SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY
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In the Matter of

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

Petitioners,

against

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

Index No. 906514-19

ORAL ARGUMENT REQUESTED

Respondents.

For a Judgment Under Article 78 of the Civil Practice Law And Rules in the Nature of ANNULMENT, DECLARATORY JUDGMENT AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF.
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MEMORANDUM OF LAW IN SUPPORT OF VERIFIED PETITION AND MOTION FOR TEMPORARY, PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

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Petitioners Vapor Technology Association ("VTA"), Benevolent ELiquids, Inc. ("Benevolent ELiquids"), and Perfection Vapes, Inc. ("Perfection Vapes" and together with VTA and Benevolent ELiquids, collectively, "Petitioners"), by and through their undersigned counsel, Thompson Hine LLP, respectfully submit this memorandum of law, together with the Affidavit of Anthony L. Abboud sworn to the 23rd day of September 2019 ("Abboud Aff."), the Affidavit of M. Jonathan Glauser sworn to the 23rd day of September 2019 (the "Glauser Aff."), the Affidavit of Victor Canastraro sworn to the 23rd day of September 2019 (the "Canastraro Aff."), the Affidavit of John Dunham sworn to the 23rd day of September 2019 (the "Dunham Aff."), the Affirmation of Richard De Palma, Esq. dated the 24th day of September 2019 (the "De Palma Aff.") and the Affirmation of Emergency of Richard De Palma, Esq. dated the 24th day of September 2019 ("Emergency Aff."), and the exhibits annexed thereto, all in support of their Verified Petition herein dated September 24, 2019 (the "Petition") and in support of their motion, made by Order to Show Cause, for a temporary restraining order and preliminary injunction pending a determination on the Petition.

PRELIMINARY STATEMENT

This is a Special Proceeding, pursuant to Articles 63 and 78 of the Civil Practice Law And Rules seeking: (i) a declaratory judgment that Respondents have improperly enacted, by emergency executive action, an amendment to Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR") to add a new Subpart 9-3, titled "Prohibition on the Sale of Electronic Liquids with Characterizing Flavors" (the "Emergency Rule") in excess of constitutional, statutory and administrative authority; (ii) judgment annulling the Emergency Rule; and (iii) a temporary restraining order, a preliminary injunction and a permanent injunction preventing Respondents from enforcing the Emergency Rule.

The Emergency Rule imposing a ban on non-tobacco- and non-menthol-flavored vapor products enacted by Respondents exceeds their statutory authority, is arbitrary and capricious, and fails to comply with the State Administrative Procedure Act. Petitioners, including Benevolent ELiquids, a Buffalo, New York-based e-liquid manufacturer, and Perfection Vapes, a Buffalo-based retailer of vapor products, will be irreparably harmed by the Emergency Rule's imminent enforcement, as they will be forced to shut down their business operations entirely.

Indeed, virtually all of the over 700 businesses that comprise New York's vapor products industry confront the same imminent fate. The balance of equities also favors Petitioners, as they merely seek to preserve the status quo while Respondents pursue stricter regulation of "flavored" vapor products through legislation.

For these reasons, as explained in greater detail below, the Court should temporarily preliminarily enjoin enforcement of the Emergency Rule pending a determination on the Petition, and should ultimately enter a declaratory judgment and permanent injunction that the Emergency Rule is *ultra vires*, void, and unenforceable.

FACTUAL BACKGROUND

I. Vapor Products Are a Less Harmful Alternative to Combustible Cigarettes that Are Widely Used by Former Smokers in a Variety of Flavors, Including Non-Tobacco- and Non-Menthol Flavors.

Vapor devices, also known as "electronic cigarettes," "e-cigarettes," or "electronic nicotine delivery systems (ENDS)" are handheld electronic devices that are used to heat and aerosolize a liquid mixture ("e-liquid") that contains nicotine.[1] *See* Canastraro Aff. at ¶ 4. Once

[1] The vapor products at issue in this case only involve nicotine-containing vapor products, not products derived from or containing cannabis, tetrahydrocannabinol (THC), or cannabidiol (CBD). This distinction is crucial in light of the recent certain health effects that have been portrayed as being associated with "vaping." The publicly available evidence makes clear that these health issues have all been associated with adulterated THC products, which products

the e-liquid is aerosolized, the user of the vapor device inhales the aerosolized "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without the fire, flame, tar, carbon monoxide, ash, stub, or smell associated with traditional combustible cigarettes. *Id*.

The e-liquids used in vapor devices are typically made with a mixture of propylene glycol and/or vegetable glycerin, flavorings, and pharmaceutical grade nicotine. *Id*., ¶ 6. E-liquids can be found in both "open system" and "closed system" vapor products. *Id*. In an "open" system, the device does not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device's e-liquid reservoir, or "tank." *Id*., ¶ 5. In contrast, in a "closed" system, either the device itself or interchangeable pods or cartridges intended for use with the device will come pre-filled with a particular type of e-liquid. *Id*. E-liquids are sold to consumers in a variety of flavors, bottle sizes (for open systems), and nicotine concentrations, including zero nicotine products, and users thus have the option to reduce their nicotine intake and/or wean themselves from nicotine use entirely. *Id*., ¶ 6.

Vapor products first gained traction in the United States around 2009. *See* Abboud Aff. at ¶ 19. The vapor products and e-liquids available on the market today contain a wide array of offerings to meet the varied needs and demands of adult consumers, many of whom are current or former smokers. Canastraro Aff. at ¶ 7; *see also* Glauser Aff. at ¶ 6.

In their role as an alternative to combustible cigarettes, vapor products have been studied extensively, with a consensus that they pose far lesser risk than combustible cigarettes and hold great potential as a public health harm reduction tool. By way of example, a comprehensive

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containing vitamin E acetate, not the nicotine-containing products that are the subject of this Petition. *See* Lena H. Sun, "Contaminant found in marijuana vaping products linked to deadly lung illnesses, tests show," Washington Post, September 6, 2019, available at https://www.washingtonpost.com/health/2019/09/05/contaminant-found-vaping-products-linked-deadly-lung-illnesses-state-federal-labs-show/.

study of all peer-reviewed literature on vapor products conducted by the National Academies of Sciences, Engineering and Medicine that was commissioned by FDA found that: "across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes," including conclusive evidence that substituting such products for combustible cigarettes "reduces users' exposure to numerous toxicants and carcinogens" and substantial evidence that switching results in reduced short-term adverse health outcomes in several organ systems. Abboud Aff. at ¶ 16. The United Kingdom's Royal College of Physicians has concluded that the potential hazard to health arising from long-term use of vapor products is, at most, five percent (5%) of the comparable harm resulting from the use of traditional combustible cigarettes. *Id*., ¶ 14. Another study concluded that switching from traditional cigarettes to vapor products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the United States. *Id*., ¶ 15. Finally, one randomized clinical study published in the New England Journal of Medicine earlier this year concluded that cigarette smokers were almost twice as likely to quit smoking when using e-cigarettes than when using nicotine replacement therapies such as lozenges and patches, while another study of over 18,000 smokers found that those using e-cigarettes as a quitting aid were almost three times more likely to succeeded in their efforts to quit after 12 months than those using nicotine gums, patches, and lozenges. *Id*., ¶ 17.

The impact of the availability of a wide variety of vapor products, including non-tobacco and non-menthol e-liquids, on consumer demand for traditional combustible cigarettes has been significant. The Centers for Disease Control reports that the number of smokers as a percentage of the U.S. population dropped dramatically from 20.6 percent in 2009, to only 14 percent as of

2017. *Id.*, ¶ 19. Similarly, between June 2018 and June 2019, U.S. cigarette sales volumes fell by more than 10 percent. *Id*.

In short, the science makes clear that vapor products are ultimately harm-reducing—decreasing dependency on harmful combustible cigarettes and even assisting individuals in ceasing nicotine use completely.

II. Nicotine-Containing Vapor Products Are Heavily Regulated at the Federal Level by the U.S. Food and Drug Administration.

Nicotine-containing vapor products, including flavored e-liquids, are heavily regulated by the Food and Drug Administration. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (the "TCA" or the "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387, *et seq.*). The TCA added a new Chapter IX to the federal Food, Drug and Cosmetic Act ("FDCA") and significantly altered federal regulation of tobacco products by, for the first time, granting FDA the statutory authority to regulate tobacco products. On May 10, 2016, FDA finalized its so-called "Deeming Rule"[2] under the TCA that, for the first time, deemed e-liquids containing, and vapor devices containing or intended to be used with, nicotine derived from tobacco plants to be "tobacco products" under the FDCA's definition (the "Newly Deemed Products"). *See* 81 Fed. Reg. 28,974 – 29,106 (May 10, 2016). The Deeming Rule took effect on August 8, 2016. 81 Fed. Reg. at 28,974.

In the three years since the Deeming Rule took effect, all Newly Deemed Products, including vapor products, have been required to comply with a number of regulatory requirements imposed by the TCA and enforced by FDA. By way of example, immediately

[2] U.S. Food & Drug Admin., *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at 21 C.F.R. § 1143.1) (hereafter, "Deeming Rule").

upon the August 8, 2016, effective date of the Deeming Rule, vapor product companies became subject to certain record preservation requirements and could no longer market their products with certain advertising and labeling claims—so called "modified risk" claims. *See* 81 Fed. Reg. at 28,974, 28,976; 21 U.S.C. §§ 387i, 387k. FDA was also authorized to regulate the methods used in manufacturing and testing vapor products and to mandate new product standards regarding the composition and characteristics of vapor products. 21 U.S.C. §§ 387f(e), 387g. In 2017, vapor product manufacturers were required to file with FDA copies of "health documents" relating to "health, toxicological, behavioral, or physiologic effects" of their products under 21 U.S.C. § 387d(a)(4).

That same year, all U.S. businesses engaged in the manufacture of vapor products were required to register their establishment(s) with FDA and open them to FDA inspection under 21 U.S.C. § 387e(a)(1), (b), (g). Each business was also required to identify every one of its vapor products to FDA, including providing copies of product labels and samples of advertisements. 21 U.S.C. § 387e(i)(1). In 2018, manufacturers and importers of vapor products submitted to FDA all ingredients found in their finished tobacco products as required by 21 U.S.C. § 387d(a)(3). These companies also complied with comprehensive new labeling, packaging and advertising requirements, including the nicotine warning requirement set forth in 21 C.F.R. § 1143.3(a)(1)-(2), which requires prominently placing the following nicotine addiction warning on any vapor products containing e-liquid: **"WARNING: This product contains nicotine. Nicotine is an addictive chemical."** Like the Petitioner VTA's other members, Petitioner Benevolent ELiquids has complied with each of these federal regulatory requirements. Canastraro Aff. at ¶ 21.

As a result of the Deeming Rule, FDA now has robust information regarding the vapor industry and vapor products, including: (i) the identities and locations of vapor product manufacturers; (ii) the products manufactured and sold by those manufacturers; (iii) the ingredients found in those products; and (iv) studies performed by vapor businesses regarding the health effects of those products.

III. Scientific Evidence and Petitioners' Experiences Suggest that Many Former Smokers Rely on Non-Tobacco and Non-Menthol-Flavored Vapor Products.

Both extensive scientific research and the personal experiences of Petitioners suggest that former smokers tend to rely on non-tobacco and non-menthol-flavored vapor products to avoid smoking combustible cigarettes. The extensive peer-reviewed scientific evidence suggests that adults of all ages prefer many categories of e-liquid flavors – including fruits, sweets, and cool flavors – and widely use non-tobacco- and non-menthol-flavored products. *See* Abboud Aff. at Ex. 3 "VTA ANPRM Flavor Comments" at 15. Indeed, two studies of data from the Population Assessment of Tobacco and Health (PATH) longitudinal survey have demonstrated the harm reduction potential of access to a variety of non-tobacco flavors by finding use of non-tobacco flavored e-cigarettes to be positively associated with a lower quantity of combustible cigarette use over time and greater success with quit attempts. *Id*. at 16-17 (citing Buu, et al. (2018), and Chen (2018)). Numerous surveys and peer-reviewed scientific literature have found that flavor availability and use of flavored vapor products was important to, and played a key role in, smokers shifting from combustible cigarettes and towards less harmful options and smoking cessation. *Id.* at 17-20. The authors of one study even went so far as to state that "regulators should carefully examine the cost-benefit of banning flavors," as "the current available science would **not** support a decision to do so." *Id*. at 19 (emphasis added) (citing Tackett, et al.).

Indeed, one study, a discrete choice experiment by Buckell, et al. (2018), paints a stark and deeply troubling picture of the adverse impact a flavor ban will have for former cigarette smokers. Abboud Aff. at Exhibit 3 "VTA ANPRM Flavor Comments" at 38-39. In that study, a sample of 2,031 adult smokers and recent quitters indicated that a ban on all non-tobacco flavors in vapor products, while allowing menthol in cigarettes, would result in an **8.3 percent *increase* in demand for cigarettes**. *Id.* These results led the authors to conclude that **"[a] ban on flavored e-cigarettes alone would likely increase the choice of cigarettes in smokers, arguably the most harmful way of obtaining nicotine."** *Id.*

These scientific studies are backed up by of New York vape shop owners' observations of their clientele. Victor Canastraro, the owner of Petitioner Benevolent ELiquids and Perfection Vapes, reports that approximately 90 percent of the e-liquid orders Benevolent ELiquids receives are for non-tobacco flavored e-liquids and that retailers that distribute Benevolent's product lines tend to order significantly less tobacco flavored e-liquid than other flavors. Canastraro Aff. at ¶¶ 14-15. Additionally, less than 1 percent of Benevolent's total revenues come from the sale of menthol-flavored e-liquid. *Id.*, ¶ 14. Canastraro reports that the customer base of his vape shop, Perfection Vapes, is composed of current and former combustible cigarette smokers with an average age of 36. *Id.*, ¶¶ 16-17. His regular customers have been able to reduce dramatically or eliminate entirely their nicotine consumption over time, with between 25 and 30 percent stopping not only smoking, but vaping as well. *Id.*, ¶ 18. As reported in the scientific literature, Canastraro has observed that while new customers who are smokers will often start vaping with a tobacco flavored e-cigarette, they will often switch to a non-tobacco flavor in short order so that they are not reminded of the taste of combustible cigarettes. *Id.*, ¶ 20.

IV. Scientific Evidence Suggests that Illegal Youth Use of Vapor Products Is Not Driven Primarily by the Existence of Non-Tobacco and Non-Menthol Flavors.

As regards illegal use of vapor products by youth, the existing data and scientific literature does not support the conclusion, stated in the Emergency Rule, that "youth e-cigarette use has [been] . . . driven primarily by the abundance of e-liquid flavors," nor that "restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use." De Palma Aff. at Exhibit A "Emergency Rule" at 4. First, e-liquids have been available in hundreds, if not thousands, of flavors since vapor products first gained traction in the United States over ten years ago, yet, according to Respondents, the significant increase in illegal youth use of vapor products occurred only in the last several years. *See* De Palma Aff. at Ex. A "Emergency Rule" at 5.

Second, much of the existing scientific evidence only demonstrates that, at best, flavors may be one factor among several for why youth illegally use vapor products. For example, one longitudinal study found that a "good flavors" response for why middle and high school students had tried e-cigarettes was **not** a significant predictor of either continued use or more frequent use of e-cigarettes. Abboud Aff. at Ex. 3 "VTA ANPRM Flavor Comments" at 29-30. Rather, using e-cigarettes to quit smoking was the most robust predictor of continued e-cigarette use. *Id*. Many other studies have found that reasons besides flavors are often equally or more frequently cited by youth as their reasons for illegally using vapor products and some studies have found the availability of flavors as not even being among the top three to four reasons why youth use vapor products. *Id*. at 30.

Nevertheless, to address concerns about illegal youth use of vapor products, in 2017, Petitioner VTA, an 800-member national trade association, developed and then promoted the VTA Marketing Standards for Membership, which consists of twelve marketing standards

intended to prevent minor access to vapor products and ensure that all marketing of such products is directed only to adults to the greatest extent possible. *See* Abboud Aff. at ¶ 6. As a VTA member, Benevolent ELiquids adheres to the marketing standards in its own operations. Canastraro Aff at ¶ 16. VTA has also suggested several concrete steps that FDA and other regulators could take to combat this issue that would be more effective than restricting the availability of flavored vapor products from the market entirely. Abboud Aff. at ¶ 11. These steps include requiring online retailers to conduct third-party authentication of a purchaser's age, more rigorously restricting improper sales of vapor products through online third-party marketplaces, issuing more "no tobacco sale" orders to businesses that have been caught repeatedly selling to minors, and imposing additional marketing and advertising restrictions along the lines of those set forth in the VTA's Marketing Standards for Membership. *Id.*

V. In its Last Legislative Session New York's Legislature Sought to Address Concerns About Illegal Youth Vaping by Increasing the Minimum Age to Purchase Vapor Products from 18 to 21.

In light of concerns regarding the recent increase in illegal youth vaping in its 2019 legislative session the New York State Assembly actively considered, but then ultimately tabled, a bill that would have imposed a ban on the sale of non-tobacco- and non-menthol-flavored vapor products. *See* De Palma Aff. at Ex. D (2019 N.Y. SB 1181); Ex. E (2019 N.Y. AB 4787); *see also Id.* at Ex. B (2017 N.Y. SB 8610); and Ex. C (2017 N.Y. AB 8688). These bills would have had the same effect as the Emergency Rule.

Instead, to address the issue of illegal youth vapor product use, the Assembly enacted legislation that increases the age for purchase of vapor products to 21, which goes into effect on November 13, 2019. *See* De Palma Aff. at Ex. I (2019 N.Y. ALS 100, 2019 N.Y. AB 558).

VI. Despite the Scientific Evidence Regarding the Public Health Dangers of Such a Move, Respondents Took Advantage of Public Concern Regarding Severe Respiratory Illnesses Resulting from Adulterated or Black-Market THC Products to Enact the Emergency Rule Prohibiting the Manufacture, Possession, or Sale of Nicotine-Containing Vapor Products that Are Not Tobacco or Menthol Flavored.

On September 15, 2019, Respondent Governor Andrew Cuomo announced he would take executive action to ban the sale of flavored vapor products in New York. Press Release, *Governor Cuomo Announces Emergency Executive Action to Ban the Sale of Flavored E-Cigarettes*, September 15, 2019, available at https://www.governor.ny.gov/news/governor-cuomo-announces-emergency-executive-action-ban-sale-flavored-e-cigarettes. Despite the fact that the New York Department of Health had already reported that it had identified adulterated or black-market THC products as a principal area of investigation into the recent spate of severe respiratory illnesses,[3] the Governor's September 15, 2019 press release failed to differentiate in any manner these illegal and unregulated THC-containing products from the legal and heavily regulated nicotine-containing vapor products that have existed in the U.S. and New York markets for more than ten years.

On September 15, 2019, Governor Cuomo further announced that the Commissioner would hold an emergency meeting with the Council to ban flavored vapor products. *Id.* Without any supporting citation, and directly contrary to known evidence about the use of flavored vapor products, Governor Cuomo claimed that manufacturers of flavored e-cigarettes "are intentionally and recklessly targeting young people." *Id.* On September 16, 2019, the Council announced that it would hold meetings starting at 2:30 p.m. the following day regarding the planned flavor ban

[3] *See* Press Release, *New York State Department of Health Announces Update on Investigation into Vaping-Associated Pulmonary Illnesses*, September 5, 2019, available at https://health.ny.gov/press/releases/2019/2019-09-05_vaping.htm.

via videoconference in New York City, Buffalo, Rochester, and Albany.[4] The Council also released the proposed emergency rule (the "Emergency Rule").[5]

The Emergency Rule provides that "[i]t shall be unlawful for any individual or entity to possess, manufacture, distribute, sell or offer for sale any flavored e-liquid or product containing the same." 10 NYCRR Subpart 9.3-2. The Emergency Rule defines "flavored e-liquid" as "e-liquid with a distinguishable taste or aroma, other than the taste or aroma of tobacco or menthol, ... including but not limited to tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, mint, wintergreen, herb, or spice, or any 'concept flavor' that imparts a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor." *Id.* at Subpart 9.3-1(b).

In its "Emergency Justification" and "Regulatory Impact Statement" published as part of the Emergency Rule, the Council stated that the Emergency Rule is necessary "to address the alarming increase of e-cigarette use among New York's youth." *Id.* at 4. The Council claimed that in a "survey of adolescent e-cigarette users in NYS, 46.3 percent preferred fruit flavors, followed by mint/menthol (19.9%) and chocolate, candy or other sweets (18.2%)." *Id.* at 6. The Council further claimed the same survey showed "27.3 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 19.3 percent of adolescent e-cigarette users, flavors were the primary reason for first use." *Id.* The Council did not state

[4] *See* New York Department of Health, Public Health and Health Planning Council, Documents for the September 17, 2019 Public Health and Health Planning Council Meeting, available at *https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2019-09-17/index.htm*.

[5] *See* "Prohibition on the Sale of Electronic Liquids with Characterizing Flavors" Subpart 9-3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York, available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2019-09-17/docs/title_10_nycrr.pdf; De Palma Aff. at Ex. A.

whether the survey considered adult vapor product users, what flavors they preferred, or the reason why they use or first used vapor products. Nor did the Council identify the reasons for current e-cigarette use reported by the remaining 72.7 percent of adolescents or the primary reason(s) for first use identified by the remaining 80.7 percent of respondents.

Despite asserting multiple claims regarding the supposed health risks of vapor products and "flavored" e-liquids, the Council provided little citation or evidentiary basis for its claims or statements, instead relying on unsupported conclusory allegations.

In the Emergency Rule, the Council also failed to provide any explanation for why the regular notice-and-comment rulemaking process was insufficient or why legislative action was not an option. On page 10 of the Emergency Rule, the only "alternative" to the action taken in the Emergency Rule that the Council identified is "to wait for the FDA to regulate in this area." *Id.* at 10.[6] The Council addressed this "alternative" by stating merely that "due to the health concerns associated with increased e-cigarette use among youths, this alternative was rejected." *Id.* However, the Council's suggestion that FDA regulation was the only "alternative" available to address illegal youth e-cigarette use is patently false. The State Legislature has the ability to enact statutory restrictions on the manufacture and sale of vapor products. Indeed, as noted above, in the last legislative session, the State Legislature actively considered, but then ultimately tabled, bills that would have imposed a ban on the sale of non-tobacco- and non-menthol-flavored vapor products.

Other than observing that users of vapor products can continue to access unflavored, tobacco-flavored, and menthol-flavored e-liquids, the Emergency Rule entirely fails to address the potential detrimental impact of the ban of "flavored" e-liquids on adult vapor product users,

[6] As described above, the Council's suggestion that FDA has not taken any action to date to regulate vapor products is grossly incomplete at best and intentionally misleading at worst.

including former smokers who rely heavily on such products, or the potential negative public health impact on these individuals of the sudden removal of all non-tobacco- and non-menthol-flavored e-liquids from the market.

On September 17, 2019, with less than 24 hours' notice, the Council held the above-described meetings at the four locations specified, with members of the public and from the vapor industry speaking out in large numbers against the Emergency Rule. Due to the number of individuals seeking to be heard, the Council ultimately limited the speakers to only one minute of time, with Council members repeatedly interrupting speakers to advise of the time restrictions. With only 24 hours' notice, the vapor industry and members of the public had virtually no opportunity to submit written comments to the Council. But even if they had, it likely would not have mattered as the Council voted immediately upon the conclusion of the speakers' comments. Despite the overwhelming public opposition, and concerns voiced by dissenting Council member, Dr. Glenn Martin, that the Emergency Rule was being adopted without an actual emergency that warranted the emergency rulemaking process, the Council voted to adopt the Emergency Rule. Governor Cuomo then announced that the Emergency Rule was effective immediately and that enforcement by Respondent New York State Police would begin October 4, 2019, with retailers who violate the flavor ban subject to penalties of up to $2,000 per unit of flavored e-liquid that is possessed, manufactured, sold or offered for sale.[7]

[7] Pres Release, *Governor Cuomo Announces New York State Implements First-in-the-Nation Ban on Flavored E-Cigarettes*, September 17, 2019, available at https://www.governor.ny.gov/news/governor-cuomo-announces-new-york-state-implements-first-nation-ban-flavored-e-cigarettes.

VII. Enforcement of the Flavor Ban Will Require Virtually All Vape Shops and E-Liquid Manufacturers in the State to Shut Down, Resulting in the Immediate Closure of Almost 700 Businesses and Eliminating Over 3,100 Jobs.

Enforcement of the Emergency Rule will all but destroy the New York vapor products industry and put thousands of individuals immediately out of work. The vapor industry is a dynamic part of the U.S. economy, slightly larger than the national steel and iron forging industry and employs almost as many people as the commercial fishing industry. *See* Dunham Aff. at ¶ 5. In New York alone, the vapor industry accounts for over $1,197,229,000 annually in economic output and generates jobs for approximately 8,110 individuals who collectively earn annual wages and benefits totaling $508,872,500. *Id.*, ¶ 6.

The vapor industry in New York consists of 8 e-liquid manufacturers and 63 vape shop manufacturers, with a total of 694 vape shops statewide. *Id.*, ¶ 7. Together, these businesses employ 3,288 New Yorkers. *Id.* These figures do not include tobacco shops and other general retail outlets that sell vapor products as part of their broadest product offerings, nor do they include the wholesalers that distribute these products. *Id.* The vapor industry directly employs 4,416 people in New York, including 3,185 individuals employed by retail vape shops and another 103 individuals employed in the manufacturing of e-liquid. *Id.*, ¶ 8. The wages and benefits of these 3,288 individuals totals $164,524,700 and the direct economic output attributable to retail vape shops and e-liquid manufacturing totals $275,521,500. *Id.*

The vapor industry also contributes $99,080,100 in New York state taxes and vapor product consumers generate an additional $30,940,000 in sales taxes. *Id*, ¶ 9. If not for the recent enactment of the Emergency Rule, and prohibition of non-tobacco and non-menthol e-liquid flavors, the vapor industry's tax contributions would increase even further because of a new 20 percent state excise tax on vapor products that will go into effect as of December 1, 2019. *Id.*; *see* N.Y. TAX LAW § 1181: "In addition to any other tax imposed by this chapter or

other law, there is hereby imposed a tax of twenty percent on receipts from the retail sale of vapor products sold in this state.")

Most of the vape shops in New York are small businesses, with many having five or fewer employees. *See* Glauser Aff. at ¶ 6; Canastraro Aff. at ¶ 11. The vast majority of e-liquids distributed to vape shops in New York would qualify as "flavored e-liquid" under the Emergency Rule. *See* Glauser Aff. at ¶ 7 ("Of the e-liquid products that we have distributed to vape shops in the state of New York since January 1, 2018, some 90 percent are products that would qualify as "flavored e-liquid" under Section 9-3.1 of the emergency flavor ban regulation."); Canastraro Aff. at ¶ 15 ("Approximately 90 percent of the e-liquid orders that [Benevolent Eliquids] receive[s] from other vapor businesses are for a non-tobacco-flavored e-liquid and less than 10 percent are for tobacco-flavored e-liquids."). For many distributers and manufacturers, including Benevolent Eliquids, tobacco-flavored e-liquids account for less than 10 percent of their orders and sales. *Id.* These numbers are proportionate and reflective of the of the percentage of e-liquids sold to vapor consumers that are "flavored e-liquid" under the Emergency Rule. *See* Glauser Aff. at ¶ 8.

The New York vapor industry will be devastated once enforcement of the Emergency Rule begins on October 4, 2019, with nearly all vapor product businesses closing and laying off employees. Indeed, Petitioners Benevolent Eliquids and Perfection Vapes will be <u>forced to close immediately and lay off their employees</u> if the Emergency Rule is not enjoined. Canastraro Aff. at ¶ 26. The loss of income and closure of their businesses will result in defaults on leases and mortgages, which have been personally guaranteed by the owner. *Id.*, ¶¶ 27-28. Benevolent Eliquids and Perfection Vapes are not the exception, but rather the rule. Almost all of the vape shop businesses in New York will have to immediately close their doors and lay off employees.

Id. As the vast majority of the vapor product orders and sales are for products considered "flavored e-liquid," businesses in the vapor industry rely heavily on continued manufacture and sale of these products to survive. Glauser Aff at ¶ 9. As vape shops are small businesses and so dependent on sales of "flavored e-liquid" vapor products, their sales of e-cigarette devices and tobacco- and menthol-flavored e-liquids alone will not make up for the lost revenue from the sale of flavored e-liquid and will be insufficient to keep their businesses alive. *Id.* Like Perfection Vapes, these businesses will be unable to afford their rents and mortgages, and bankruptcy will be a common recourse for many owners faced with personal exposure as they similarly had to personally guarantee leases. *Id.* Aware of these consequences, some vapor product businesses already are relocating their businesses out of state and in the process closing their New York locations and laying off employees in advance of enforcement of the Emergency Rule. This does not account for the impact on the additional thousands of New Yorkers who will suddenly find themselves without jobs as the New York vapor industry is shut down.

ARGUMENT

PETITIONERS ARE ENTITLED TO THE RELIEF REQUESTED

I. THE EMERGENCY RULE MUST BE ANNULLED

Enactment of the Emergency Rule violates the New York State Constitution, exceeds Respondents' statutory authority, is arbitrary and capricious, and fails to otherwise comply with the New York State Administrative Procedure Act. *1234 Broadway LLC v. West Side SRO Law Project,* 86 A.D.3d 18, 23-24, 924 N.Y.S.2d 35, 39-40 (1st Dep't 2011). Essentially, Respondents engaged in unlawful regulation by exceeding their statutory authority and engaging in unauthorized lawmaking.

A. The Emergency Rule Exceeds Respondents' Statutory Authority

Respondents' issuance of the Emergency Rule is a unilateral act of policymaking beyond their delegated authority and usurps the State Legislature's role. Contrary to New York law, the Emergency Rule required no special expertise and was enacted without legislative guidance and while debate as to how to address youth usage of vapor products was still ongoing in the legislature. Therefore, as explained in further detail below, the Emergency Rule should be invalidated.

(i) The New York State Constitution enforces a separation of legislative and executive *powers*.

It is fundamental that New York's governmental powers are divided among the three branches – the executive, the legislative, and the judicial. *See Matter of NYC C.L.A.S.H., Inc. v. New York State Off. Of Parks, Recreation & Historic Preserv.*, 27 N.Y.3d 174, 51 N.E.3d 512 (2016) ("The concept of the 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."); NY Const., art III § 1; art IV, §1; art VI.

None of the branches may grant itself the "powers residing wholly in another branch." *See Nicholas v. Kahn*, 47 N.Y. 2d 24, 30-31, 389 N.E.2d 1086, 1089-1090, (1979) (citing *Youngstown Co. v. Sawyer*, 434 U.S. 579 (1952)). This mandates "that the Legislature make the critical policy decisions, while the executive branch's responsibility is to implement those policies." *Matter of LeadingAge N.Y., Inc. v. Shah*, 32 N.Y.3d 249, 259, 114 N.E.3d 1032, 1040 (2018). "Because of the constitutional provision that the legislative power of this State shall be vested in the Senate and the Assembly, the Legislature cannot pass on its law-making functions to other bodies but there is no constitutional prohibition against the delegation of power, with reasonable safeguards and standards, to an agency or commission to administer the law as

enacted by the Legislature." *Boreali v. Axelrod*, 71 N.Y.2d 1, 10-11, 517 N.E.2d 1350, 1354-1355 (1987) (emphasis added; internal citations omitted); *see Matter of Levine v. Whalen*, 39 N.Y.2d 510, 515, 384 N.Y.S.2d 721, 723 (1976); NY Const., art III, § 1.

"Agencies, as creatures of the Legislature, act pursuant to specific grants of authority conferred by their creator." *Shah*, 32 N.Y.3d at 260. "[A]dministrative agencies are but creatures of the Legislature and are possessed only of those powers expressly or impliedly delegated by that body." *Nicholas*, 47 N.Y. 2d at 31. "[I]n the absence of such delegation, the administrative action would constitute an unauthorized exercise of legislative power in contravention of the separation of powers doctrine." *Id.* at 30. "If an agency promulgates a rule beyond the power it was granted by the legislature, it usurps the legislative role and violates the doctrine of separation of powers." *Shah*, 32 N.Y.3d at 260.

(ii) Respondents' Ban is *ultra vires* under *Boreali*

In *Boreali v. Axelrod*, 71 N.Y.2d 1, 517 N.E.2d 1350 (1987), the seminal decision concerning New York's constitutional limitations on agency rulemaking, the Court of Appeals addressed a challenge to anti-smoking regulations adopted by the New York Public Health Council ("PHC") a predecessor entity to Respondent PHHPC[8]—that prohibited smoking in certain indoor areas. At the time, the harmful effects of smoking and second-hand smoke had been known for years and the State Legislature had declined to adopt prohibitions on indoor smoking. *Id*. Nevertheless, the PHC, relying on its purported authority under Public Health Law § 225 to "deal with any matters affecting the . . . . public health"—the same authority cited by Respondents in this case—promulgated regulations prohibiting smoking in a wide variety of

[8] Effective December 1, 2010, Chapter 58 of the Laws of 2010 consolidated the responsibilities and functions of the Public Health Council (PHC) and the State Hospital Review and Planning Council (SHRPC) into a newly established council, the Public Health and Health Planning Council (PHHPC).

indoor areas, along with certain exclusions and exceptions to the regulatory scheme. *Id.* at 7. The Court of Appeals struck down the regulations, holding that the broad authority granted to the PHC was insufficient to support the agency's unilateral action, even though the action was aimed at perceived social ills and would have been appropriate had it been legislatively authorized. *Id.*

The court considered four factors in determining that the PCH's regulations crossed the line from "administrative rule-making to legislative policy-making." *Id.* at 11. Whether the agency engaged in impermissible lawmaking required analysis of whether the regulation: (1) was issued on a "clean slate" without legislative guidance; (2) intruded on an area of ongoing legislative debate; (3) reflected a balancing of social and economic concerns beyond the agency's authority; and (4) while "unquestionably" involving a "health issue," was not a product of "special expertise or technical competence" nor "necessary to flesh out details" of legislative policy. *Boreali v. Axelrod*, 71 N.Y. 2d at 11-14 (1987).

The Court of Appeals has made clear that "these are not 'criteria that should be rigidly applied in every case' but rather 'overlapping, closely related factors' that, viewed together, may signal that an agency has exceeded its authority." *Shah*, 32 N.Y.3d at 261 (quoting *Matter of New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Dep't of Health & Mental Hygiene*, 23 N.Y.3d 681, 696, 16 N.E.3d 538 (2014) (finding New York City regulation of soda invalid)). Courts "treat the circumstances as overlapping, closely related factors that, taken together, support the conclusion that an agency has crossed that line. Consequently, respondents may not counter petitioners' argument merely by showing that one *Boreali* factor does not obtain." *Statewide Coalition*, 23 N.Y.3d at 696-97. Accordingly, no single factor is dispositive, nor are all four factors necessary for a finding that an agency exceeded its authority and acted in a legislative capacity.

Here, the Emergency Rule's flavor ban fails to pass muster under *Boreali*. Like the ban at issue in *Boreali*, Respondents impermissibly rely on the same general statutory authority as the PHC, and, similarly, the Emergency Rule exceeds the scope of permissible agency rulemaking and usurps the role of the legislature. As explained below, the Emergency Rule should be declared invalid, and a temporary restraining order and preliminary injunction should be entered.

(iii) Respondents promulgated the Emergency Rule on a "clean slate."

Respondents issued the Emergency Rule's flavor ban on a "clean slate, creating [their] own comprehensive set of rules without benefit of legislative guidance" and "did not merely fill in the details of broad legislation describing the over-all policies to be implemented." *Boreali*, 71 N.Y.2d at 13. Respondents' actions were a "far cry" from interstitial rulemaking that represents proper administrative rulemaking. *See id.*; *see also Nicholas*, 47 N.Y.2d at 31 (explaining that "interstitial rulemaking" as "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 interstices in the legislative product by prescribing rules and regulations consistent with the enabling legislation").

Like the PHC in *Boreali*, Respondents improply rely on the broad and general authority of Public Health Law § 225 to "deal with any matters affecting the . . . public health" as authority to issue the Emergency Rule. As the Appellate Division held in reviewing the invalidity of the anti-smoking regulations, "this grant of authority is not limitless, for to hold otherwise would work a complete abdication of legislative responsibility in the area of public health." *Boreali v. Axelrod*, 130 A.D.2d 107, 113, 518 N.Y.S.2d 440, 444 (3d Dep't 1987).

Rather than simply filling in the gaps of legislation or issuing regulations to implement or interpret specific legislation, Respondents' Emergency Rule creates out of whole cloth an

entirely new policy and regulatory regime for flavored vapor products, without any guidance whatsoever from the legislature.[9] By prohibiting the sale, manufacture, distribution, or possession of non-tobacco- and non-menthol-flavored vapor products, the regulation affects the lives not only of millions of adult New Yorkers who legally used flavored vapor products, but also hundreds of businesses that will be destroyed by the flavor ban. This is a "profound change in social and economic policy" that will affect how millions of New Yorkers live their lives" and "such dramatic changes in public policy, however meritorious in terms of the public health, are the function of the Legislature, not an administrative agency." *Boreali,* 130 A.D.2d at 114.

(iv) Respondents' Emergency Rule intrudes upon an area of ongoing legislative debate and usurps the legislative process.

Respondents' Emergency Rule is not only enacted on a clean slate, but it also intrudes upon an unsettled legislative debate. In *Boreali,* "the fact that the agency acted in an area in which the Legislature had repeatedly tried—and failed—to reach agreement in the face of substantial public debate and vigorous lobbying by a variety of interested factions" indicated that it exceeded the scope of its authority. 71 N.Y.2d at 13. Agency regulation is improper under *Boreali* in the face of "legislative indecisiveness on the policy issue." *See Health Ins. Ass'n of Am.,* 154 A.D.2d 61, 551 N.Y.S.2d 615 (3d Dep't. 1990). The legislature's failure, or lack of opportunity, to determine or enact the most appropriate method for reducing youth vapor product use does not mean the Respondents could take it upon themselves "to fill the vacuum and impose a solution of [their] own." *See Boreali,* 71 N.Y.2d at 13.

Respondents acted unilaterally, without legislative guidance, and with disregard to the legislature's previous actions or rejections on the same issues of limiting youth use of vapor

[9] Indeed, as noted infra, Section I.A.iv, Respondents enactment of the Emergency Rules actually runs contrary to the current prerogatives of the State Legislature.

products and banning flavored vapor products. A ban of flavored vapor products was introduced in both the State Assembly and State Senate in the last legislative session. *See* De Palma Aff. at Ex. D (2019 N.Y. SB 1181); *id.* at Ex. E (2019 N.Y. AB 4787); *see also id.* At Ex. B (2017 N.Y. SB 8610); *id.* At Ex. C (2017 N.Y. AB 8688). These proposed bills never advanced past the committee stage. Further, the bills' sponsors claimed basis for the proposed bills was the same as the supposed basis for Respondents' Emergency Rule—to discourage youth use of vapor products. *See, e.g., id.* at Ex. F (Sponsor Memo, May 10, 2018, 2017 Legis. Bill Hist. N.Y. SB 8610).

Similarly, the Legislature has considered several other bills to address the same or similar concerns as the Respondents' Ban. This includes a proposed bill to prohibit or limit advertisement of e-cigarettes and vapor products as well as a proposed bill to restrict where "retail electronic cigarette stores and tobacco businesses" can be located in New York. *See id.* at Ex. G (2019 N.Y. SB 5056) & Ex. H (2019 N.Y. AB 6842).

Respondents' Emergency Rule further disregarded the most significant action taken by the legislature, and evidence of the ongoing legislative debate as to how handle youth use of vapor products—the raising of the minimum age for purchasing such products from 18 to 21 years of age. *See id.* at Ex. I (2019 N.Y. ALS 100, 2019 N.Y. AB 558). The raising of the purchase age to 21 does not take effect until November 13, 2019, and so the effects of this legislative solution to the problem of youth use of vapor products have yet to play out.

"Manifestly, it is the province of the people's elected representatives, rather than appointed administrators, to resolve difficult social problems by making choices among competing ends." *Boreali,* 71 N.Y.2d at 13. Here, the Legislature has made a clear and deliberate choice this past session to eschew more far reaching or nuanced legislation of vapor

products and instead enact a law raising the age of legality to 21. However, rather than allow the will of the Legislature to be carried out and see the potential effect of its efforts to address youth vapor product use, Respondents unilaterally determined and enacted sweeping social policy change. Respondents' action and the Emergency Rule are a blatant usurpation of the Legislature's role, and in violation of the separation of powers under the New York Constitution and *Boreali*.

(v) Respondents balanced social and economic concerns beyond their expertise.

The third factor is whether the regulation reflected the agency's balancing of social and economic concerns beyond the agency's authority. "An agency that adopts a regulation . . . or an outright prohibition . . . that interferes with commonplace daily activities preferred by large numbers of people must necessarily wrestle with complex value judgments concerning personal autonomy and economics. This is policymaking, not rulemaking." *Statewide Coalition*, 23 N.Y.3d at 699. By selecting which flavors or types of vapor products would be prohibited, while continuing to allow others, as well as combustible cigarettes, Respondents "did more than balance[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." *Boreali*, 71 N.Y.2d at 11.

(vi) The Ban is not an exercise of special expertise or technical competence in fleshing out legislative policy.

Like the indoor smoking ban in *Boreali*, Respondents' Emergency Rule does not result from the exercise of any special expertise or technical competence. Similar to the PHC's indoor smoking ban, Respondents' flavor ban is a "simple code" that bars the manufacture, distribution, sale, or offer for sale of "flavored e-liquid or product containing the same." *See Boreali*, 71 N.Y.2d at 14. Respondents were not asked to "flesh out details of the broadly stated legislative

policies embodied in the Public Health Law," for which they possessed technical competence. *Id.* Indeed, as explained above, there are no legislative policies to flesh out. Instead Respondents promulgated a regulation that enacts new social policy that cannot be traced to any specific legislation.

"[N]o special expertise or technical competence in the field was involved in the development of the challenged regulations," which reflect mere social, economic, or political judgments not anchored in the implementation of any legislative instruction. *New York Blue Line Council, Inc. v. Adirondack Park Agency*, No. 36-09, 2009 N.Y. Misc. LEXIS 6705, at *36-37 (Sup. Ct. Essex Cnty. Nov. 19, 2009). Respondents' claims of scientific or technical basis or health justification, or any requirement of scientific or technical expertise, is undercut by the fact that the flavor ban is nearly identical to the previously failed legislative proposal that would have prohibited flavored vapor products. Despite Respondents' claim that the intended purpose is to reduce youth usage, the promulgated rule and accompanying "Emergency Justification" and "Regulatory Impact Statement" cite to minimal scientific or health studies or research to support issuance of the rule or any basis to believe it will be effective. Furthermore, Respondents do not appear to have considered any contrary or comprehensive data regarding use of vapor products or flavored vapor products that would require any type of health or technical expertise, nor do they appear to have considered the extensive scientific evidence noted above that current and former smokers rely on flavored vapor products to end their combustible cigarette use. (And, as demonstrated above, extensive countervailing scientific evidence was publicly available for them to review had they desired.) Moreover, the claimed intended purpose is undercut by Respondents' flavor ban excluding menthol-flavored vapor products despite acknowledging that

mint/menthol was the second most preferred flavor of "adolescent e-cigarette users" in New York.

(vii) The authority Respondents cite is no broader than the PHC's authority in *Boreali* and must be strictly construed.

Respondents engaged in legislative policy-making without proper statutory basis and therefore their promulgation of the Emergency Rule constitutes an *ultra vires*, invalid action beyond their statutory jurisdiction and authority. Respondents rely on the authority as cited by PHC in *Boreali* and the well-established principles of statutory interpretation demand a narrow construction of their jurisdiction that avoids serious constitutional problems.

"The principle is well-settled in New York: that '[g]overmental agencies have only those powers which are conferred expressly or by necessary implication; power is not to be inferred, and the principle of strict construction should be applied in interpreting statutory grants of power." Public Health Law § 225(4) authorizes the PHHPC "by the affirmative vote of a majority of its members to establish, and from time to time, amend and repeal sanitary regulations, to be known as the sanitary code of New York, subject to approval by the commissioner." Public Health Law § 225(5)(a) authorizes the sanitary code to "deal with any matters affecting the . . . public health." As previously discussed, the Appellate Division in *Boreali* found that the power under Public Health Law § 225 "is not limitless, for to hold otherwise would work a complete abdication of legislative responsibility in the area of public health." *Boreali*, 130 A.D.2d at 113.

As the Court of Appeals further noted in affirmance, "the agency stretched [its authority under Pub. Health Law § 225] beyond its constitutionally valid reach when it used the statute as a basis for drafting a code embodying its own assessment of what public policy ought to be." 71 N.Y.2d at 9. Respondents cannot rely upon a statutory mandate "as a basis for engaging in

inherently legislative activities" or promulgating rules "embodying its own assessment of what public policy ought to be." *Id.*

Respondents, like the PHC in *Boreali* exceeded their statutory authority and engaged in unlawful lawmaking when they passed the flavor ban contained in the Emergency Rule. Therefore, the Emergency Rule should be invalidated as *ultra vires* by this Court.

B. The Emergency Rule Is Arbitrary And Capricious

Even if Respondents had authority to promulgate the flavor ban (which they do not), the Emergency Rule would nevertheless be invalid because it is unlawfully "arbitrary and capricious." An administrative regulation will be upheld only if it has a "rational basis, and is not unreasonable, arbitrary or capricious." *N.Y. State Ass'n of Counties v. Axelrod*, 78 N.Y.2d 158, 166, 573 N.Y.S.2d 25, 29 (1991); CPLR § 7803(3). Agency rules "are not judicially reviewed pro forma in a vacuum, but are scrutinized for genuine reasonableness and rationality in the specific context." *N.Y. State Ass'n of Counties*, 78 N.Y.2d at 166.

The arbitrary and capricious standard "'relates to whether a particular action should have been taken or is justified . . . and whether the administrative action is without foundation in fact.'" *Pell v. Bd. of Educ.*, 34 N.Y.2d 222, 231, 356 N.Y.S.2d 833, 839 (1974) (citation omitted). Otherwise stated, agency action is arbitrary when it is "without sound basis in reason" or "taken without regard to the facts." *Id.* As such, agency rules and classifications will be invalidated unless they "bear some rational relationship to the goals sought to be achieved, and must otherwise be factually based." *Kelly v. Kaladjian*, 155 Misc. 2d 652, 655, 589 N.Y.S.2d 730, 731 (Sup. Ct. N.Y. Cnty. 1992). In making this assessment, the Court is limited to considering the reasons the Board gave "for its action, at the time that it t[ook] the action." *Street Vendor Project v. City of N.Y.*, 10 Misc. 3d 978, 986, 811 N.Y.S.2d 555, 562 (Sup. Ct. N.Y. County 2005), *aff'd*, 43 A.D.3d 345 (1st Dep't 2007). "'If those grounds are inadequate or

improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.'" *Scherbyn v. Wayne-Finger Lakes Bd. of Coop. Educ. Servs.*, 77 N.Y.2d 753, 758, 570 N.Y.S.2d 474, 478 (1991); *see also Gabriele v. Metro. Suburban Bus Auth.*, 239 A.D.2d 575, 577, 657 N.Y.S.2d 761, 763 (2d Dep't 1997) ("[J]udicial review of an administrative determination is limited to the ground invoked by the agency.").

Here, the Emergency Rule is unlawfully "arbitrary and capricious" because it allows for the continued sale of combustible tobacco cigarettes—which are also illegally used by youth—while banning a significant swath of substantially less harmful vapor products, while at the same time it excludes "menthol" flavored vapor products from the flavor ban. Respondents claim that there "is . . . concern regarding human exposure to nicotine," which is also delivered by combustible cigarettes. As noted above, the National Academies of Science, Engineering, and Medicine have found that "across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes," and that there is "conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes." Abboud Aff. at ¶ 16. Nevertheless, the Emergency Rule does not purport to ban the manufacture, possession, or sale of combustible cigarettes. Similarly, despite the claim that the purpose of the flavor ban is to discourage youth use, the Emergency Rule excludes what Respondents cite as the second most preferred flavored among adolescent New York e-cigarette users—menthol. Respondents offer no explanation or justification for this exclusion.

The Emergency Rule's flavor ban is also arbitrary and capricious because Respondents—to the extent they considered any scientific data at all—entirely failed to consider an important

aspect of the problem. "An agency decision is arbitrary and capricious when the agency has relied upon factors which the legislature had not intended it to consider, entirely failed to consider an important aspect of the problem, 'offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *O'Rourke v. City of N.Y.*, No. 512565/2017, 2019 NYLJ LEXIS 2375, *23 (Sup. Ct. Kings Cnty. 2019) (quoting *Kentucky Riverkeeper, Inc. v. Rowlette*, 714 F.3d 402, 407 (6th Cir. 2013) (quoting *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658, 168 L. Ed. 2d 467 (2007))); *Matter of Hilbertz v. City of New York*, 64 Misc. 3d 697, 727, 98 N.Y.S.3d 776, 800 (Sup. Ct. Kings Cnty. 2019). Here, as noted by the extensive scientific evidence cited by the VTA in its Flavors ANPRM Comments (Abboud Aff. at Ex. 3), many adult ex-smokers rely heavily on flavored vapor products to break their dependence from combustible cigarettes and run a significant risk of returning to smoking when those flavors are removed from the market, thereby causing a significant detrimental impact to public health. Nonetheless, the Emergency Rule contains absolutely no evidence of any consideration by Respondents of this "important aspect of the problem" associated with flavored vapor products.

For these reasons, the Emergency Rule is not only *ultra vires*, but also arbitrary and capricious under well-established principles of New York administrative law, and should be invalidated on those independent grounds.

C. The Ban Fails To Comply With The State Administrative Procedure Act

The Emergency Rule is also invalid because it fails to comply with the requirements of the State Administrative Procedure Act. State Administrative Procedure Act ("SAPA") § 202(5)(b) establishes minimum procedures that an agency must follow when promulgating regulations, including the requirements that an agency publish in the New York State Register a

notice of proposed rule-making which affords the public an opportunity to submit comments on the proposed rules and, subsequently, a notice of adoption which includes an assessment of the public comment submitted on the proposed rule. Only "if an agency finds that the immediate adoption of a rule is necessary for the preservation of the public health, safety or general welfare and that compliance with the requirements of subdivision one of this section would be contrary to the public interest, the agency may dispense with all or part of such requirements and adopt the rule on an emergency basis." SAPA § 202(6)(a).

SAPA § 202(6)(d)(iv), however, requires an agency seeking an emergency rule adoption to fully articulate in writing:

> "the specific reasons for such findings and the facts and circumstances on which such findings are based. Such statement shall include, at a minimum, a description of the nature and, if applicable, location of the public health, safety or general welfare need requiring adoption of the rule on an emergency basis; a description of the cause, consequences, and expected duration of such need; an explanation of why compliance with the requirements of subdivision one of this section would be contrary to the public interest; and an explanation of why the current circumstance necessitates that the public and interested parties be given less than the minimum period for notice and comment provided for in subdivision one of this section."

SAPA § 202(6)(d)(iv) (emphasis added).

By enacting SAPA § 202(6)(d)(iv), "[t]he Legislature was attempting to stop the practice of using emergency rule making to avoid the notice and comment period otherwise required by the State Administrative Procedure Act." *Law Enforcement Officers Union, Dist. Council 82 by Engelhardt v. State*, 168 Misc. 2d 781, 784, 643 N.Y.S.2d 301, 303 (Sup. Ct. Albany Cnty. 1995); *see also Home Care Ass'n v. Dowling*, 218 A.D.2d 126, 129, 638 N.Y.S.2d 193, 195 (3d Dep't 1996) ("[G]iven the statute's intent of providing the public with simple, uniform administrative procedures (State Administrative Procedure Act § 100), this [emergency] exception should be narrowly construed."). As stated in the sponsor's memorandum, "[u]nder

this legislation, an agency would have to disclose the specific reason as to the need to adopt the emergency rule ***and*** why it was necessary to forgo the required notice and comment period that is required by SAPA." *Law Enforcement Officers Union, Dist. Council 82 by Engelhardt*, 168 Misc. 2d at 784, 643 N.Y.S.2d at 303 (citing Bill Jacket, L. 1990, ch 850, Sponsor's Mem., Assemblyman Sanders, Assembly Bill 10271-A, at 3 (emphasis added)).

A mere showing of a "problem" or that a "challenge" exists such that the rule could be rationally based and reasonably related to the promotion of public health, safety or general welfare is a far cry from the SAPA "statement" requirements. The record before this Court must support a finding of immediate necessity, emergency, or undue delay. *See United Water N.Y., Inc. v. PSC*, 252 A.D.2d 810, 812, 676 N.Y.S.2d 709, 711 (3d Dep't 1998) ("[R]espondent's refusal to process the belated filing on an emergency basis pursuant to State Administrative Procedure Act § 202(6) was not irrational since immediate action was not necessary for the preservation of the public health, safety or general welfare."); *Law Enforcement Officers Union, Dist. Council 82 by Engelhardt*, 168 Misc. 2d. at 784, 643 N.Y.S.2d at 303; *Matter of Gill v. New York State Racing & Wagering Bd.*, No. 118095/04, 2006 N.Y. Misc. LEXIS 565 (Sup. Ct. N.Y. Cnty. Feb. 9, 2006); *Matter of Chinese Staff & Workers Ass'n v. Reardon*, No. 450789/2018, 2018 N.Y. Misc. LEXIS 4231, *13 (Sup. Ct. N.Y. Cnty. Sept. 25, 2018). Pursuant to the statutory "statement" requirement, the emergency rule must explain in detail as to why "compliance with the normal rule making procedure would be contrary to the public interest or why the current circumstances necessitated the use of emergency rule making procedure." *Law Enforcement Officers Union, Dist. Council 82 by Engelhardt*, 168 Misc. 2d. at 784, 643 N.Y.S.2d at 303; *Matter of Gill*, 2006 N.Y. Misc. LEXIS 565; *cf. Matter of Hague Corp. v. Empire Zone Designation Bd.*, 96 A.D.3d 1144, 1145-46, 947 N.Y.S.2d 622, 624 (3d Dep't

2012) (finding no need for agency to comply with SAPA when "adopting the regulations on an emergency basis without first identifying the circumstances necessitating such and providing the public with an opportunity to comment" because "[a]lthough, generally, agencies must comply with the provisions of SAPA prior to the adoption of rules or regulations, here, the Legislature specifically provided [the agency] with the authority to promulgate the regulations necessary to effectuate its review of the empire zone participants on an emergency basis, "notwithstanding any provision to the contrary in [SAPA]").

Courts have previously invalidated emergency rules when the record was devoid of any facts upon which to base such an "immediate necessity, emergency, undue delay" finding. *Matter of Gill*, 2006 N.Y. Misc. LEXIS 565, at *21; *Matter of Chinese Staff & Workers Ass'n*, 2018 N.Y. Misc. LEXIS 4231, at *13; *see also Law Enforcement Officers Union, Dist. Council 82 v. State*, 229 A.D.2d 286, 288-91, 655 N.Y.S.2d 770, 772 (3d Dep't 1997) (finding that trial court properly vacated rule and acted within its discretion where agency "had failed to specify any facts or circumstances demonstrating that the immediate adoption of the original regulation was necessary or that compliance with regular rule-making procedures would be contrary to the public interest, and because the notice of emergency adoption failed to specify the cause, consequences or expected duration of the alleged threat to the public health, safety, and general welfare as is required by State Administrative Procedure Act"). In *Law Enforcement Officers Union, Dist. Council 82 by Engelhardt*, the Supreme Court of New York for Albany County invalidated the emergency ruling for double occupancy housing units where "there [wa]s 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 the State Administrative Procedure Act" even though

"prison overcrowding may well be a difficult challenge." 168 Misc. 2d. at 785, 643 N.Y.S.2d at 303.

In *Matter of Gill*, the New York County Supreme Court similarly vacated an emergency rule because "the record [did] not explain why the rule had to be dealt with prior to public notice and comment allowed by SAPA" and "did not explain in any detail why compliance with the normal rule making procedure would be contrary to the public interest" even if "there was sufficient evidence that the drug 'fluphenazine' was apparently being used on horses who were racing and the Board's expert stated that it served no legitimate purpose." 2006 N.Y. Misc. LEXIS 656, at *20-21.

The court in *Matter of Gill* found that a claim of emergency was wholly contradicted by the fact that the New York Racing and Wagering Board delayed in addressing the problem of "fluphenazine" abuse in horse racing when it did not issue an "emergency" rule to address this abuse until 2013 after knowing about the problem for years, particularly when the normal rule-making process for a permanent rule was rather swift:

> The record does not explain why the rule had to be dealt with prior to the public notice and comment allowed by the SAPA. Moreover, the Notice of Adoption did not explain in any detail why compliance with the normal rule making procedure would be contrary to the public interest or why the current circumstances necessitated the use of emergency rule making procedure. The Board apparently knew there was a problem in 2000 with "fluphenazine" abuse. They waited until 2003 to propose even an emergency rule prohibiting its use in horse racing. When the Board finally made the rule permanent in May of 2005, they proposed the rule on May 2, 2005 in the State Registry as a Proposed Rule Making, no public comment was received. In less [than] two weeks, on May 11, 2005, the Board was able to file a Notice of Adoption and 9(E) NYCRR 4043.7 was able to become effective as a permanent rule. Thus, the expediency with which the Board was able to make the rule permanent belies the need for the five Emergency Rulemakings.

Id. at *21-22.

In this case, the Council claimed that "[emergency] regulations are necessary to address the alarming increase of e-cigarette use among New York's youth." De Palma Aff. at Ex. A, Emergency Rule at 4, 18. In justifying the emergency, the Council relied on FDA's statement—which was issued 12 months ago in September 2018—that the use of e-cigarettes by youth has reached epidemic proportions nationally. *Id.* at Ex. A, Emergency Rule at 5, 18; *cf. N.Y. State Ass'n of Homes & Servs. for the Aging, Inc. v. Perales*, 179 A.D.2d 296, 297, 502 N.Y.S.2d 839, 840 (3d Dep't 1992) ("[The] Supreme Court determined that the regulations were improperly adopted on an emergency basis by finding that a long simmering fiscal crisis within the State budget was not an emergency contemplated by State Administrative Procedure Act § 202 (6)."). This "epidemic" of youth abuse of e-cigarette products apparently started years ago according to DOH's own data, which it "began tracking" since 2014: The growth rate of "use by youth in high school" has increased from 10.5 percent in 2014 to 20.6 percent in 2016, to "an astounding 27.4 percent in 2018." *Id.* There is, however, no evidence that the Council took any steps to promulgate or draft any rules to address this issue until it issued this emergency rule before the Court. Like *Gill*, nothing in the Council's emergency rule explained why it "had to deal with the problem prior to public notice and comment allowed by SAPA." The record does not support a "genuine emergency" to which the courts emphasized the emergency rule-making procedure was limited.

According to the court in *Matter of Chinese Staff and Workers Ass'n*, a claim that "emergency regulation is needed to preserve the status quo" based on speculation of potential harm is inadequate to qualify as a "genuine emergency," either. *Matter of Chinese Staff & Workers Ass'n,* 2018 N.Y. Misc. LEXIS 4231, at *13. In *Matter of Chinese Staff & Workers Ass'n*, the New York State Department of Labor and its Commissioner issued emergency rules in

response to court rulings it believed contrary to an opinion letter it issued regarding minimum pay requirements for "live-in employees" based on a concern that "home care agencies may cease to provide home care aides, thereby threatening the continued operation of this [health-care service industry]." 2018 N.Y. Misc. LEXIS 4231, at *13 (emphasis added). The Supreme Court of New York for New York County annulled the emergency rule revising wage orders because "[a] mere need for the monitoring of the health-care service industry . . . and a potential concern about a disruption is not sufficient to justify the use of SAPA's administrative procedures for emergency rulemaking." *Id.* As in *Matter of Chinese Staff & Workers Ass'n*, the Council's concern for the damaging effects arising from the dramatic increase of youth vapor product use is similarly speculative to justify emergency action as the Council itself stated in the Emergency Rule that "it is too soon to understand the long-term health effects of a lifetime of e-cigarette use" and that it "will continue to closely monitor the research literature for health impact related to e-cigarettes." De Palma Aff. at Ex. A, Emergency Rule at 21.

Indeed, against the backdrop of this uncertainty, the emergency rule fails to even identify the "expected duration of [the public health, safety or general welfare need requiring adoption the rule on an emergency basis]" mandated by SAPA. SAPA § 202(6)(d)(iv). The Emergency Rule's complete failure to comply with the statutory requirements renders it a mere nullity and void.

The 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." *See Korean Am. Nail Salon Ass'n of New York, Inc. v. Cuomo*, 50 Misc. 3d 731, 735, 26 N.Y.S.3d 826, 830 (Sup. Ct. Albany Cnty. 2015) (holding that respondents have "sufficiently demonstrated that nail salon workers are being deprived of legally

due wages and that immediate adoption of the September 4, 2015 emergency regulation was necessary for the preservation of the public health, safety or general welfare of nail salon workers."). Unlike the inactivity by the Council during the entire period from 2016 to 2018 after youth vapor product use doubled from 10.5 percent in 2014 to 20.6 percent in 2016, 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 immediately 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.

D. The Emergency Rule Must Be Annulled And Petitioners Are Entitled To A Permanent Injunction

For the reasons set forth above, Petitioners are entitled to a Judgment declaring that the Emergency Rule is unconstitutional, invalid, and arbitrary and capricious. *See* CPLR §3001; *Jones v. Banner Moving & Storage, Inc.*, 78 Misc. 2d 762, 358 N.Y.S.2d 885, 1974 N.Y. Misc. LEXIS 1489 (N.Y. Sup. Ct. 1974), *aff'd in part, modified*, 48 A.D.2d 928, 369 N.Y.S.2d 804, 1975 N.Y. App. Div. LEXIS 10208 (2d Dep't 1975) ("Declaratory judgments have a broad range of permitted uses. One of them is to declare upon the validity of a contested statute, ordinance, rule, regulation, etc."); *Council for Owner Occupied Housing, Inc. v. Abrams*, 135 A.D.2d 13, 15, 523 N.Y.S.2d 663, 665, 1988 N.Y. App. Div. LEXIS 269, *4 (N.Y. App. Div. 3d Dep't 1988); *New York Horse & Carriage Ass'n v. New York, Dep't of Consumer Affairs*, 144 Misc. 2d 883, 545 N.Y.S. 2d 439 (Sup. Ct. New York Cnty. 1989); *Doe v. Axelrod*, 136 A.D.2d 410, 527 N.Y.S. 2d 385 (N.Y. App. Div. 1st Dep't 1988).

And, because the Emergency Rule is unconstitutional, invalid, and arbitrary and capricious, Petitioners are entitled to a Permanent Injunction prohibiting Respondents, and all those acting in concert with them, from enforcing or attempting to enforce the Emergency Rule.

See Aumick v. Bane, 161 Misc. 2d 271, 612 N.Y.S. 2d 766 (Sup. Ct. Monroe Cnty. 1994); *Darweger v. Staats*, 243 A.D. 380, 278 N.Y.S. 87 (3d Dep't 1935).

II. PETITIONERS ARE ENTITLED TO TEMPORARY AND PRELIMINARY INJUNCTIVE RELIEF PREVENTING ENFORCEMENT OF THE EMERGENCY RULE PENDING A DETERMINATION ON THE PETITION

A. Standard For Injunctive Relief

Temporary restraining orders and preliminary injunctions are impermanent remedies designed to "maintain the status quo until there can be a full hearing on the merits." *Pamela Equities Corp. v. 270 Park Ave. Cafe Corp.*, 62 A.D.3d 620, 620 881 N.Y.S.2d 44, 45 (1st Dep't 2009); *see also Gerald Modell Inc. v. Morgenthau*, 196 Misc. 2d 354, 359, 764 N.Y.S.2d 779, 784 (Sup. Ct. N.Y. Cnty. 2003). "A temporary restraining order may be granted pending a hearing for a preliminary injunction where it appears that immediate and irreparable injury, loss or damage will result unless the defendant is restrained before the hearing can be had." CPLR §§ 6301, 6313.

A temporary restraining order and preliminary injunction should be granted upon a showing that (1) the petitioner is likely to succeed on the merits; (2) the petitioner will be irreparably injured absent the injunctive relief; and (3) the balance of equities weighs in the petitioner's favor. *See, e.g.*, *Nobu Next Door, LLC v. Fine Arts Hous., Inc.*, 4 N.Y.3d 839, 840, 800 N.Y.S.2d 48, 49 (2005); *Bernheim v. Matthew Bender & Co.*, 244 A.D.2d 161, 663 N.Y.S.2d 577 (1st Dep't 1997). "[A] showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction[.]" *Madden Int'l, Ltd. V. Lew Footwear Holdings Pty. Ltd.*, 50 Mis. 3d 1210(A), 2016 N.Y. Misc. LEXIS 160, *15 (Sup. Ct. N.Y. Cnty. Jan 15, 2016) (quoting *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990)), *aff'd*, 143 A.D.3d 418, 2016 N.Y. App. Div. LEXIS 6333 (1st Dep't 2016).

When a party seeking injunctive relief merely seeks to preserve the status quo, the usual legal requirements are relaxed, "as the denial of injunctive relief would render the final judgment ineffectual." *See State v. City of New York*, 275 A.D.2d 740, 741, 713 N.Y.S.2d 360, 361 (2d Dep't 2000). In such cases, the party has a "reduced degree of proof" in establishing its likelihood of success on the merits. *Id.*; *Masjid Usman, Inc. v. Beech 140, LLC*, 68 A.D.3d 942, 943, 892 N.Y.S.2d 430, 431 (2d Dep't 2009). Further, the balance of equities tilts in favor of the party seeking to preserve the status quo. *See State v. City of New York*, 275 A.D.2d at 741, 713 N.Y.S.2d at 361; *CanWest Global Communications Corp. v. Mirkaei Tikshoret Ltd.*, 9 Misc. 3d 845, 868, 804 N.Y.S.2d 549, 568 (Sup. Ct. N.Y. Cnty. 2005); *Sp.Q.R. Co., Inc. v. United Rockland Stairs, Inc.*, 57 A.D.3d 642, 643, 868 N.Y.S.2d 318 (2nd Dep't 2008). Temporary relief in the form of a stay is appropriate where the stay is sought in connection with an application for a writ of prohibition. *See* CPLR § 7805; *see also* David D. Siegel, New York Practice § 567 (5th ed., 2011) ("The value of a stay . . . [is that it] gives the aggrieved person some breathing space while a court looks into the . . . activity [underlying the application].").

Finally, a temporary restraining order can be entered against a public officer, board or municipal corporation of the state where it appears that they will act illegally and thereby outside the performance of their statutory duties. *Komyathy v. Board of Education*, 75 Misc. 2d 859, 862, 348 N.Y.S.2d 28, 33-34, 1973 N.Y. Misc. LEXIS 1387, *7 (citing *110 Manno Realty Corp. v. Town of Huntington*, 61 Misc 2d 702) (Sup. Ct. Dutchess Cnty. 1973); *also see Matter of Fortuna v. Prusinowski*, 22 Misc. 3d 974, 976, 870 N.Y.S.2d 742, 744, 2008 N.Y. Misc. LEXIS 7112, *4, 2008 NY Slip Op 28508, 2 (Suffolk Cnty. 2008) ("Being discretionary in nature, said decisions are not statutorily compelled and thus do not constitute "the performance of statutory duties" within the purview of CPLR § 6313(a)."). In short, "[i]f State officials act in excess of

their legal authority or pursuant to an unconstitutional statute, such persons are stripped of their official character and undoubtedly could be enjoined as individuals." *Gaynor v. Rockefeller,* 21 A.D.2d 92, 99, 248 N.Y.S.2d 792, 802 (1st Dep't 1964).

Each of the elements is satisfied in this matter, and a stay of the implementation and enforcement of the flavor ban established by the Emergency Rule is appropriate and should be ordered.

B. Petitioners Are Likely To Prevail On The Merits

As set forth in detail above, and as established in the Petition and the Affidavits and other record evidence submitted in connection therewith, Petitioners are likely ultimately to prevail on the merits in the underlying proceeding because the Emergency Rule exceeds Respondents' statutory authority, is arbitrary and capricious, and fails to otherwise comply with the New York State Administrative Procedure Act. *1234 Broadway LLC v. West Side SRO Law Project,* 86 A.D.3d 18, 23-24, 924 N.Y.S.2d 35, 39-40 (1st Dep't 2011).

All that is required to justify injunctive relief is a likelihood of success; the proponent of a temporary stay need not offer conclusive proof beyond any factual dispute establishing ultimate success in the underlying proceeding. *See Moy v. Umeki,* 10 A.D.3d 604, 605, 781 N.Y.S.2d 684, 686 (2d Dep't 2004) ("[T]he mere fact that there indeed may be questions of fact for trial does not preclude a court from exercising its discretion in granting an injunction.") (quoting *Egan v. New York Care Plus Ins. Co.*, 266 A.D.2d 600, 601, 697 N.Y.S.2d 776 (3d Dep't 1999)).

As set forth above in Section I, Petitioners have succeeded in establishing that:

- The Emergency Rule Exceeds Respondents' Statutory Authority, *see* Point I.A, *supra*, at pp. 18-27.
- The Emergency Rule Is Arbitrary And Capricious, *see* Point I.B, *supra*, at pp. 27-30.
- The Ban Fails To Comply With The State Administrative Procedure Act, *see* Point I.C, *supra*, at pp. 30-36.

Thus, given its abundance of substantive and procedural defects, Petitioners are likely to prevail on the merits of their claims and the Emergency Rule must be enjoined.

C. Petitioners Will Suffer Irreparable Harm Absent An Order Staying The Implementation And Enforcement Of The Emergency Rule's Flavor Ban

Petitioners will unquestionably suffer significant and multiple forms of irreparable harm if the Emergency Rule's flavor ban is implemented and enforced. To warrant preliminary injunctive relief, the irreparable harm alleged must be immediate, specific, nonspeculative, and nonconclusory. *Matter of New York State Inspection, Sec. & Law Enforcement Empls. v Cuomo,* 64 N.Y.2d 233, 475 N.E.2d 90 (1984). Irreparable harm exists where an award for monetary damages is not adequate compensation. *See, e.g.*, *Credit Agricole Indosuez v Rossiyskiy Kredit Bank,* 94 N.Y.2d 541, 544-45, 729 N.E.2d 683 (2000); *Credit Index, L.L.C. v RiskWise Intl., L.L.C.*, 282 A.D.2d 246, 247, 722 N.Y.S.2d 862 (1st Dep't 2001); *SportsChannel Am. Assocs. v. National Hockey League*, 186 A.D.2d 417, 418, 589 N.Y.S.2d 2 (1st Dep't 1982). 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. *See Bank of Am., N.A. v. PSW NYC LLC*, 29 Misc. 3d 1216A, 918 N.Y.S.2d 396 (Sup. Ct. N.Y. Cnty. 2010) (citing *Natsource LLC v Paribello*, 151 F. Supp. 2d 465, 469 (S.D.N.Y. 2001).

"A complete loss of a business constitutes irreparable harm." *VOOM HD Holdings LLC v Echostar Satellite L.L.C.*, 2008 N.Y. Misc. LEXIS 9855, *6-8, 2008 NY Slip Op 31278(U), 6-7 (Sup. Ct. N.Y. Cnty. 2008); *see also Semmes Motors, Inc. v Ford Motor Co.*, 429 F.2d 1197 (2d

Cir. 1970) (termination of auto dealership constitutes irreparable harm where right to continue a business in which plaintiff had engaged for twenty years and into which his son had recently entered is not measurable entirely in monetary terms); *Roso-Lino Beverage Distributors, Inc. v Coca-Cola Bottling Co. of New York, Inc.*, 749 F.2d 124 (2d Cir. 1984); *GPA Inc. v Liggett Group, Inc.*, 862 F Supp 1062, 1068 (S.D.N.Y. 1994) (where the injunction will prevent damage to the business as a whole, irreparable harm can be established); *Mr. Natural, Inc. v Unadulterated Food Products, Inc.*, 152 A.D.2d 729, 544 N.Y.S.2d 182 (2d Dep't 1989) (termination of exclusive distributorship agreements placed plaintiff in real danger of losing its business or suffering dissolution). Further, loss of even a significant part of a company's business may constitute irreparable harm if the loss is not compensable in monetary damages. *See Galvin v New York Racing Ass'n*, 70 F. Supp. 2d 163, 170 (E.D.N.Y. 1998) (the loss of business need not be total, so long as it is so great as to seriously compromise the company's ability to continue in its current form); *see also VOOM HD Holdings, LLC*, 2008 N.Y. Misc. LEXIS 9855, at *10; *Staples, Inc. v Moses*, 9 Misc. 3d 1102(A), 1102A, 806 N.Y.S.2d 448, 448 (Sup. Ct. N.Y. Cnty. 2005).

Here, Petitioners are merely seeking to maintain the status quo while the question of the validity of the Respondents' Emergency Rule is litigated. The effect of enforcement of the Emergency Rule on the vapor industry in New York, as well as the broader New York economy and tax base, would be profound. If the Emergency Rule is enforced, Petitioner Perfection Vapes, Inc. and all but approximately five retail chains among New York's nearly 700 vape shops will be required to completely shut down operations. *See* Dunham Aff. at ¶ 7; Canastraro Aff. at ¶ ; Glauser Aff. at ¶ 9. As previously discussed, this is because the vast majority of vapor products sold would be considered "flavored e-liquid" under Subpart 9-3.1 of the Emergency

Rule, and thus the manufacturing, sale, and even possession of these products would be prohibited. Without their primary source of revenue, vapor product businesses will be immediately forced to close and layoff employees. Furthermore, in this instance, legitimate small business owners will potentially be deemed criminals the moment enforcement begins for simply possessing flavored e-liquid subject to the Emergency Rule. To avoid potential civil and criminal penalties, they will be forced to act *prior* to the Emergency Rule's enforcement, including potentially destroying inventory and further damaging their financial position.

For individual vape shop owners, the unexpected loss of their business will likely lead to personal financial crises in many situations. By way of example, Victor Canastraro, the owner of a vape shop and e-liquid manufacturer in Buffalo who lost four siblings and his father to cancer from cigarettes and made helping others stop smoking combustible cigarettes his life's goal, has personally guaranteed two leases for commercial buildings that will now go into default. Canastraro Aff. at ¶ 27. He also took out a loan for the purchase of a third building that will now also go into default and be lost through a foreclose sale. *Id.* at ¶ 28. Further, because he had been investing a portion of the revenues from his vapor businesses in a local restaurant which he also owned, he will also be required to close that restaurant and lay off its six employees in addition to the five employees of his vapor businesses. The Emergency Rule's cold observation that "[s]ome e-cigarette retailers [who] focus the bulk of their business on e-cigarettes and e-liquids . . . will be affected by this regulation" (Emergency Rule at 16), does not begin to address the economic destruction that the Emergency Rule already has introduced into the lives of well-meaning individuals who wanted nothing more than to save their friends, neighbors, and fellow New York citizens from the ravages of combustible cigarettes—the leading preventable cause of death and disease in the United States.

For Victor Canastraro's companies and those of hundreds of other e-liquid manufacturers and vape shop owners, the irreparable harm posed by the Emergency Rule is all too immediate, specific, nonspeculative, and nonconclusory. As explained in Section III, *supra*, the flavor ban is *ultra vires* and violates the State Administrative Procedure Act. A temporary restraining order and preliminary injunction are necessary to preserve the status quo while Petitioners seek to determine the validity of the Respondents' Emergency Rule.

D. The Balance Of Equities Favors Petitioners

The balance of equities and hardship unquestionably tilts in favor of Petitioners. Respondents will not suffer any harm if the requested temporary restraining order and injunction are granted. Whereas the irreparable harm that Petitions face if an injunction is the substantial damage to and certain ceasing of Petitioners' business operations.

This temporary restraining order and injunction are about preserving Petitioners' businesses and livelihoods, not simply monetary damages. A granting of the requested relief will merely preserve the status quo. Traditionally the balance of equities tilt in favor of the party seeking to preserve the status quo. *See State v. City of New York*, 275 A.D.2d 740, 741; *CanWest Global Commc'ns Corp. v. Mirkaei Tikshoret Ltd.*, 804 N.Y.S.2d 549, 574 (Sup. Ct. N.Y. Cnty. 2005); *Sp.Q.R. Co., Inc. v. United Rockland Stairs, Inc.*, 57 A.D.3d 642, 643, 868 N.Y.S.2d 318 (2d Dep't 2008).

For the Respondents, the requested relief only requires that they pursue their goals through the legislative process. As previously discussed, this issue has been, and continues to be, considered by the Legislature. That avenue would provide Respondents the opportunity to achieve their objective while allowing all interested stakeholders to comment and be heard on the issue. Additionally, it would allow Respondents to evaluate the effectiveness of the

Legislature's recent actions on the issue, in particular the raising of the minimum purchase age to 21.

Furthermore, Petitioners' requested relief is in the public interest. As previously noted, limiting or barring access to flavored vapor products will likely cause former smokers to relapse and return to far more harmful cigarettes. *See* Abboud Aff. at ¶ 20. Many smokers rely on non-tobacco-flavored vapor products to aid them in transitioning from combustible cigarettes and down the spectrum towards cessation of all nicotine-containing products. *See id.* at ¶¶ 17-18. As the Buckell, et al., study suggests, a ban on non-tobacco-flavored vapor products will likely result in a substantial increase in the demand for combustible cigarettes—an unpardonable offense to public health. *Id*. at ¶ 20.

A ban on non-tobacco flavors likely would also lead to the establishment or growth of an illicit black market for banned flavors. As has become evident over the last several months, products sold on the black market pose a much greater health risk to the public. Products sold on a black market are not subject to the ingredient listing requirements and rigorous inspections of manufacturing facilities that are required of establishments registered with the FDA, thereby leaving increased opportunity for such black-market products to be contaminated with potentially dangerous ingredients, including Vitamin E Acetate, a focus of DOH's investigations into recent illnesses related to the vaping of THC-containing products.

A ban on flavored products also lends itself to encouraging individuals to create do-it-yourself ("DIY") flavored e-liquids. A Google search for "DIY e-liquid" returns millions of results, including numerous videos demonstrating how individuals can formulate their own flavored e-liquids. *See* Abboud Aff. at Ex. 3, VTA ANPRM Flavor Comments, at 40. Rather than simply stop using e-cigarettes, individuals may be inclined to purchase the supplies

necessary to craft their own flavored e-liquids, without the safeguards and supervision that is found in and required of manufacturers registered with the FDA.

Lastly, in addition to destroying numerous businesses and eliminating thousands of jobs, the ban will likely serve to shift the benefits to the economies of other jurisdictions as consumers can still readily obtain the prohibited products from the surrounding jurisdictions. Of course this avenue would not be used solely by individuals purchasing for themselves, but likely also by individuals hoping to exploit the growing black market. For these reasons, then the balance of equities also favors immediately enjoining the Emergency Rule and its ill-justified flavor ban.

*** * ***

Petitioners readily satisfy the elements required for temporary and preliminary relief to enjoin enforcement of the Emergency Rule pending a final judicial determination on the validity of that regulation. Accordingly, this Court should issues a temporary restraining order and preliminarily enjoy Respondents.

CONCLUSION

WHEREFORE, Petitioners respectfully requests that this Court issue a Judgment and Order:

(i) declaring that Respondents have improperly enacted the Emergency Rule in excess of their constitutional, statutory and administrative authority;

(ii) declaring the Emergency Rule to be null, void and unenforceable;

(iii) temporarily, permanently and preliminarily enjoining and preventing Respondents from enforcing the Emergency Rule; and

(iv) granting to Petitioners such other and further relief as the Court may deem just and proper.

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