the Petitioners, more dangerous than vaping products. The Petitioners do not explain why consumers would choose a more expensive and dangerous product, other than to state that consumers do not like the taste of tobacco-flavored e-liquid because it is "not particularly satisfying." (**Appendix 2** Barry Aff. ¶ 19). Petitioners', though, wholly fail to address the fact that *non*-flavored e-liquids are not subject to the Emergency Rule and will still be available.

Finally, to the extent that the Petitioner-distributor's sales dropped during the month of September, (*see* Supplemental Affidavit of Jonathan Glauser, dated September 30, 2019 ¶ 6, attached hereto as **Appendix 4)**, the other affidavits show that the decline in sales was caused by the other affiants' speculative conclusion that they will close their businesses when the Emergency Rule is enforced. In other words, the September decline was not caused by the Emergency Rule but rather by the shop owners' actions.

Even more importantly, the argument that the Emergency Rule is the sole cause of any loss of business ignores the fact that the recent spate of deaths and serious injuries due to the ongoing, nationwide outbreak of a vaping-related severe respiratory illness have been well-documented throughout the local and national media. It is no secret that Michigan, Massachusetts, Rhode Island, Montana, Oregon and Washington have all issued vaping bans of varying scope by way of emergency regulations. (Hutton Aff. ¶ 54). Indeed, the vaping-related national death toll currently

stands at 26 people in 21 states. (Hutton Aff. at ¶ 39). As of October 8, 2019, the Centers for Disease Control ("CDC") reported that there are currently 1,299 reported vaping-associated pulmonary illness cases across 49 states, the District of Columbia and the U.S. Virgin Islands—an alarming increase of 494 additional newly reported cases from the 805 cases reported as of September 24, 2019. (Hutton Aff. at ¶ 39). Based on the data the CDC has received from the reported patients, all of whom have a history of e-cigarette and vaping use, 21% of patients are between the ages of 18-20 and 15% of patients are under the age of 18. (Hutton Aff. at ¶ 40). The CDC even went so far as to recommend that consumers avoid all vaping products. (Hutton Aff. ¶ 42).

In New York State specifically, as of October 9, 2019, the Department of Health has reports of 117 cases of severe pulmonary illnesses associated with vaping products, which is an increase of 36 cases since September 20, 2019. (Hutton Aff. ¶ 43). Of those 117 reported cases, 20% of patients were under the age of 18, while 41% were under the age of 21 at the time illness. (Hutton Aff. at ¶ 44). The reported cases were severe in nature— 80% of patients required hospitalization, and at least 9 patients required intubation. (Hutton Aff. ¶ 45). Further, on October 8, 2019, the Department learned of the first confirmed vaping-associated death in New York State, involving a 17-year-old teenager from the Bronx. (Hutton Aff. ¶ 45).

This public health emergency has been discussed in a wide variety of media outlets, from traditional news organizations such as the New York Times and CNN to entertainment-focused programs such as Good Morning America, the View, and the Daily Show. (Hutton Aff. ¶ 49). Even the most casual of media consumers would find it nearly impossible to avoid these alarming stories. And these reports have resonated with New Yorkers: an October 7, 2019 Siena College poll found that 78% of New Yorkers think that e-cigarette use is somewhat (28%) or very (50%)

dangerous. (Hutton Aff. ¶ 49). To blame the Emergency Rule—which has not yet been enforced—for any anticipated loss of business in light of the ever-worsening onslaught of bad news is misleading. The Petitioners are therefore unable to show irreparable harm.

POINT II

PETITIONERS FAIL TO DEMONSTRATE THE LIKLIEHOOD OF SUCCESS ON THE MERITS

Petitioners fail to establish, by "clear and convincing evidence", a likelihood of their success on the merits. Instead, as set forth below, the record shows that Petitioners cannot prevail on the merits of their claims because the promulgation of the Emergency Rule was supported by a rational basis and is not unconstitutional or otherwise contrary to law.

A. The Boreali Factors Favor Respondents

Petitioners argue that the Respondents "engaged in unlawful regulation by exceeding their statutory authority and engaging in unauthorized rule making." (Pet. Mem of Law. at 17). "The concept of separation of powers is the bedrock of the system of government adopted by this State in establishing three coordinate and coequal branches of government, each charged with performing particular functions." *Matter of NYC C.L.A.S.H., Inc. v. New York State Off. of Parks, Recreation & Historic Preserv.*, 27 N.Y.3d 174, 178 (2016) (quoting *Matter of Soares v. Carter*, 25 N.Y.3d 1011, 1013 (2015)).

The "constitutional principle of separation of powers . . . requires that the legislature make the critical policy decisions, while the executive branch's responsibility is to implement those policies." *Greater N.Y. Taxi Ass'n v. NYC Taxi and Limousine Comm'n*, 25 N.Y.3d 600, 609 (2015) (citations omitted). The Court of Appeals has recognized that "some overlap" between the three branches of government is allowed and that "in this State the executive has the

power to enforce legislation and is accorded great flexibility in determining the methods of enforcement." *Clark v. Cuomo*, 66 N.Y.2d 185, 189 (1985). The Legislature may "declare its policy in general terms," and "endow administrative agencies with the power and flexibility to fill in details and interstices and to make subsidiary policy choices consistent with the enabling legislation." *Citizens for an Orderly Energy Policy v. Cuomo*, 78 N.Y.2d 398, 410 (1991). The "enabling legislation need not detail an agency's role." *Matter of LeadingAge N.Y., Inc. v. Shah*, 32 N.Y.3d 249, 263 (2018).

"The cornerstone of administrative law is derived from the principle that the Legislature may declare its will, and after fixing a primary standard, endow administrative agencies with the power to fill in the legislative product by prescribing rules and regulations consistent with the enabling legislation." *Matter of Nicholas v. Kahn*, 47 N.Y.2d 24, 31 (1970).

The Court of Appeals in *Boreali v. Axelrod*, 71 N.Y.2d 1 (1987), articulated four factors to determine whether agency rulemaking exceeded legislative fiat:

> whether (1) the agency did more than balanc[e] costs and benefits according to preexisting guidelines, but instead made value judgments entail[ing] difficult and complex choices between broad policy goals to resolve social problems; (2) the agency merely filled in details of a broad policy or if it wrote on a clean slate, creating its own comprehensive set of rules without benefit of legislative guidance; (3) the legislature has unsuccessfully tried to reach agreement on the issue, which would indicate that the matter is a policy consideration for the elected body to resolve; and (4) the agency used special expertise or competence in the field to develop the challenged regulation.

NYC C.L.A.S.H., 27 N.Y.3d at 179-80 (internal quotation marks and citations omitted). Importantly, these considerations (sometimes known as the *Boreali* factors) "are not to be applied rigidly." *Id*. at 180. "In fact, they are not mandatory, need not be weighed evenly, and are essentially guidelines for conducting an analysis of an agency's exercise of power." *Id*.

(citing *Greater New York Taxi Ass'n,* 25 N.Y.3d at 612). All factors weigh in favor of the Respondents.

1. The First *Boreali* Factor

The Court must first consider whether the Respondents "did more than balance the costs and benefits according to pre-existing guidelines, but instead made value judgments entailing difficult and complex choices between broad policy goals to resolve social problems." *NYC C.L.A.S.H.*, 27 N.Y.3d at 181. The "focus" of the analysis "must be on whether the challenged regulation attempts to resolve difficult social problems" by "making choices among competing ends." *Nat'l Rest. Ass'n v. New York City Dept of Health & Mental Hygiene*, 148 A.D.3d 169, 174 (1st Dept 2017) (citing *New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Dept of Health & Mental Hygiene*, 23 N.Y.3d 681, 697 (2014)).

Case law shows that such improper "choices" or "value judgments" are evidenced by the adoption of exceptions which attempt to balance the policy goal (i.e. public health) with economic concerns that are unrelated to the policy goal. *See, e.g., NYC C.L.A.S.H.*, 27 N.Y.3d at 181 n.5 (analyzing *Statewide Coalition*, 23 N.Y.3d at 690, and stating that the sugary drink ban in that case was an inappropriate attempt to choose between competing policy goals as evidenced by the fact that the decision to reduce consumption sizes was a "compromise that attempted to promote a healthy diet without significantly affecting the beverage industry"); *id*. n.5 (analyzing *Boreali* and observing that the agency improperly weighed competing business interests when it created a scheme "laden with exceptions based solely upon economic and social concerns, including exceptions . . . for bars, convention centers, small restaurants, and the like, . . . based on financial hardship." (internal quotations omitted)).

On the other hand, this factor will weigh in favor of the agency when the rule does not

include an attempt to compromise with concerns that are unrelated to the policy goal. *See, e.g.*, *Garcia v. New York City Dept of Health & Mental Hygiene*, 31 N.Y.3d 601, 612-13 (2018) ("There is no indication that the Board limited the scope of its rules [requiring flu vaccination] based on financial considerations of special or business interests."); *NYC C.L.A.S.H.*, 27 N.Y.3d at 181, n.5 (no evidence of economic considerations where regulation "merely prohibits smoking in designated outdoor areas under the jurisdiction of" the agency). Similarly, the first *Boreali* factor weighs in favor of the agency when the rule includes exceptions that are designed to further the legislative interests. *See, e.g.*, *LeadingAge*, 32 N.Y.3d at 265 ("[I]nstead of improperly weighing competing special interests against the public health goal, the waiver provisions of the hard cap regulations are designed to *further* the legislative goal." (emphasis in original)).

Here, the first factor favors the Respondents because the Emergency Rule—unlike the rule at issue in *Boreali*—does not include any attempt to weigh competing or special interests which are unrelated to the public health goal through exceptions to the rule. It is quite simply a ban on flavored vaping products. The Petitioners argue (in conclusory fashion and without explanation) that the Respondents made inappropriate value judgments and improperly balanced social and economic concerns by allowing combustible cigarettes to remain on the market. Pet. Mem. at 24. But this argument is flawed because the failure to include combustible cigarettes is not an "exception" to the rule. As illustrated by the Court of Appeals, an inappropriate exception would be, for example, an exception made "based on financial hardship." *See NYC C.L.A.S.H.*, 27 N.Y.3d at 181 n.5 (analyzing *Boreali* and observing that the exceptions to the public smoking ban for bars, convention centers, and small restaurants were improperly based on financial concerns). Omitting combustible cigarettes from the Emergency Rule is not analogous to the

inappropriate exceptions at issue in *Boreali*. Indeed, the Emergency Rule does not include any exceptions that are unrelated to the policy goal of public health. There is absolutely no indication that the decision to omit combustible cigarettes was based on economic or special interests. The Respondents here merely responded to data which shows an alarming increase in e-cigarette use among youth. (*See, e.g.*, Hutton Aff. ¶ 15 [160% increase in e-cigarette use by high school youth from 2014 to 2018]; ¶ 16 [36.7% of high school seniors use e-cigarettes]; ¶ 17 [222,000 middle and high school students in New York use e-cigarettes]; ¶ 22 [flavors are a principle reason youth initiate and maintain e-cigarette use]). Absent any evidence of exceptions catering to interests that are unrelated to the policy goal of public health, this factor favors the Respondent.

2. The Second *Boreali* Factor

The second *Boreali* factor is called the "tabla rasa" or clean slate consideration, where the court assesses "whether the agency merely filled in details of a broad policy or if it wrote on a clean slate, creating its own comprehensive set of rules without benefit of legislative guidance." *NYC C.L.A.S.H.*, 27 N.Y.3d at 182 (internal citations and quotation marks omitted). If an agency writes on a "clean slate," it can run afoul of the separation of powers. If, however, the agency has a longstanding history of regulating in a particular subject area, then the agency is not writing on a clean slate. *See, e.g.*, *Garcia*, 31 N.Y.3d at 613-14 ("long history of mandating immunization" supported agency action under the clean slate factor); *Greater N.Y. Taxi Ass'n*, 25 N.Y.3d at 611 (holding that the taxi limousine commission was not writing on a clean slate by adopting regulations selecting specific vehicle model as official NYC taxi because it "has always regulated the taxis industry as to almost every detail of its operation"). Similarly, the agency is not writing on a clean slate where the legislature has set forth a policy by statute or statutory

scheme. *LeadingAge*, 32 N.Y.3d at 265 (legislature created a "statutory framework directing" the agency to use state health funds in the most efficient manner possible); *NYC C.L.A.S.H.*, 27 N.Y.3d at 184 (upholding public smoking ban and observing that "the legislature has spoken against secondhand smoke").

Here, the Respondents are not regulating a new area for the first time but rather are executing policy decisions articulated by the Legislature through a comprehensive statutory scheme. For example, Public Health Law § 225 gives the Respondent Public Health and Health Planning Council the authority to "deal with matters affecting the security of life or health or the preservation and improvement of public health in the state of New York." This broad authority undisputedly includes the ability to regulate youth access to nicotine products. Similarly, with regard to nicotine use, the Legislature articulated its preference that youth be unable to obtain tobacco and nicotine products through a series of statutes. *See, e.g.*, Public Health Law § 1399-ii(2)(f) (DOH must support restrictions on youth access to tobacco products); Public Health Law § 1399-ii(2)(c)(requires DOH to engage in marketing and advertising to discourage tobacco and nicotine use); Public Health Law § 1399-ii(2)(h) (authorizing DOH to take "any other activities determined by the commissioner to be necessary to implement the provisions of this section," which is titled, "Tobacco use prevention and control program"). The Legislature's policy decision is further evidence by the statute prohibiting vaping in certain locations, Public Health Law § 1399-O-1, and the law prohibiting the sale of e-cigarette products to individuals under twenty-one years of age, Public Health Law § 1399-BB (effective Nov. 13, 2019). Indeed, entire Articles of the Public Health Law are devoted to tobacco and nicotine regulation. *See, e.g.*, Public Health Law Art. 13-E, 13-F, 13-G. Beginning on December 1, 2019, vapor products will be subject to a 20% sales tax. Tax Law, Art. 28-C. These statutes are part of a comprehensive

legislative strategy to limit youth access to nicotine and vaping products through education, taxation, age limits, and location limits. The Respondents were acting within this scheme, and pursuant to pre-existing legislative policy decisions, when they issued the Emergency Rule.

3. The Third *Boreali* Factor

The third *Boreali* factor has been called the "consensus consideration," pursuant to which courts asses "whether the legislature has unsuccessfully tried to reach agreement on the issue, which would indicate that the matter is a policy consideration for the elected body to resolve." *NYC C.L.A.S.H.*, 27 N.Y.3d at 183. The Court of Appeals has warned that "Legislative inaction, because of its inherent ambiguity, afford the most dubious foundation for drawing positive inferences." *Id*. at 184. For this reason, courts have repeatedly found that the existence of prior unsuccessful legislation—even in greater amounts than present here—does not indicate that an agency has exceeded its mandate. *See, e.g., Rent Stabilization Ass'n of N.Y.C. v. Higgins*, 83 N.Y.2d 156, 170 (1993) (27 prior unsuccessful bills on same subject); *N.Y. State Health Facilities Ass'n v. Axelrod*, 77 N.Y.2d 340, 348 n.2 (1991), *rev'g* 155 A.D.2d 208 (3d Dept 1990) (ten prior unsuccessful bills). Furthermore, unsuccessful bills—such as those which do not make it out of committee—do not favor the Petitioners because such bills were not "the subject of vigorous debate." *See Nat'l Rest. Ass'n*, 148 A.D.3d at 178 ("However, on each occasion, the proposed legislation was sent to committee, and no further action was taken, so there is no indication that it was the subject of vigorous debate."); *LeadingAge*, 32 N.Y.3d at 265 ("While bills have been introduced in the legislature relating to executive compensation caps, they never made it out of committee."). *See also id.* (stating that "a single unsuccessful proposal is not in the same class as the repeated unsuccessful legislative efforts we have deemed indicative of the type of broad public policy issue reserved exclusively to the legislature").

Here, the Petitioners rely on two bills—one in the Senate and another in the Assembly—neither of which (by the Petitioners' own admission) advanced past the committee stage. Pet. Mem. at 23. The Petitioners, in relying so heavily on these two unsuccessful bills, disregarded the Court of Appeals' warning that legislative inaction "affords the most dubious foundation for drawing positive inferences." *NYC C.L.A.S.H.*, 27 N.Y.3d at 184.

The Petitioners also argue that the Emergency Rule "disregard[s] the most significant action" taken by the Legislature, i.e., raising the minimum age. Pet. Mem. at 23. This argument fails because the "mere fact that the Legislature has enacted specific legislation in a particular field does not necessarily lead to the conclusion that broader agency regulation of the same field is foreclosed." *Consol. Edison Co. of New York v. Dep't of Envtl. Conservation*, 71 N.Y.2d 186, 193, 519 N.E.2d 320 (1988). By leaving intact DOH's broad discretion over protecting the public health while continuing to find other ways to strengthen laws to protect against youth nicotine addiction, the Legislature has signaled its intent to defer to DOH's expertise in addressing the problem. *See Med. Soc'y of State v. Serio*, 100 N.Y.2d 854, 865-66 (2003).

Far from creating new public policy, the Emergency Rule is the quintessential example of interstitial rulemaking. It implements legislatively-expressed policies—to restrict adolescent access to nicotine products—and responds to a rapidly developing public health crisis, filling in the gaps in the statutory enforcement scheme. This factor therefore weighs in favor of the Respondents.

4. The Fourth *Boreali* Factor

The fourth factor "turns on agency knowledge, and specifically whether the agency used special expertise or competence in the field to develop the challenged regulation." *NYC C.L.A.SH.*, 27 N.Y.3d at 184. This factor will weigh in favor of the agency when, for example,

the agency's "expertise is essential to its determination," *Garcia*, 31 N.Y.3d at 616 (DOH expertise essential to determination of whether to require influenza vaccine); when the agency "utilized special expertise" in crafting its regulations, *LeadingAge*, 32 N.Y.3d at 266 (DOH drew on its understanding of the health care industry in adopting regulation); or when the regulation is "driven by several concerns that are within the realm of [the agency's] expertise," *NYC C.L.A.SH.*, 27 N.Y.3d at 184-85 (agency's outdoor smoking ban in public parks was driven by concerns within its area of expertise).

Here, it is beyond dispute that the Department of Public Health and the Public Health and Health Planning Council has special expertise in matters involving the public health, including the use of nicotine products such as e-cigarettes and vaping devices. The record shows that the Respondents relied on this expertise in developing the Emergency Rule. In creating the Emergency Rule, the Respondents accumulated, compiled and analyzed data and research regarding the detrimental health effects related to e-cigarette use (particularly, but not limited to respiratory illnesses), the prevalence of e-cigarette use among minors, and the skyrocketing (and still increasing) rates of e-cigarette use by minors in recent years. (*See, e.g.*, Hutton Aff. ¶ 15 [160% increase in e-cigarette use by high school students from 2014-2018]; ¶ 16 [36.7% of high school seniors use e-cigarettes]; ¶ 17 [222,000 middle and high school students in New York use e-cigarettes]; ¶ 22 [flavors are a principle reason youth initiate and maintain e-cigarette use]. *See also*, Hutton Aff. Exhibit "A" *Emergency Rule* at p. 5 [DOH research showed an 160% increase among youth in high school from 2014 to 2018]). They relied upon the U.S. Food and Drug Administration's report that "the use of e-cigarettes by youth has reached epidemic proportions nationally." (Hutton Aff. Exhibit "A" *Emergency Rule* at p. 18; Hutton Aff. ¶ 12). They relied upon recent National Academy of Science, Engineering, and Medicine publications showing

"substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults." (Hutton Aff. Exhibit "A" *Emergency Rule* at p. 5). Indeed, the Respondents' work here is wholly analogous to the respondents' efforts in *Garcia*, which concerned a rule requiring influenza immunizations in city-supervised schools and day cares. *See Garcia*, 31 N.Y.3d at 615-16 (fourth *Boreali* element favored agency where it compiled data and research concerning severity of the problem, explained that the rules are supported by research, and relied on Federal Advisory Committee on Immunization Practices in promulgating its rule). This factor weighs in favor of the Respondents.

The Petitioners are unable to show a likelihood of success on the merits as to their separation of powers claim because all *Boreali* factors weigh in favor of the Respondents. The request relief must be denied.

B. The Emergency Rule Was Properly Enacted Pursuant to SAPA

The standard of review in matters regarding the State Administrative Procedure Act ("SAPA") is one of substantial agency compliance. *See* SAPA § 202(8); *see also, Medical Society of the State of N.Y. v. Serio*, 100 N.Y.2d 854, 869 (2003) (each rule or regulation proposed by an agency must be promulgated "in substantial compliance"). "[T]he determination of an agency acting pursuant to its authority and within its area of expertise is [] entitled to judicial deference." *Entergy Nuclear Indian Point 2, LLC v. N.Y. State Dept of State*, 130 A.D.3d 1190, 1192 (3d Dept 2015) *accord, Seneca Nation of Indians v. State*, Index No. 2011-00714, 2011 WL 2436815, at *5 (Sup. Ct. Erie Cty. 2011) (a court reviewing the SAPA process is "required to give deference to agency findings."). As such, "[i]f the State has substantially complied with the State's Administrative Procedure Act, the Rule must stand." Seneca Nation, 2011 WL 2436815, at *5.

Pursuant to SAPA §202(6), a state agency may adopt a rule on an emergency basis if the agency determines that "immediate adoption of [the] rule is necessary for the preservation of the public health, safety or general welfare" and courts have upheld emergency rule making under such circumstances. *See*, *Korean Am. Nail Salon Ass'n of New York v. Cuomo*, 50 Misc. 3d 731, 735 (Sup. Ct. Albany County 2015). An emergency regulation may remain in effect for ninety days, although it may be readopted within the ninety-day period. SAPA § 202(6). If an emergency regulation is readopted, it may remain in effect for an additional sixty days. *Id.*

In reviewing an agency's determination to issue emergency regulations, the standard of review to be applied by the Court "is not whether [the Court] would have concluded that a limited emergency exists; it is rather whether the determination by the [agency] that such an emergency exists was irrational or arbitrary and capricious." *Board of Visitors-Marcy Psychiatric Center v. Coughlin*, 60 N.Y.2d 14, 20 (1983). SAPA §202(6)(d)(iv) simply requires that an agency promulgating an emergency rule illustrate circumstances underlying its resort to the urgent measure. *See*, *Brodsky, et al v. Zagata*,165 Misc.2d 510, 515 (Sup. Ct. Albany County 1995). Here, Respondents have done just that and have complied with SAPA in promulgating the Emergency Rule.

Petitioners have submitted the Emergency Rule with accompanying "Regulatory Impact Statement" and "Emergency Justification" statement with their underlying papers, attached to the September 24, 2019 Affirmation of Richard De Palma as Exhibit "A". (For the court's convenience, a copy of the Emergency Rule with statements is also attached to the Hutton Affidavit as Exhibit "A"). Pursuant to the "Emergency Justification" statement regarding the Emergency Rule, it was adopted based on determinations by the Department of Health and the Public Health and Health Planning Council that emergency regulations are necessary to address

the alarming, ongoing and rapid increase of e-cigarette use among New York's youth; that significant numbers of adolescent e-cigarette users report that flavored e-liquids are the reason they currently use e-cigarettes; that a significant portion of adolescent e-cigarette users report that flavored e-liquids were the primary reason they first began using addictive e-cigarettes; that adolescents are more likely to believe that fruit and chocolate or other sweet flavored e-cigarette e-liquids are less harmful than flavors like alcohol, tobacco, and spice flavors; that over the past four (4) years, e-cigarette use among adolescents in New York State has skyrocketed, from 10% of all high school children in 2014 to 27.4% of all high school children in 2018; that enforcement of laws banning the sale of e-cigarettes to those under 18 years of age is difficult and has not stemmed the dramatic rise in e-cigarette use among adolescents; that adolescents who use e-cigarettes are more likely to eventually smoke combustible tobacco cigarettes; that e-cigarette e-liquids contain nicotine, which is addictive; that nicotine has damaging effects on the developing brain, posing a particular risk to adolescents since brain development continues into the mid-twenties; that existing regulations were inadequate to address these alarming and increasing problems; that restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use among adolescents; that inhaling flavorant chemicals and aerosols have a direct negative impact on lung tissue and directly enter the circulatory system and are not detoxified through the liver; that research is accumulating about certain negative health effects from e-cigarette use related to cardiovascular conditions and respiratory conditions; and that immediate action was required to preserve the public health, safety and general welfare. (Hutton Aff. Exhibit "A" p.p 18-21).

In addition, as set forth in the "Regulatory Impact Statement" for the Emergency Rule, "the alternative to the proposed regulation is to wait for the FDA to regulate in this area;

however, due to the health concerns associated with increase[d] e-cigarette use among youths, this alternative was rejected." (Hutton Aff., Exhibit "A", p. 10).

Thus, the statements accompanying the Emergency Rule do indeed provide a description of the nature, cause and consequences of the problems addressed by it, and contains information explaining why the Public Health and Health Planning Council, and the Department of Health determined that that the rule needed to be promulgated on an emergency basis.

As noted above, once an agency has articulated bases for its emergency rulemaking, the standard of review is not whether a court would conclude that an emergency exists; the question is whether the agency's determination was irrational or arbitrary or capricious. *See, e.g., Board of Visitors--Marcy Psychiatric Ctr. v. Coughlin*, 60 N.Y.2d 14, 20 (1983). If the Public Health and Health Planning Council could reasonably find that emergency circumstances required a departure from ordinary rulemaking procedures, the action should be upheld. *Id.* at 20-21; *Empire State Ass'n of Adult Homes v. Novello*, 193 Misc.2d 543, 544 (Sup. Ct. Albany County 2002) (applying rational basis review to emergency regulations challenge). Nor can it be said that the decision to take immediate action at the time was unreasonable because the situation being addressed was a problem which had emerged over a relatively long period of time. *See, Board of Visitors-Marcy Psychiatric Center v Coughlin*, 60 NY2d at 20.

As also noted above, the Emergency Rule was adopted based on rational, well-reasoned determinations by the Department of Health and the Public Health and Health Planning Council, within their area of expertise, that it was necessary to immediately address a rapidly worsening public health crisis among adolescents and the public at large. These considerations clearly provided a rational basis for the promulgation of the regulation in question on an emergency basis and Respondents did indeed substantially comply with SAPA in doing so.

Petitioners attempt to convince this Court otherwise by citing to a number of cases that are inapposite to the present matter.

Petitioners repeatedly cite to *Matter of Gill v. New York State Racing & Wagering Bd.*, No. 118095/04, 2006 N.Y. Misc. LEXIS 565 (Sup. Ct. N.Y. County February 9, 2006) as offering an example of a situation in which a regulation adopted on an emergency basis should be invalidated as failing to comply with SAPA. Yet in that proceeding, the petitioners in question challenged a regulation – which banned the use of "fluphenazine" in race horses - that had been initially adopted and then repeatedly re-adopted on an emergency basis *a total of five (5) times over the course of more than a year* (on October 21, 2003, January 30, 2004, April 30, 2004, August 2, 2004 and November 1, 2004), had then been allowed to lapse between one of those re-adoptions, and then had been allowed to lapse again for months after the fifth emergency adoption (in November, 2004) before it was eventually adopted as a permanent regulation in May, 2005. *Matter of Gill*, 2006 N.Y. Misc. LEXIS 565 at * 7, 11, 15 - 16. The Article 78 Petition in that matter specifically dealt with a determination by that respondent based on the regulation in question which was dated August 26, 2004 – after the fourth time said regulation had been adopted/re-adopted on an emergency basis, and nearly a year after it had first been adopted on an emergency basis, but still had not yet been promulgated as a permanent regulation. *Id*., at * 14. Indeed, the court in *Matter of Gill* specifically noted that the Petition in that matter "argue[d] that the Board's 'Emergency Rule' … should be annulled, its implementation or enforcement enjoined, and the Board's August 26, 2004 ruling vacated, because the Board violated or otherwise failed to comply with the emergency rule provisions of the SAPA § 202 **by impermissibly readopting the rule a total of five times** - all on a supposedly 'emergency' basis", and stated that the proprietary of that repeated "seriatim"

readopting of that rule was "[t]he question before [that] Court …." (Emphasis added). *Id*., at * 14 - 16. Further, evidence in that matter revealed that, during the lengthy period of time the rule was in place on an "emergency" basis, a test for "fluphenazine" needed to enforce said rule was not reliable enough for the respondent to promulgate the rule as a permanent regulation under SAPA, and that its claim of "emergency" was a pretense "to circumvent the provisions of SAPA." *Id.*, at * 23 – 24, 29 – 30.

Thus, the court in *Matter of Gill* made it abundantly clear that it vacated the regulation, as it existed on an emergency basis during the time relevant to that matter, because the alleged need to adopt it on an emergency basis was an improper attempt by that respondent "to circumvent the SAPA and do indirectly what it could not do directly", as the evidence there clearly demonstrated that: (1) the regulation had been adopted and then re-adopted on a supposedly "emergency" basis a total of five (5) times over the course of more than a year; (2) the regulation had repeatedly been allowed to lapse before that respondent made any attempt to promulgate it as a permanent regulation; (3) the regulation had eventually been quickly adopted as a permanent regulation, without delay or complication, once the respondent finally attempted to do so; and (4) the evidence indicated that the real reason the regulation had been adopted and then time and again re-adopted on an "emergency" basis was not that there was any genuine pressing need for it to be adopted on such a basis, but rather "because of questions surrounding the reliability of the test used" to enforce said regulation which would have prevented it from being adopted on a permanent basis.

As a result, while *Matter of Gill* is indeed instructive regarding what courts may construe as an unsupported claim that a regulation should be adopted on an emergency basis, and a violation of SAPA, the facts of that proceeding are wholly inapposite to those of the present

matter. Here, Respondents promulgated the Emergency Rule in question on a single occasion and did so for the first time mere weeks ago.

Petitioners also cite to *Law Enforcement Officers Union, Dist. Council 82 v. State*, 168 Misc. 2d 781 (Sup. Ct. Albany County November 22, 1995). Indeed, Petitioners place heavy reliance on that case offering it as an example of a situation in which an emergency regulation should be invalidated for failing to comply with SAPA. Petitioners attempt to convince this Court that the situation in that matter is analogous to the present proceeding. But in *Law Enforcement Officers Union, Dist. Council 82 v. State*, the trial court found that "[i]n response to the requirements of State Administrative Procedure Act § 202(6)(d)(iv) respondents provided the following [statement as justifying the regulation's adoption on an "emergency" basis]: 'The Department of Correctional Services is over capacity and needs additional beds to confine statutorily committed individuals. This amendment is necessary to address the capacity shortfall' ". *Law Enforcement Officers Union, Dist. Council 82 v. State*, 168 Misc. 2d at 784. That was the entirety of the statement meant to justify the regulation's adoption on an emergency basis, and nothing further was offered to explain "the circumstances which [gave] rise to the adoption on an emergency basis" or to justify its promulgation as an emergency regulation. The respondents' statement in that matter failed to offer any statistics, data or any other information to support the need for the regulation or that might show why it should be adopted on an emergency basis. Given that marked paucity of information, the trial court found that "[w]hile prison overcrowding may well be a difficult challenge for respondents, there [was] a complete absence of showing that it must be dealt with by double celling prior to the period of public notice and comment allowed by [SAPA]" and that respondents thus did not comply with SAPA.

Petitioners also cite to *Matter of Chinese Staff & Workers Ass'n v. Reardon*, 2018 N.Y.

Misc. LEXIS 4231 (Sup. Ct. N.Y. County September 25, 2018) as another case that they claim illustrates Respondents' supposed violation of SAPA by promulgating the Emergency Rule on an emergency basis. Similar to Petitioners' reliance on *Matter of Gill* and *Law Enforcement Officers Union, Dist. Council 82 v. State*, their reliance on *Matter of Chinese Staff & Workers Ass'n* is misguided. In *Matter of Chinese Staff & Workers Ass'n*, the respondents – the New York State Department of Labor and its Commissioner - adopted a regulation "to exclude sleeping and meal breaks from work hours for which home care attendants working 24-hour shifts in clients' homes are required to be compensated" on an emergency basis in October 2017, then repeatedly re-adopted it, also on an "emergency" basis, in January 2018, April 2018 and then again in June 2018. *Id.*, at * 1, 4. The Petition challenging the regulation in that matter was filed on May 4, 2018, after the regulation in question had been adopted and re-adopted on an "emergency" basis three (3) times over the course of seven (7) months. *Id*. While the court in *Matter of Chinese Staff & Workers Ass'n* did indeed find that the regulation in question was improperly promulgated on an "emergency" basis, it did so because the alleged harm that the regulation was adopted to address was speculative and had not even yet occurred and because the record was entirely devoid of evidence that justified adopting the regulation on an emergency basis, much less adopting it and then re-adopting it on such a basis a total of four (4) times. As the court in that matter noted, the statement from respondents in support of adopting said regulation on an emergency basis merely noted that, in light of then recent court decisions, "home care agencies **may cease** to provide home care aides" but said nothing about that actually occurring or even beginning to occur. (Emphasis in the original). *Matter of Chinese Staff & Workers Ass'n*, 2018 N.Y. Misc. LEXIS 4231 at * 9.

The court further noted that "[b]ased on the record before the Court, to justify the

Emergency Rulemakings at issue", the respondents "relied on a July 14, 2017 Notice … to home health providers" which simply stated that in light of recent court decisions, the respondent and other state agencies "will continue to evaluate **whether action *may* be needed** to prevent unnecessary disruption to home care services in New York State", but offered no information indicating that any harm was actually occurring or that might show an actual, non-speculative need for swift action. (Emphasis added) *Id*., at *10. In light of that particular record, the court in *Chinese Staff & Workers Ass'n*, then held:

> Here, although Respondents claim that the "emergency regulation is needed to preserve the status quo, prevent the collapse of the home care industry, and avoid institutionalizing patients who could be cared for at home, in the face of recent decisions by the State Appellate Divisions," the record is devoid of **any** facts upon which to base a finding of "immediate necessity, emergency or undue delay." (see *Law Enf. Officers Union*, 168 Misc. 2d at 784.). **A mere need for the monitoring** of the home care service industry in light of the Appellate Division rulings **and a potential concern** about a disruption is not sufficient to justify the use of SAPA's administrative procedures for emergency rulemaking. **It does not constitute a situation where "bad things are happening,"** as was the case in *Korean Am. Nail Salon Ass'n of New York, Inc. v. Cuomo*, 50 Misc. 3d [731] at 735.

(Emphasis added). *Chinese Staff & Workers Ass'n*, 2018 N.Y. Misc. LEXIS 4231 at * 12 – 13.

The facts of the present matter stand in remarkably stark contrast to the above-discussed record presented to the courts in *Law Enforcement Officers Union, Dist. Council 82 v. State* and *Chinese Staff & Workers Ass'n*. Unlike the skeletal, one-sentence, factually deficient statement regarding the regulation in *Law Enforcement Officers Union, Dist. Council 82 v. State*, the "Emergency Justification" statement regarding the Emergency Rule in this matter is several pages long and sets forth hard data, statistics, study results and other information clearly summarizing an ongoing and rapidly worsening public health crisis involving use of addictive, harmful e-cigarette products by adolescents, fueled by the particular allure of flavored vaping e-liquids to adolescents and magnified by the especially harmful effects of nicotine on youth. (*See*,

Hutton Aff. Exhibit A, p.p. 18-21). Further, unlike the speculative nature of the yet-to-occur harm addressed by the regulation in *Chinese Staff & Workers Ass'n*., the harm addressed by the Emergency Rule in the present matter is very real, well-documented, ongoing and worsening, even as this case is pending.

Thus, unlike the easily differentiated facts of *Matter of Gill, Law Enforcement Officers Union, Dist. Council 82 v. State*, and/or *Chinese Staff & Workers Ass'n*, the record in the present matter shows that Respondents provided a rational basis for the promulgation of the Emergency Rule on an emergency basis and Respondents did indeed substantially comply with SAPA in doing so.

Petitioners also claim that "[t]he record here stands in stark contrast to previous cases where courts have upheld emergency rule making under SAPA § 202(6)(d) when 'necessary for the preservation of the public health, safety or general welfare'", citing to *Korean Am. Nail Salon Ass'n of New York, Inc. v. Cuomo*, 50 Misc. 3d 731 (Sup. Ct. Albany County December 1, 2015). (Petitioners' Memorandum of Law p.p. 35 - 36). Petitioners claim that "unlike the inactivity" of the Public Health and Health Planning Council here, after accumulating data and information on the startling rise in adolescent e-cigarette usage from 2014 through 2018, the New York Department of State in *Korean Am. Nail Salon Ass'n of New York*, adopted a series of emergency rules to protect workers in the nail salon industry <u>immediately</u> after the DOL undertook an investigation of nail salons that resulted in the finding of 116 wage violations at 29 nail salons. 50 Misc. 3d at 732, 26 N.Y.S.3d at 828." (Emphasis in the original) (Petitioners' Memorandum of Law p. 36). This claim is not only unsupported by the decision in *Korean Am. Nail Salon Ass'n of New York, Inc.*, it is quite simply false.

While the court in *Korean Am. Nail Salon Ass'n of New York, Inc.* cited to that DOL investigation of nail salons, as well as its finding "of 116 wage violations at 29 nail salons across New York State", and noted that the emergency regulation in question dealing with that issue was promulgated "[a]fter" that DOL investigation, it made no mention of when that investigation took place. *Korean Am. Nail Salon Ass'n of New York, Inc. v. Cuomo*, 50 Misc. 3d 731 at * 732 - 733 (Sup. Ct. Albany County December 1, 2015). Contrary to Petitioners' assertion, the court did not state that the regulation was promulgated "immediately" after that investigation. In fact, the DOL investigation in question was actually completed in May ***2014*** – fully a year before the regulation at issue in *Korean Am. Nail Salon Ass'n of New York, Inc.* was first promulgated on an emergency basis on May 18, 2015, and nearly sixteen (16) months before it was then re-adopted on an emergency basis in September, 2015. Attached hereto as **Appendix 5** is a true and complete copy of the May 11, 2015 press release from Governor Cuomo announcing the creation of a multi-agency task force "to prevent unlawful practices and unsafe working conditions in the nail salon industry", which specifically states that "[i]n May 2014, the Department of Labor conducted a comprehensive investigation into nail salons that was recently highlighted as part of a two-part series in The New York Times. The investigation of 29 nail salons resulted in the finding of 116 violations of state labor law." (**Appendix 5**, p. 3). Attached hereto as **Appendix 6** is a true and complete copy of former Assistant Attorney General Justin Engel's affidavit, submitted to the court in *Korean Am. Nail Salon Ass'n of New York, Inc.* which also noted that "[t]he formation of the task force and implementation of the wage bond requirement was motivated, in part, by a comprehensive investigation of nail salons conducted in May 2014 by the Department of Labor that resulted in the finding of 116 wage violations at 29 nail salons." (**Appendix 6**, ¶ 4). Thus, despite Petitioners' specious and unsupported claim to the contrary, far

from supporting Petitioners' arguments in this matter, the decision in *Korean Am. Nail Salon Ass'n of New York, Inc.* strongly supports Respondents' position and highlights the propriety of their promulgation of the Emergency Rule on an emergency basis.

The public health issue targeted by the Emergency Rule - adolescents using (and first starting to use, on a daily basis), an addictive, harmful substance, as well as the harmful effects of vaping products on public health (and adolescents in particular), including, but not limited to the ongoing, and worsening nationwide outbreak of vaping-related severe respiratory illnesses discussed above - has not remained static and unchanging in nature over the course of many years, but rather is an ongoing, evolving crisis which has been worsening with increasing rapidity. As is described at length throughout the accompanying Affidavit of Deputy Commissioner Brad Hutton, the Department of Health did not begin monitoring adolescent use of vaping products until 2014, and the most recent data, much of which did not become available until 2019, demonstrates the need to act now. As is set forth in Hutton's Affidavit, the data from many of the studies and surveys relied on by the Department of Health and the Public Health and Health Planning Council in promulgating the Emergency Rule was not available, published and/or analyzed until 2019 – much of it just within the past few months and some of it mere days before the Emergency Rule was promulgated on September 17, 2019. (*see, e.g.* Hutton Aff. ¶¶ 15, 16, 19, 23, 69, 74, 80; Hutton Aff. footnotes 2 – 14, 18, 23, 27, 29, 33, 34, 79, 80, 85, 90, 92, 93, 101, 102, 105).

Further, the New York State Court of Appeals itself has specifically held that "[n]either can it be said that the decision to take immediate action at this time is unreasonable because [the problem at issue] is a problem of long standing in this State." *Bd. of Visitors--Marcy Psychiatric Ctr. v. Coughlin*, 60 N.Y.2d 14, 20, 453 N.E.2d 1085 (1983).

Finally, on page 35 their memorandum of law, Petitioners' briefly claim that the Emergency Rule does not specifically state the "expected duration" of the need for said rule and appear to argue that this invalidates the rule. This Court has previously held, though, that the omission of such a termination/expected duration date does not "rise to the level of error which would nullify" an emergency regulation. *Council for Owner Occupied Hous. v. Abrams*, 133 Misc. 2d 574, at * 577 (Sup. Ct. Albany County October 6, 1986), *aff'd* 125 A.D.2d 10 (3d Dep't. 1987).

Thus, Petitioners' fail to show, by "clear and convincing evidence", the likelihood of their success on the merits with regard to their erroneous SAPA claim.

C. The Emergency Rule Has A Rational Basis and its Enactment Was Not Arbitrary or Capricious

The standard for judicial review in an Article 78 proceeding is whether the challenged determination had a rational basis, or whether it was arbitrary and capricious. *Matter of Coleman v. State of New York*, 38 A.D.3d 1044, 1045-1046 (3d Dept 2007). An "[a]ction is arbitrary and capricious when it is without sound basis in reason and is . . . taken without regard to the facts." *Matter of Prestige Towing & Recovery, Inc. v. State of New York*, 74 A.D.3d 1606, 1607 (3d Dept 2010). The test applied in deciding whether a determination was arbitrary and capricious is whether the determination had a rational basis. *Matter of Peckham v. Calogero*, 12 N.Y.3d 424, 431 (2009). An agency's "determination will not be set aside by the courts unless it is unsupported by proof sufficient to satisfy a reasonable [person] of all the facts necessary to be proved in order to authorize the determination." *Matter of Pell v. Board of Educ. of Union Free School Dist. No. 1 of Towns of Scarsdale & Mamaroneck, Westchester County*, 34 N.Y.2d 222, 231 (1974) (quotation marks and quoted case omitted). In other words, "a court may not

substitute its judgment for that of the board or body it reviews unless the decision under review is arbitrary and unreasonable and constitutes an abuse of discretion." *Id.*, at 232.

The "Court's role in reviewing an agency action is not to determine if the agency action was correct or to substitute its judgment for that of the agency, but rather to determine if the action taken by the agency was reasonable." *Chemical Specialties Mfrs. Ass'n v. Jorling*, 85 N.Y.2d 382, 396 (1995). "If the court finds that that the determination is supported by a rational basis, it must sustain the determination even if . . . it would have reached a different result than the one reached by the agency." *Id.*; *see also Matter of Eastern Niagara Project Power Alliance v. New York State Dep't of Envtl. Conservation*, 42 A.D.3d 857, 861 (3d Dep't 2007) ("in reviewing an administrative determination [a court's] role is not to 'reweigh facts and substitute [its] judgment for that of the agency'") (citation omitted).

"[T]he determination of an agency acting pursuant to its authority and within its area of expertise is entitled to judicial deference." *Matter of Riverkeeper, Inc. v. Johnson*, 52 A.D.3d 1072, 1074 (3d Dept 2008). "[W]here, as here, the judgment of the agency involves factual evaluations in the area of the agency's expertise and is supported by the record, such judgment must be accorded great weight and judicial deference." *Matter of Flacke v. Onondaga Landfill System*, 69 N.Y.2d 355, 363 (1987). Moreover, in order to maintain the limited nature of review, courts defer to the agency's construction of statutes and regulations that it administers so long as that construction is not irrational or unreasonable. *Albano v. Kirby*, 36 N.Y.2d 526 (1975).

"Where the interpretation of a statute or its application involves knowledge and understanding of underlying operational practices or entails an evaluation of factual data and inferences to be drawn therefrom, the courts regularly defer to the governmental agency charged with the responsibility for administration of the statute." *Kurcsics v. Merchants Mut. Ins. Co.*, 49

N.Y.2d 451, 459 (1980). If the agency's "interpretation is not irrational or unreasonable, it will be upheld." *Id.* In other words, a state agency is entitled to a "high degree of judicial deference, especially when . . . act[ing] in the area of its particular expertise" and, thus, Petitioners bear the "heavy burden of showing" that Respondents' conclusions are "unreasonable and unsupported by any evidence." *Matter of Nazareth Home of the Franciscan Sisters v. Novello*, 7 N.Y.3d 538, 544 (2006) (quotation marks and quoted case omitted).

In addition, "[i]t is well-settled that a State regulation should be upheld if it has a rational basis and is not unreasonable, arbitrary, capricious or contrary to the statute under which it was promulgated." *Kuppersmith v. Dowling*, 93 N.Y.2d 90, 96 (1999). "If a regulation is to be nullified, the challenger must establish that it is so lacking in reason for its promulgation that it is essentially arbitrary." *Id.*

To prevail on such a claim, Petitioners must demonstrate that promulgation of the Emergency Rule was "irrational, arbitrary, or otherwise unlawful, to overcome the presumption of regularity that attaches to official action". *Hunts Point Terminal Produce Co-Op Ass'n, Inc. v. New York City*, 13 Misc 3d 988, 1002 (Bronx County 2006). In such cases, the reviewing court is charged not to substitute its judgment for that of the agency unless it clearly appears to be arbitrary, capricious or contrary to the law. *Id.* The terms "arbitrary" and "capricious" mean "willful and unreasoning action without consideration of or in disregard of the facts or without determining principle." *Elwood Investors Co. v. Behme*, 79 Misc.2d 910, 913 (N.Y.Sup. 1974).

Thus, in reviewing the rationale underpinning the Emergency Rule, the Department is entitled to considerable deference.

Here, the Department of Health and the Public Health and Health Planning Council are charged with promulgating regulations, and may promulgate emergency regulations, that "deal

with any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York …." Public Health Law ("PHL") §§ 225 (4) and (5)(a). Both the Public Health and Health Planning Council and the Department of Health have undeniable expertise in the area of public health. Further, discouraging and minimizing the use of addictive, harmful, nicotine-containing e-cigarettes among adolescents; moving to stem the considerable flow of adolescents who begin using these e-cigarettes on a daily basis, by prohibiting flavored, nicotine-containing liquids for use in e-cigarettes; and acting swiftly to curtail the spread of the ongoing outbreak of vaping-related severe respiratory illnesses – which has already led to the death of an adolescent in New York State - are all undeniably legitimate state interests.

As is discussed in Point II (B), above, as was set forth in the "Regulatory Impact Statement", and "Emergency Justification" statement for the Emergency Rule, and as is discussed at length in the accompanying Affidavit of Deputy Commissioner Hutton, said regulation is the result of a thorough, well-reasoned rationale designed to protect and improve public health across New York State, and specifically to combat the rapid and ongoing increase in use of addictive, harmful e-cigarette products by adolescents, significant numbers of whom are initially attracted to the use of such products by, and/or who continue to use e-cigarettes primarily because of the flavored e- liquids banned by this Emergency Rule.

Therefore, the Court should only intervene upon a compelling showing that the rationale underlying the Emergency Rule was unreasonable. It is respectfully submitted that Petitioners clearly fail to make such a compelling showing by "clear and convincing evidence", and, therefore fail to show that promulgation of the Emergency Rule was arbitrary and capricious.

POINT III

A BALANCE OF THE EQUITIES IS NOT IN PETITIONERS' FAVOR AND DOES NOT OUTWEIGH THE PUBLIC INTEREST

In addition to setting forth a non-speculative, non-conclusory demonstration of irreparable harm, and demonstrating their likelihood of success on the merits, Petitioners' must further show that a balance of the equities is in their favor and that their interests outweigh the public interest. *Matter of Riccelli Enters., Inc. v State of New York Workers' Comp. Bd.*, 2012 N.Y. Misc. LEXIS 2241 at * 244 - 246 (Sup. Ct. Onondaga County 2012).

Petitioners fail to demonstrate that a balance of the equities tips in their favor and that their interests outweigh the public interest. As is discussed above, the State is faced with a pressing public health matter in the form of an ongoing and worsening epidemic of adolescent use of addictive and harmful nicotine-containing e-cigarette products. Petitioners' claims of alleged irreparable injury are highly speculative and conclusory. Whatever economic harm petitioners may suffer is, on balance, outweighed by the compelling interest in protecting public health. As a result, Petitioners cannot show that the balance of the equities is in their favor or that their speculative claims of potential future harm outweigh the pressing public interest.

CONCLUSION

Because Petitioners fail to demonstrate their entitlement to a preliminary injunction, their request for same should be denied.

Dated: Albany, New York
October 10, 2019

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