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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REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

State Cases

State Statutes

Regulations

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 reply memorandum in support of their motion, made by Order to Show Cause, for a preliminary injunction pending a determination on their Verified Petition herein dated September 24, 2019.

PRELIMINARY STATEMENT

On October 3, 2019, four justices of the Appellate Division, Third Department, entered a temporary restraining order enjoining Respondents from enforcing the Emergency Rule placed at issue through Petitioners' Verified Petition.[1] (*See* October 3, 2019 Decision and Order on Motion attached as Exhibit A to the Reply Affirmation of Richard De Palma ("De Palma Reply Aff.") filed herewith.) This Court should effectively continue that injunction by granting Petitioners' motion for a preliminary injunction. As explained in Petitioner's opening memorandum, and as the Appellate Division has already implicitly found,[2] Petitioners are likely to succeed on the merits of their claims that the Emergency Rule, which imposes a ban on non-tobacco- and non-menthol-flavored vapor products, exceeds Respondents' statutory authority, is arbitrary and capricious, and fails to comply with the State Administrative Procedure Act. Indeed, as regards Petitioners' likelihood of success on the merits, the Respondents' memorandum of law in opposition fails to advance any new arguments that were not already

[1] The Emergency Rule consists of 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."

[2] The standard for a temporary restraining order like that imposed by the Appellate Division is, if anything, *more* demanding than the standard applicable to a request for a preliminary injunction. *See* Siegel, New York Practice § 330, at 603 (6th ed. 2018) ("Whatever showing of urgency is needed to sustain a preliminary injunction, presumably that much more is needed to justify a TRO.").

advanced before the Appellate Division (either on paper or during oral argument) prior to its entering the temporary restraining order currently in effect. Further, if anything, the events of the last two weeks have further demonstrated that one of the justifications for the Emergency Rule belatedly cited by Respondents—that of the outbreak of severe respiratory illnesses—is, as Petitioners have consistently maintained, unrelated to the nicotine-containing vapor products affected by Emergency Rule. The irreparable harm that Petitioners face if Respondents are allowed to enforce the flavor ban imposed by the Emergency Rule, as well as the fact that Petitioners merely seek to preserve the status quo—including the remedy for youth vaping selected by the Legislature of increasing the age for purchase to 21—also support continuing the injunction against enforcement of the Emergency Rule already interposed by the Appellate Division and granting Petitioners' request for a preliminary injunction.

ARGUMENT

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 621, 620 881 N.Y.S.2d 44, 45 (1st Dep't 2009) (internal quotation marks and citation omitted). To establish their entitlement to preliminary injunctive relief, Petitioners must establish (1) a likelihood of success on the merits; (2) irreparable injury absent injunctive relief; and (3) that the balance of equities weighs in Petitioners' 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, 161, 663 N.Y.S.2d 577, 578 (1st Dep't 1997).

As regards the first factor, likelihood of success on the merits, a "reduced degree of proof" exists when the party seeking injunctive relief merely seeks to preserve the status quo. *Masjid Usman, Inc. v. Beech 140, LLC*, 68 A.D.3d 942, 943, 892 N.Y.S.2d 430, 431 (2d Dep't

2009); *see State v. City of New York*, 275 A.D.2d 740, 741, 713 N.Y.S.2d 360, 361 (2d Dep't 2000). This is the case because "the denial of injunctive relief would render the final judgment ineffectual." *State v. City of New York*, 275 A.D.2d at 741, 713 N.Y.S.2d at 361.

The second factor, the likelihood of 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.*, No. 650209/2015, 2016 N.Y. Misc. LEXIS 160, at *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, 38 N.Y.S.3d 178 (1st Dep't 2016). Finally, when a movant merely seeks to preserve the status quo, the third prong—the balance of equities—also tilts in the movant's favor. *See State v. City of New York*, 275 A.D.2d at 741, 713 N.Y.S.2d at 361; *see also 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). For the reasons explained below, each of the three elements is satisfied here and a preliminary injunction should be granted.

A. THE IRREPARABLE HARM PETITIONERS WOULD SUFFER ABSENT INJUNCTIVE RELIEF IS IMMEDIATE, CERTAIN, AND SPECIFIC, NOT SPECULATIVE OR CONCLUSORY.

The irreparable harm that Petitioners would suffer absent injunctive relief is immediate, certain, and specific, not speculative or conclusory, as Respondents contend. Not only would Petitioners suffer a complete loss of their businesses but, even if they did not, principles of sovereign immunity would protect Respondents from any subsequent liability in a suit for damages for *any* quantum of lost sales, which in and of itself constitutes *per se* irreparable harm.

1. Any Loss to Petitioners as a Result of the Emergency Rule Would Constitute Irreparable Harm Because Sovereign Immunity Would Prevent Them from Recovering Money Damages from Respondents.

As a matter of law, *any* loss of revenue to Petitioners as a result of the flavor ban would constitute irreparable harm. This is the case because, if Respondents are allowed to begin

enforcing the Emergency Rule, Petitioners would not be able to bring any claims against Respondents for money damages resulting from the losses to their businesses because Respondents would contend that they are immune from suit. *See, e.g.*, *Bowen v. State Bd. of Soc. Welfare*, 55 A.D.2d 235, 237, 390 N.Y.S.2d 617, 620 (2d Dep't 1976) ("Sovereign immunity, where it exists, extends not only to State officers and agencies, such as the defendant agencies here engaged in carrying on governmental functions, but also to State officers acting in a similar capacity. A suit against such an officer or agency is regarded as one against the State itself."), *rev'd on other grounds by Jones v. Beame*, 45 N.Y.2d 402, 408 N.Y.S.2d 449 (1978). Federal courts in New York, faced with similar circumstances, have held that a party's immunity to damages constitutes *per se* irreparable harm under a preliminary injunctive relief analysis. *See, e.g.*, *N.Y. State Trawlers Ass'n v. Jorling*, 764 F. Supp. 24, 26 (E.D.N.Y. 1991) ("[T]he [Second Circuit] Court of Appeals has recognized that, where such damages cannot be later collected because the defendant enjoys eleventh amendment immunity, the damages become irreparable." (citing *United States v. State of New York*, 708 F.2d 92, 93 (2d Cir. 1983))), *aff'd without opinion by*, 940 F.2d 649 (2d Cir. 1991); *John E. Andrus Mem'l, Inc. v. Daines*, 600 F. Supp. 2d 563, 572 n.6 (S.D.N.Y. 2009) ("Plaintiff is unable to collect a judgment for monetary damages in this action because Defendant is a state official entitled to sovereign immunity under the Eleventh Amendment. Thus, in addition to the actual and imminent harms established by the record, irreparable harm *may be presumed* here because the only relief available to the [plaintiff] is injunctive." (emphasis added; citation omitted)).[3]

[3] *See also Smoking Everywhere, Inc. v. United States FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (quoting *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) ("Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by [the] plaintiff is irreparable *per se*.'") (citation omitted; alteration in original), *aff'd*, 627 F.3d 891 (D.C. Cir. 2010); *E. Bay Sanctuary Covenant v. Trump*, 354 F.

2. Petitioners are Threatened With the Complete Loss of Their Businesses, Which Constitutes Irreparable Harm as a Matter of Law.

Further, the harm threatened here is not a mere partial loss of Petitioners' businesses, but a complete loss. "A complete loss of a business constitutes irreparable harm." *VOOM HD Holdings LLC v Echostar Satellite L.L.C.*, No. 600292/08, 2008 N.Y. Misc. LEXIS 9855, at *6-8 (Sup. Ct. N.Y. Cnty. Mar. 5, 2008); *see also Mr. Natural, Inc. v. Unadulterated Food Prods., Inc.*, 152 A.D.2d 729, 730, 544 N.Y.S.2d 182, 183 (2d Dep't 1989) (termination of exclusive distributorship agreements placed plaintiff in real danger of losing its business or suffering dissolution); *Galvin v N.Y. 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); *Staples, Inc. v. Moses*, 9 Misc. 3d 1102(A), 1102A, 806 N.Y.S.2d 448, 448 (Sup. Ct. N.Y. Cnty. 2005). 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; Glauser Aff. at ¶ 9.

Respondents' contentions that these injuries are speculative or conclusory reflects Respondents' fundamental lack of knowledge about the small businesses that would be forced to shutter if the Emergency Rule took effect. Indeed, these injuries were already concrete and felt by vapor product business owners in New York prior to the entry of the Appellate Division's temporary restraining order. Michelle Troyer, owner of Cloud Chasers, LLC, a vape shop located in Depew, New York, had already begun shutting down her operations as a result of the

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Supp. 3d 1094, 1116 (N.D. Cal. 2018) (citing *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018), and observing that "as the Ninth Circuit recently reiterated, the general rule that '[e]conomic hardship is not normally considered irreparable' does not apply where there is no adequate remedy to recover those damages").

Emergency Rule, as more than 90 percent of the business's revenue was derived from non-tobacco and non-menthol-flavored e-liquids. *See* Troyer Aff. at ¶¶ 5-7. There is almost no demand for tobacco-flavored vapor products, as only two or three of Cloud Chasers' approximately 700 regular customers use tobacco-flavored vapor products. *Id.* ¶13. Many of these customers have already told Ms. Troyer they intend to return to combustible cigarettes once the Emergency Rule is enforced and flavored vapor products are no longer available. *Id.* Prior to entry of the temporary restraining order, Ms. Troyer had already stopped placing orders for additional products and had begun laying off employees and liquidating inventory at "fire sale" prices. *Id.* Both of the employees that were laid off are in the process of filing for state unemployment benefits. *Id.* ¶ 9. With the closing of her shop, Ms. Troyer would not be able to pay the mortgage for either the store or her own home, and expects to lose both in foreclosure. *Id.* ¶ 14.

Similarly, Jeffrey Barry, owner of Slomomo LLC, which operates three vape shops under the name Fresh Vapes in Western New York, began shutting down his business as a result of the Emergency Rule. *See* Barry Aff. at ¶¶ 6-7. Immediately following announcement of the Emergency Rule, Mr. Barry drastically cut down his re-stock orders of flavored vapor products to try to avoid having excess inventory when enforcement began as he already anticipated having to shut down his shops as a result of the flavor ban. *Id.* ¶ 5. On September 28, 2019, Mr. Barry announced he was permanently closing the Dansville Fresh Vapes location as a result of the Emergency Rule, and the store's last day was September 30, 2019. *Id.* ¶ 6. Prior to entry of the temporary restraining order, Mr. Barry also announced that he would have to permanently close the other two remaining stores by Friday, October 4, 2019, because of the Emergency Rule. *Id.* As part of shutting down the three stores, Mr. Barry laid off one employee on the day that

Governor Cuomo announced the statewide flavor ban and told his three remaining employees that their last day of work would be October 3, 2019. *Id.* ¶ 7. Mr. Barry also expected to be stuck with $80,000 in unsellable inventory once enforcement began. *Id.* ¶ 8.

The sudden decline in orders and sales since Governor Cuomo's announcement was experienced by the vapor product industry throughout New York as more and more businesses prepared to shut down once enforcement of the Emergency Rule began on October 4, 2019. During the fourth week of September (September 23 through September 27), one of the largest wholesalers and distributors of vapor products in New York saw e-liquid sales that were barely more than one-third of sales that occurred during the first week of September 2019. *See* Glauser Supp. Aff. ¶ 6. Once again, Respondents' bald suggestion that this is just a matter of stores or consumers switching to tobacco or menthol-flavored vapor products reflects their complete lack of understanding of the small businesses and current and former smokers that are affected. Indeed, sales of tobacco and menthol-flavored e-liquid products in the fourth week of September were 38 percent *lower* than sales during the first week of September. *Id.* ¶ 8. These statistics were indicative of vapor product businesses throughout New York already closing or winding down for closure once enforcement was poised to begin. *See id.* These facts demonstrate that there is no viable business model for small vapor businesses to sell only tobacco- and menthol-flavored products.

Further, sales to New York vape shops since the Appellate Division's temporary restraining order took effect further demonstrate that the severe decline in sales in the second half of September was due to the announcement and planned enforcement of the Emergency Rule's flavor ban, and not negative media attention surrounding the vaping industry as a whole or the recent spate of severe respiratory illnesses tied to illegal THC-containing vape cartridges,

as Respondents suggest.[4] During the week starting October 6, 2019, immediately after the temporary restraining order went into effect, the same distributor sold per-shop average quantities of non-tobacco-flavored e-liquids to New York vape shops that were comparable to those sold during the last week of August and first week of September. (*See* Second Supplemental Affidavit of Jon Glauser at ¶ 7.)

Notably, in preliminarily enjoining a similar statewide flavor ban on October 15, 2019, some two weeks *after* it had taken effect (and after that court had initially denied a temporary restraining order), the Michigan Court of Claims found that the plaintiffs there had proven irreparable harm, as one of the plaintiffs had been forced to shutter his business as a result of the flavor ban and, instead of switching to tobacco-flavored e-liquid, his customers were instead traveling to Wisconsin to obtain flavored nicotine vapor products. *See* Oct. 15, 2019 Opinion and Order in *Marc Slis v. State of Michigan*, Case No. 19-000152-MZ (Mich. Ct. Claims) annexed as Exhibit B to the Reply De Palma Aff. This actual, contemporaneous experience underscores that, contrary to Respondents' speculation that perhaps all of Petitioners' customers would switch to tobacco-flavored or non-flavored vapor products, like the plaintiff in the Michigan case, Petitioners would be forced to shutter their operations if the Court does not continue the *status quo* and preliminary enjoin the Emergency Rule.

To be clear, there is nothing speculative or uncertain about the damages that have already been caused and that would be greatly exacerbated by the threatened and actual enforcement of the Emergency Rule. These are real businesses and real people that were affected by the

[4] Respondents' argument is also ironic in that, as discussed below, the Department of Health's own statistics demonstrated that the cases of severe respiratory illnesses were directly related to black market THC products, not the FDA-regulated nicotine products sold by Petitioners, yet the State continued to stoke a media narrative that falsely associated the cases of severe respiratory illnesses with the products sold by Petitioners in an attempt to create a *post hoc* justification for executive overreach.

Emergency Rule before enforcement even began. These are people with families to support that, if the Court does not enjoin the Emergency Rule, would be stripped of their livelihoods or forced to the unemployment line without any recourse. For Petitioner'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.

B. PETITIONERS HAVE DEMONSTRATED A STRONG LIKELIHOOD OF SUCCESS ON THE MERITS.

1. The Emergency Rule Exceeds Respondents' Statutory Authority.

The Emergency Rule usurps the State Legislature's role and exceeds Respondents' authority under the New York State Constitution.

Whether an agency engaged in impermissible policymaking requires 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 1, 11-14, 523 N.Y.S.2d 464, 469-71 (1987). "[T]hese 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." *LeadingAge N.Y., Inc. v. Shah*, 32 N.Y.3d 249, 261, 90 N.Y.S.3d 579, 588 (2018) (quoting *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene*, 23 N.Y.3d 681, 696, 992 N.Y.S.2d 480, 487-88 (2014)). 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." *N.Y. Statewide Coal.*, 23 N.Y.3d at 696-97.

Here, all four *Boreali* factors weigh in favor of Petitioners, and Respondents' Opposition even offers further support for Petitioners' position. The Emergency Rule is "simply a ban" that was enacted on a clean slate without appropriate legislative guidance while legislative debate was ongoing. It did not require any special expertise and reflects Respondents' balancing and consideration of concerns beyond their authority or expertise. Accordingly, a preliminary injunction should be entered and the Emergency Rule should ultimately be declared invalid as *ultra vires* pursuant to *Boreali*.

a. Respondents made improper value judgments to attempt to resolve difficult social problems.

"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." *N.Y. Statewide Coal.*, 23 N.Y.3d at 699. In developing and enacting the Emergency Rule, Respondents "made value judgments entail[ing] difficult and complex choices between broad policy goals to resolve social problems." *Id.*

The Emergency Rule is an "outright prohibition" on flavored vapor products, clearly requiring Respondents to make value judgments as to which products to prohibit. Despite claiming that the motivation for the ban is the risks stemming from adolescent exposure to nicotine, a general scientific consensus that vapor products are less harmful than combustible cigarettes, and data suggesting that youth use of combustible cigarettes recently increased for the first time in years, Respondents chose to exclude from the ban combustible cigarettes, including

those that are menthol flavored.[5] Respondents also chose to exclude from the ban tobacco-flavored vapor products, despite the alleged concern over youth usage of vapor products and the risks posed by nicotine use. They also excluded "unflavored" vapor products, which would allow for individuals, including youth, to not only obtain these products but also to potentially mix their own flavored vapor products on a "do-it-yourself" basis without any oversight or safety precautions in place. Respondents also excluded menthol-flavored vapor products, despite claiming it was the second most preferred flavor by youth in the data cited by Respondents.

Respondents' exclusion of all combustible tobacco and particular vapor products, despite claiming concern over youth usage, the risks of nicotine, and potential lung injury or illness, demonstrates that Respondents considered and balanced factors beyond the health considerations within their authority and expertise. If any of those claimed justifications were the sole basis for the Emergency Rule, then it would seem that Respondents' prohibition would have been even broader and without these exclusions.

b. Respondents enacted the Emergency Rule on a clean slate without adequate legislative guidance.

The Emergency Rule imposes a comprehensive rule without legislative guidance and does not "merely fill in the details of broad legislation describing over-all policies to be implemented." *Boreali*, N.Y.2d at 13.

Unlike the agencies in *Garcia* and *Greater N.Y. Taxi Ass'n*, Respondents are not acting in a manner and realm in which they have regularly and repeatedly enacted regulations. In both of

[5] Respondents' attempt (Resp. Mem. at 10-11) to justify the exclusion of combustible cigarettes from the ban as an exclusion, instead of an "exemption," amounts to a game of semantics that fails to adequately justify this carve-out from a ban purportedly motivated by concerns about youth nicotine exposure, especially when one considers the far more harmful individual and public health effects of combustible tobacco use. (*See* Affidavit of Dr. Michael Siegel at ¶¶ 20-24.)

those cases, the agencies were acting under clear statutory delegations of authority in subject areas they had regulated for decades. In *Garcia*, the New York City Department of Health & Mental Hygiene's regulation requiring influenza vaccination for toddlers was merely the latest in a long line of vaccination-requirement regulations, dating back to 1866. *See Garcia v. New York City Dep't of Health & Mental Hygiene*, 31 N.Y.3d 601, 615-16, 81 N.Y.S.3d 827, 838-39 (2018). Similarly, in *Greater N.Y. Taxi Ass'n*, the New York City Taxi & Limousine Commission regulation selection of the "Taxi of Tomorrow" was well within its authority to identify the specifications for taxi cabs, and in a subject area that it regulated for decades – "almost every detail of operation" in the New York City tax industry. *Greater N.Y. Taxi Ass'n v. New York City Tax & Limousine Comm'n*, 25 N.Y.3d 600, 611, 15 N.Y.S.3d 725, 732 (2015). Here, Respondents are enacting regulations in a relatively new subject area – vapor products – without clear statutory authority or guidance.

Respondents' actions are more akin to the Public Health Council's ("PHC") enactment of regulations further restricting smoking in public places in *Boreali*. Like the PHC, Respondents rely on the general authority under Public Health Law § 225 to "deal with any matters affecting the . . . public health" as authority to issue the Emergency Rule. The PHC attempted to buttress its position by pointing to the Legislature's prior actions limiting public smoking. Similarly, Respondents, after failing to cite to such additional statutory basis upon issuance of Emergency Rule, now attempt to justify their unconstitutional actions by citing to other legislative enactments relating to tobacco or vapor product use, including, coincidentally, Public Health Law § 1399-o, which restricts smoking or vapor product use in certain public areas. *See Boreali*, 71 N.Y.2d at 6-7; *Boreali v. Axelrod*, 130 A.D.2d 107, 111-12, 518 N.Y.S.2d 440, 442-43 (3d Dep't 1987); Resp. Mem. at 11-12.

Just as the PHC failed to justify its unlawful usurpation of the Legislature's role, so do Respondents. The grant of authority 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" and "'governmental 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.'" *Boreali*, 130 A.D.2d at 113; *Baker v. CNY Agency for Children Servs.*, No. 98 CV 5970 (SJ), 1999 U.S. Dist. LEXIS 12480, at *5 (E.D.N.Y. Apr. 29, 1999) (citation omitted). Indeed, the over-reaching impact of the flavor ban is underscored by considering that its primary effect is to make illegal *for adults* products that the Legislature has implicitly determined could legally be used by them; use of all vapor products, including flavored vapor products, by individuals under 18 years of age has already been illegal in the State of New York for years. By increasing that minimum age to 21 in its last legislative session, the Legislature implicitly adopted the position that the sale of such products to those 21 and over should continue to be permitted—a position that is trampled on by the Emergency Rule.

Respondents' interpretation of the statutes cited in their Opposition requires the Court to ignore the plain language of the statutes and the context in which they must be read. For example, Respondents' suggestion that Public Health Law §1399-ii(2)(h) gives carte blanche to enact bans on otherwise legal products requires ignoring that the provision is in the context of "tobacco use prevention and control activities," such as community and school-based programs to prevent and reduce tobacco studies, and even requires that any such programs be selected by the commission through an application process. Respondents' argument opens the door for them to act without restriction in implementing any regulations they so choose unless specifically prohibited by the Legislature. This is contrary to the separation of powers that is fundamental to

New York's Constitution, and the law of New York. Here, the Emergency Rule was enacted on a clean slate without statutory authority or guidance from the Legislature supporting such action.

c. Respondents' Opposition confirms the Emergency Rule was enacted in an area of ongoing legislative debate.

Respondents' conclusory assertion that the Emergency Rule is a "quintessential example of interstitial rulemaking" is not only unsupported, but also contradicted by their own arguments and citations, which show that the Emergency Rule was imposed in an area still subject to legislative debate.

Respondents' reliance on *Consolidated Edison* is misplaced. In that case, the court specifically stated that the issue was not whether the administrative agency exceeded its authority under *Boreali*, but that the "case pose[d] an entirely different question." *Consol. Edison Co. of New York v. Dep't of Envtl. Conservation*, 71 N.Y.2d 186, 192, 524 N.Y.S.2d 409, 412 (1988). Instead, the issue was "whether the Legislature, by the 1977 and 1983 Acts, intended to limit its previous grant of broad regulatory powers to DEC so at to leave DEC without authority to promulgate petroleum storage regulations now at issue." *Id.* In that instance, the court found that the statutes at issue did not conflict and the statutes, when read together, did not repeal or otherwise restrict the agency's previously delegated regulatory authority. *Id.* at 196.

Respondents attempt to confuse and blur the *Boreali* factors and mischaracterize Petitioners' arguments on the issue of whether legislative debate is still ongoing. Unlike *Consolidated Edison*, Petitioners' reference to the recent enactment by the Legislature raising the minimum age for purchasing vapor products to 21 years old is not to argue that this enactment necessarily precludes any type of regulation but rather as evidence of the ongoing legislative debate as to how to best address youth use of vapor products. The multiple legislative proposals

in recent sessions setting forth a variety of potential policy options, including proposals that would enact the same ban on flavored vapor products as the Emergency Rule, indicate that the Legislature is still determining the best course for reducing youth use of vapor products.

Indeed, Respondents' Opposition offers further support for the finding that the Emergency Rule intrudes upon ongoing legislative debate. Within the last year, the Legislature has obviously engaged in significant debate on the issue, resulting in the enactment of additional legislation, as well as amending existing legislation on indoor smoking and tobacco prevention programs to include vapor products. *See* Resp. Mem. at 12; Public Health § 1399-o (amended effective June 12, 2019); Public Health Law § 1399-ii (amended effective Sept. 12, 2019); Public Health Law § 1399-BB (effective Nov. 13, 2019); Tax Law, Art. § 28-C.

"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. The Legislature has made clear and deliberate choices in its legislative enactments and refrained from passing a complete ban on flavored vapor products, despite multiple proposed bills which would enact such a prohibition. The Legislature's failure to enact a particular 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 id.* Rather than respect the will of the Legislature and allow its solution of raising the minimum age to 21 to go fully into effect, Respondents unilaterally enacted a sweeping social policy change without even waiting to see the impact of the Legislature's chosen solution. While the Executive is empowered to veto bills passed by the Legislature, the Executive is *not* empowered to effectively enforce a ban that the Legislature rejected just a few months earlier.

d. The Emergency Rule is "simply a ban" that did not require special expertise or technical competence.

Respondents admit that the Emergency Rule is "simply a ban." Resp. Mem. at 10. A simple, blanket prohibition on the possession, manufacture, distribution, sale, or offer for sale of flavored vapor products does not require the exercise of '"special expertise or competence in the field to develop the challenged regulation.'" *Matter of NYC C.L.A.S.H., Inc. v. New York State Off. Of Parks, Recreation & Historic Preserv.*, 27 N.Y.3d 174, 184, 32 N.Y.S.3d 1, 6 (citation omitted); *see also Boreali*, 71 N.Y.2d at 14.

Respondents are not fleshing out or filing in the gaps on legislative policies, but rather creating a wholesale new social policy. "[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). Unlike *Garcia*, in which the Department of Health & Mental Hygiene compiled and analyzed data and research regarding the dangers posed to infants by influenza as well as the safety and effectiveness of vaccinations before mandating vaccinations for infants under its long-held and repeatedly exercised authority to require vaccinations, Respondents are not merely carrying out their previously delegated or exercised statutory responsibilities. Instead, they are enacting new social policy without any consideration of any contrary or comprehensive data regarding the use or potential public health benefits of vapor products or flavored vapor products. *See* 31 N.Y.3d at 615-16.

After citing minimal scientific or medical data in their original justification issued with the Emergency Rule and instead relying primarily on basic survey data and general and conclusory statements about the alleged risks of flavored vapor products and nicotine,

Respondents now argue that the Emergency Rule's development required significant analysis of data and research. This ignores and is undercut by the reality that legislators had previously proposed unsuccessful legislation that would have enacted similar prohibitions. Nor does Respondents' analysis of the cited data seem particularly sophisticated. By way of example, Respondents emphasize that 36.7 percent of high school seniors have used e-cigarettes but fail to acknowledge that, until November 13, 2019—when the Legislature's chosen solution to the youth vaping issue will take effect—the purchase of such products by high school seniors that are 18 years of age remains *legal* in most of the State. Further, as noted in Respondents' Opposition, other jurisdictions have implemented similar prohibitions. Significantly, Respondents do not appear to have considered any contrary or comprehensive data or studies on vapor products. This suggests that a regulation like the Emergency Rule, consisting of a simple ban, does not require any particularized expertise or competence allegedly possessed by the Respondents. Only after their deliberate violation of the separation of powers was challenged and enforcement of the Emergency Rule enjoined did Respondents attempt to offer any evidence that might imply any specialized scientific or medical judgment was exercised in advancement of the Emergency Rule.

2. The Emergency Rule Fails to Comply with the State Administrative Procedure Act.

Respondents, while spending much time trying to parse Petitioners' cases,[6] utterly fail to demonstrate that they complied with SAPA when they enacted the Emergency Rule. Rather,

[6] While some of these cases may involve slightly different underlying circumstances surrounding emergency rulemaking, they all stand for the same proposition: An agency may not attempt to circumvent the statutorily required rulemaking processes with the attendant due process safeguards—including the right for the public and, most importantly, those to be affected by the proposed rule, to comment on, and attending hearings for, the proposed rule. Here, Respondents did just that, and each of the cases cited by Petitioners in their opening brief support Petitioners' claim that Respondents violated SAPA. Petitioners stand by their reliance on these cases cited in

Respondents try to conflate the ongoing issue related to severe respiratory illness with the stated emergency justification supporting the Emergency Rule. In so doing, not only are Respondents trying to change, on a *post hoc* basis, the stated justification for Emergency Rule, but they are also relying on a suggested linkage between flavored nicotine-containing vaping products and the recent cases of severe respiratory illness that is entirely fictional and for which no epidemiological evidence exists.

a. The Emergency Rule patently fails to comply with SAPA's requirements.

In their opposition, Respondents fail to put forth *any* facts or arguments demonstrating that they complied with the requirements of State Administrative Procedure Act ("SAPA") for emergency rulemaking. In particular, Respondents fail to show that the "Notice of Emergency," including the "Emergency Justification" statement, of the Emergency Rule, included any of the following as required by SAPA:

- "whether the notice . . . constitute[d] a notice of proposed rule making for the purposes of subdivision one of this section, and if so, . . . the date, time and place of any public hearing or hearings which are scheduled," SAPA § 202(6)(d)(iii);
- any specific "find[ing] 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

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their opening brief, with the narrow exception that Petitioners acknowledge that *Korean American Nail Salon Ass'n of New York, Inc. v. Cuomo*, 50 Misc. 3d 731, 734-35, 26 N.Y.S.3d 826, 830-31 (Sup. Ct. Albany Cnty. Dec. 1, 2015), did not state that the emergency rule at issue in that case was put in place "immediately" after the agency learned of the issue. But what *Korean American Nail Salon* makes clear is that: (i) there was a legitimate public health, safety or welfare emergency; (ii) the agency acted immediately after making the emergency determination; and (iii) the agency complied with SAPA's emergency rulemaking requirements—none of which were present here. *Id.*

requirements of subdivision one of this section would be contrary to the public interest," *id.* § 202(6)(a) & (6)(d)(iv);

- "the effective date of the rule," *id.* § (6)(d)(v);
- "the specific date the emergency rule will expire," *id.* § (6)(d)(vi); or
- "the name, public office address and telephone number of an agency representative, knowledgeable on the rule, from whom a complete text of such rule, the regulatory impact statement, regulatory flexibility analysis, and the rural area flexibility analysis may be obtained; from whom information about any public hearing may be obtained; and to whom written data, views and arguments may be submitted." *Id.* § (6)(d)(x).

These facial deficiencies are enough to invalidate the statute for its failure to comply with SAPA. *See 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), *aff'd*, 229 A.D.2d 286, 655 N.Y.S.2d 770 (3d Dep't 1997); *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) (holding that emergency exception to SAPA must be "narrowly construed").

Indeed, Respondents effectively concede that they did not strictly comply with SAPA by arguing that all that is needed is "substantial compliance" with the statute. *See* Resp. Mem. at 19 ("Respondents did indeed substantially comply with SAPA in doing so."). Yet, such a standard runs contrary to the Third Department's standard of a narrow construction in *Dowling*. Respondents fail to carry their burden and the Court should reject Respondents' attempt to rewrite the applicable law.

b. Respondents' *post hoc* attempt to justify the Emergency Rule by reference to the outbreak of severe respiratory illnesses is legally improper and unsupported by the evidence.

Instead of addressing the patent deficiencies in the Emergency Rule, Respondents instead attempt to link the ongoing outbreak of severe respiratory illnesses with the flavored nicotine-containing vapor products that would be banned by the Emergency Rule. (Resp. Mem. at 27.) However, at no point in the stated justification published as part of the Emergency Rule did Respondents cite to or reference in any manner the cases of severe respiratory illness. To the extent that Respondents now attempt to rely on vaping illness as a justification for the Emergency Rule for any reason, including under SAPA, that reliance is misplaced and not properly before this Court.

Further, no reliable evidence exists to link these cases to nicotine-containing vapor products. As explained in the affidavit of Dr. Michael Siegel, a physician and tobacco control advocate who has provided expert testimony against tobacco companies and was trained in epidemiology at the Centers for Disease Control, there is no reasonable evidence that nicotine-containing vapor products sold in retail stores are causing the observed cases of vaping-associated respiratory illness. (Siegel Aff., ¶¶ 2-3, 8.) Rather, all available evidence points to these cases of severe respiratory illness being associated with use of illegal THC-containing "vape carts"—especially those containing vitamin E acetate, a thickening agent used by drug traffickers. (*Id.*, ¶ 9.) The lack of any meaningful link between regulated nicotine-containing vapor products like those by the Petitioners here and the cases of severe respiratory illness is further underscored by the demographic data associated with the cases of illness, the characteristics of the illness itself, and public statements by the CDC and various state health departments—including, notably, the New York State Department of Health--confirming use of THC-containing vape carts by the overwhelming majority of patients suffering severe respiratory

illness symptoms. (*Id.*, ¶¶ 10-18.) This evidence leads Dr. Siegel to conclude that "[t]he Emergency Rule banning the sale of non-tobacco and non-menthol-flavored nicotine vapor products is not reasonably related to the outbreak of severe respiratory illness. . . [and] will not help prevent the outbreak of severe respiratory disease." (*Id.*, ¶ 19.) Indeed, Dr. Siegel concludes that the Emergency Rule, if allowed to take effect, will likely *harm* public health by causing many former or current adult smokers that use flavored vapor products to either return to cigarettes smoking or turn to black market flavored vapor products. (*Id.*, ¶¶ 20-24.)

Recent statements by the CDC and FDA about the outbreak of severe respiratory illness support Dr. Siegel's conclusions. In an update posted on its website on Friday, October 11, 2019, CDC confirmed that 76 percent of patients "report a history of using tetrahydrocannabinol (THC)-containing products. The latest national and state findings suggest products containing THC, particularly those obtained off the street or from other informal sources (e.g. friends, family members, illicit dealers), are linked to most of the cases and play a major role in the outbreak."[7] More importantly, the government agency that has been regulating nicotine-containing vapor products for the past three years—FDA—published its second consumer alert regarding the respiratory illness outbreak on October 4, 2019. Therein, FDA warned consumers not to use vaping products that contain THC, are obtained off the street or from other illicit or social sources, or which have been modified through the addition of THC or other oils since purchase through a retail establishment.[8] FDA has not made any similar warning with respect to

[7] Centers for Disease Control, Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html (updated Oct. 11, 2019 and last accessed Oct. 15, 2019).

[8] U.S. Food and Drug Administration, Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street, available at https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-

the nicotine-containing e-liquids sold by Petitioners or the VTA's members, including flavored e-liquids.

c. The long-standing issue of youth vaping does not justify immediate adoption of the Emergency Rule on an emergency basis.

Respondents raise one additional point that is effectively moot given Respondents' failure to comply with SAPA, but which Petitioners will address to further demonstrate that SAPA was violated. Respondents cite to *Board of Visitors—Marcy Psychiatric Ctr. v. Coughlin*, 60 N.Y.2d 14, 20, 466 N.Y.S.2d 668, 671-72 (1983), to counter Petitioners' argument that there is no emergency here because the youth vaping "crisis" has existed for several years. Contrary to Respondents' argument, *Board of Visitors* is factually and legally distinguishable from the present circumstances.

In *Board of Visitors*, the Commissioner of Correctional Services (the "CCS"), at the direction of the Governor, sought to convert unused existing state facilities, including psychiatric hospitals, into correctional facilities. 60 N.Y.2d at 16-17. The CCS identified one such facility, the Marcy Psychiatric Center ("Marcy"), as a suitable facility for conversion. *Id.* at 17. The Legislature appropriated funds necessary for the conversion, and then the CCS proceeded with the proper regulatory process, which required the filing of an environmental impact statement ("EIS"). *Id.* While ordinarily the CCS would be required to wait until review of the EIS, the relevant regulation contained an exception "for actions 'immediately necessary on a limited emergency basis for the protection or preservation of life, health, property or natural resources.'" *Id.* at 18 (quoting 6 NYCRR 617.2(o)(6)).

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vaping?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=landingpage&utm_campaign=CTP%20News%3A%20Vaping%20Update%20-%2010419 (last accessed Oct. 15, 2019).

In an Article 78 proceeding challenging the CCS's actions with respect to Marcy, the petitioners argued, and the trial court agreed, that "the project did not involve an emergency [under the regulation] because these efforts [to create more correctional facilities] indicate an ongoing process, not an emergency, and there is no immediate need to convert this particular facility to correctional uses." *Id.* The Appellate Division affirmed on this point, but the Court of Appeals reversed. *Id.* at 18-19. In disagreeing with the courts below, the Court of Appeals said that the correct standard of review is whether the CCS's determination that a limited emergency exists "was irrational or arbitrary or capricious." *Id.* at 20. The Court of Appeals rejected the petitioners' argument that because the problem—the need for additional correctional facilities—developed over time, no true emergency existed. *See id.* at 20. In so holding, the Court of Appeals focused on several facts and principles: (i) the CCS's actions were necessary to "lay the foundation for a program which may provide relief in the future;" (ii) that the prison system was "already filled to well over 100% capacity," "with an ever increasing influx of inmates;" and (iii) "[e]mergencies are often precipitated by the failure to take needed action in the past despite adequate warning." *Id.* The Court of Appeals relied heavily on the analogy of a dam bursting, noting that "no one would suggest that there was no emergency and that public officials would be required to file an environmental impact statement before they could divert a water source in the face of a bursting dam if the potential defect in the dam had long been a matter of common knowledge." *Id.*

Respondents latch on to *Board of Visitors* to justify the Emergency Rule despite the fact that teen vaping (as well as smoking of combustible cigarettes) has been a long-standing problem. But Respondents read *Board of Visitors* too broadly. First, that case involved a different statute mandating compliance, a different regulation for emergencies, and an entirely

different set of circumstances. In other words, *Board of Visitors* is not a SAPA case and does not provide guidance on the appropriateness of relying on SAPA's emergency exception to its normal rulemaking requirements.

Second, the emergency in *Board of Visitors* was objectively an emergency necessitating immediate action—prisons were already over capacity, with inmates continuing to enter the prison system, and the Legislature or traditional agency rulemaking process could not proceed quickly enough to resolve these issues. *See id.* at 17 ("The ultimate solution undoubtedly may well be for the State to construct additional correctional institutions. That, however, would require considerable time to implement and additional tax levies."); *see also id.* at 20 (noting current problem of prison overcrowding). Here, there is no similar, factually objective, emergency. Respondents' own data show that while teen vaping use has increased over the years, it has not done so at the same rate. In fact, while the rate of use increased by approximately 100% from 2014 to 2016, it only increased by approximately 33% from 2016 to 2018. *See* Emergency Rule at 18 (noting that "use by youth in high school has increased . . . from 10.5 percent in 2014, to 20.6 percent in 2016, to . . . 27.4 percent in 2018"). Thus, despite Respondents admonitions that there is a "dramatic rise" in teen use of vapor products, their own data show that the "rise" has slowed substantially in recent years, strongly undermining Respondents contention that the usual SAPA procedures had to be circumvented here due to an emergency.[9] In short, there is no "burst dam" that requires immediate, emergency action.

[9] Indeed, Respondents' claim that teen vapor product use continues to rise at an alarming rate contradicts Respondents equally fervent argument that sales of vapor products have likely decreased recently due to concerns over the risks of severe respiratory illnesses. *See* Resp. Memo. at 5 ("[T]he argument that the Emergency Rule is the sole cause of any loss of business ignores the fact that the recent spate of [vapor related illnesses] . . . have been well-documented throughout the local and national media."). There is no reason that this argument—advanced by

The data further show that the "emergency" is also a subjective construct of Respondents for an additional reason. Respondents attempt to suggest that, but for the existence of non-tobacco flavors, teens would not be using vapor products. But, again, Respondents' own data do not support this conclusion. According to Respondents' survey, only "27.3 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes," and only 19.3 percent of adolescent e-cigarette users [say] flavors were the primary reason for first use." Emergency Rule at 6. These data make clear that the presence of non-tobacco flavors influences the actions of only a small subset of teens who use vapor products. In other words, the Emergency Rule would be expected to have only a minimal impact on teen use of vapor products. (To say nothing of the fact that teens who base their vapor product use on flavoring will likely be able to obtain counterfeit flavored products after the Emergency Rule takes effect.)[10]

Third, the normal rulemaking processes avoided by reliance on an emergency need in *Board of Visitors* are entirely different than those avoided by Respondents here. In *Board of Visitors*, the CCS did not complete with the EIS review process prior to taking action. The EIS, while a statutorily required and significant protection for citizens of this State, only directly impacted the rights and interests of citizens in the immediate surrounding area of the Marcy project. In contrast, Respondents' declaration of an emergency—which was procedurally infirm,

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Respondents with regard to the licit use of flavored vapor products by adults—would not apply with equal force to illicit use of vapor products by teens.

[10] Respondents' own arguments support this likely result. Respondents spend much time arguing that adults will not cease using vapor products after the Emergency Rule is in effect because nicotine is an incredibly addictive product. *See* Resp. Mem. at 4 ("Petitioners simply ignore the highly addictive nature of their product . . . . Indeed, given the addictive nature of their products it is unreasonable to believe that" adult customers of vapor products would cease vaping after the Emergency Rule takes effect.) Respondents fail to acknowledge that the same argument applies with equal force to teens who use flavored vapor products.

as explained above—affected the rights of the hundreds of thousands of citizens of this state who use, sell, manufacture, or otherwise benefit financially or personally from flavored vapor products. These interested citizens lost their rights to meaningfully comment and review Respondents' proposed, and soon thereafter quickly enacted, Emergency Rule. The import of following SAPA, particularly here, where so many citizens of this State would be directly impacted by Respondents' actions, cannot be equated to the need for an EIS in *Board of Visitors*.

For these reasons, it is clear that Respondents' declaration of an emergency, and sidestepping of SAPA's requirements, was irrational, arbitrary, and capricious. Respondents own data and justifications supporting the Emergency Rule reveal that there was no rational basis for emergency action—particularly given Respondents' concession that the rise of vapor product use among teens is not actually rapidly increasing in recent years and that only a small subset of teens report that their primary reason for using vapor products is because of flavoring. Moreover, unlike the EIS review that did not occur in *Board of Visitors*, the need to follow SAPA was crucial and directly impacted a much larger contingent of citizens. In other words, Respondents' reliance on *Board of Visitors* not only does not support their contentions, it actually undermines them.

Although Respondents spend a great deal of effort explaining to this Court why an emergency exists, their belated and rewritten justifications for the Emergency cannot salvage Respondents' failure to strictly comply with SAPA's requirements. Enforcement of the Emergency Rule must be enjoined for lack of compliance with SAPA.

3. The Emergency Rule is Arbitrary and Capricious.

Respondents spend nearly three pages of their brief setting forth what they argue is the correct legal standard for reviewing the legality of an agency determination. *See* Resp. Mem. at 28-30. However, even after devoting several pages to repeating the exact same standard line

after line—a standard that is the same as the one relied upon by Petitioners and therefore is not in dispute—Respondents nevertheless *still get the standard wrong*. Both Petitioners and Respondents cite to law explaining that the standard for judicial review of an agency determination is whether that determination had a rational basis or whether it was arbitrary and capricious. *Compare* Pet'n Mem. at 27 ("An administrative regulation will be upheld only if it has a rational basis, and is not unreasonable, arbitrary or capricious." (internal quotation marks omitted)) *with* Resp. Mem. at 28 ("The standard for judicial review in an Article 78 proceeding is whether the challenged determination had a rational basis, or whether it was arbitrary and capricious."). Yet, at the end of the litany of repetitive citations to this same standard, Respondents, without any reference to authority, instead contend that "in reviewing the rationale underpinning the Emergency Rule, the Department [of Health] is entitled to considerable deference." Resp. Mem. at 30 (emphasis added). That simply is not the standard applicable to the decision to promulgate the Emergency Rule at issue here.

First, there is Respondents' proposed deference standard is not supported in circumstances like those presented here. Unlike the cases cited by Respondents, it is Respondents' creation of an entirely new "legislative" rule that is at issue, and not merely their interpretation or application of existing rules in an adjudicatory context. *Compare Matter of Riverkeep, Inc. v. Johnson*, 52 A.D.3d 1072, 1073-74, 861 N.Y.S.2d 155, 157-58 (3d Dep't 2008) (challenging method and basis for Department of Environmental Conservation's issuance of permit under existing rules and code); *Matter of Flacke v. Onondaga Landfill Sys.*, 69 N.Y.2d 355, 359, 514 N.Y.S.2d 689, 690 (1987) (question of whether Department of Environmental Conservation's inclusion of particular provision in landfill closure order was valid and supported); *Albano v. Kirby*, 36 N.Y.2d 526, 528. 369 N.Y.S.2d 655, 657 (1975) (reviewing the

discharge of government employee under agency's interpretation and application of rule stipulating a probationary period for permanent appointments). Second, Respondents' proposed standard runs contrary to other principles of judicial review of agency determinations, including that such determinations are "scrutinized for general reasonableness and rationality in the specific context," *N.Y. State Ass'n of Counties v. Axelrod*, 78 N.Y.2d 158, 166, 573 N.Y.S.2d 25, 29 (1991), and that the Court can only consider the reasons the agency 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. Cnty. 2005), *aff'd*, 43 A.D.3d 345, 84 N.Y.S.2d 79 (1st Dep't 2007). Thus, the Court should apply the correct standard—agreed to by the parties and supported by precedent—and not the "considerable deference" standard suggested by Respondents.

As to Respondents' substantive arguments that the Emergency Rule is not arbitrary or capricious, again Respondents fail to engage with Petitioners' substantive arguments. Instead, Respondents state—in an wholly conclusory manner—that because the Public Health and Health Planning Council and Department of Health "have undeniable expertise in the area of public health" and that the purported justifications to reduce teen use of vapor products is "undeniably" a "legitimate state interest[]," the rule has a rational basis. Resp. Mem. at 31. Respondents offer no further justification beyond these self-serving statements and thus fail to rebut Petitioners' arguments that the Emergency Rule is arbitrary and capricious.

Similarly, and as discussed *supra* in connection with SAPA, Respondents fall back on the factually unsupported arguments that the Emergency Rule is necessary "specifically to combat the rapid and ongoing increase in the use of" vapor products. *Id.* at 31. But, Respondents' own data simply do not show that "significant numbers [of teens] are initially attracted" to vapor

products "and/or continue to use [vapor products] primarily because of the flavored e-liquids banned by this Emergency Rule." *Id.* These data show the contrary—only a *small subset* of teens surveyed will likely be impacted by the Emergency Rule, as only that small subset reported that flavoring was the primary reason for using vapor products. Thus, Respondents' justification for the Emergency Rule simply is not grounded in Respondents' own evidence, and thus both lacks a rational basis in fact and is arbitrary and capricious. *See Pell v. Bd. of Educ.*, 34 N.Y.2d 222, 231, 356 N.Y.S.2d 833, 839 (1974) ("Arbitrary action is without sound basis in reason and is generally taken without regard to the facts.").

Perhaps most striking is Respondents' wholesale failure to even address Petitioners' arguments, set forth in their opening brief, that the Emergency Rule is arbitrary and capricious because (i) it fails to taken into account the impact the Emergency Rule will have on adults who will be disproportionately affected by a blanket ban, (ii) it permits the continued sale of menthol flavored vapor products that, according to Respondents' own data is the most popular flavor among teens after fruit flavor, and (iii) it does not ban the sale of combustible cigarettes or address the more substantial and well-documented deleterious effect they have on teens. Indeed, by failing to address these arguments in any form, Respondents have conceded these arguments and have waived their right to object to them in the future. *See Gordon v. ROL Realty Co.*, No. 157456/13, 2014 N.Y. Misc. LEXIS 3448, at *14 (Sup. Ct. N.Y. Cnty. July 28, 2014) ("Plaintiff has not responded to defendants' arguments based on untimeliness of this claim or the lack of specificity. The court assumes that plaintiff does not dispute the untimeliness of the claim . . . ."), *aff'd in part and modified in part by*, 150 A.D.3d 466, 55 N.Y.S.3d 165 (1st Dep't 2017); *Matter of Garrett v. NYC Dep't of Educ.*, No. 152165/2013, 2013 N.Y. Misc. LEXIS 3111, at *23 (Sup. Ct. N.Y. Cnty. July 12, 2013) ("[S]ince petitioner failed to address this allegation at the time it

occurred, she waived her right to contest it at the hearing."); *see also Warner v. Kain*, 162 A.D.3d 1384, 1385 n.2, 79 N.Y.S.3d 362, 364 n.2 (3d Dep't 2018) ("Plaintiffs abandoned any argument that defendants waived the sudden and abrupt stop defense by failing to address that issue in their brief on appeal."); *Moore v. Constantine*, 191 A.D.2d 769, 772, 594 N.Y.S.2d 395, 397 (3d Dep't 1993) ("Having failed to respond, petitioner has waived his right to object on this ground."). Petitioners are also likely to succeed on the merits of their claim that the Emergency Rule is arbitrary and capricious.

C. THE BALANCE OF EQUITIES WEIGHS IN FAVOR OF PETITIONERS.

The balance of equities and hardship also unequivocally favors Petitioners. Petitioners face substantial irreparable harm if Respondents are allowed to enforce the Emergency Rule—especially the destruction of their business operations without any recourse to monetary damages in the future. On the other hand, no harm will befall Respondents if an injunction is granted. Using the proper legislative process to achieve their goals, rather than unconstitutional policymaking, is not a harm that warrants denial of an injunction.

As noted above, the balance of equities tilts in favor of the party seeking to preserve the status quo. *See State v. City of N.Y.*, 275 A.D.2d at 741; *Sp.Q.R. Co.*, 57 A.D.3d at 643. Preservation of the status quo is exactly what Petitioners seek. Effectively continuing the injunction already entered by the Appellate Division will allow Petitioners to continue to lawfully operate their businesses. As detailed in the previously submitted affidavits and as actually occurred as a result of the flavor ban in Michigan, without a continued injunction, Petitioners face not only a substantial loss of sales or revenue, but the *complete* loss of their livelihoods through the collapse of their businesses. Indeed, the Emergency Rule has already caused some businesses to downsize or close.

Conversely, the only "harm" Respondents face is having to pursue their goals through the legislative process. The issues that supposedly necessitate the Emergency Rule have been and continue to be considered and debated by the Legislature. An injunction will also allow Respondents to evaluate the effectiveness of the Legislature's recent actions on the issue, including raising the minimum purchase age to 21 and increasing the cost of vapor products via the new 20% sales tax.

Additionally, an injunction is in the public interest. Prohibiting access to flavored vapor products will likely cause former smokers to return to smoking combustible cigarettes, a far more dangerous and unhealthy option. *See* Siegel Aff. at ¶ 24; Abboud Aff. at Exhibit 3 "VTA ANPRM Flavor Comments" at 38-39 ("A ban on flavored e-cigarettes alone would likely increase the choice of cigarettes in smokers, arguably the most harmful way of obtaining nicotine." *citing* Buckell, et al.) The health of former smokers will be significantly harmed as they return to combustible cigarettes or even black-market flavored vapor products. Siegel Aff. at ¶ 22. "Combustible tobacco products, primarily cigarettes, are the single greatest cause of cancer and kill about 7 million people worldwide each year. In the United States, 98% of all tobacco-related deaths are caused by cigarette smoking." *Id.* ¶ 24 (quoting American Cancer Society Position Statement on Electronic Cigarettes, February 2018). Indeed, even the American Cancer Society has acknowledged that the use of "e-cigarettes is preferable to continuing to smoke combustible products." *Id.*

Further, a ban on non-tobacco-flavored vapor products will likely lead to the establishment or growth of a black market for banned flavor vapor products. As discussed in Petitioners' original memorandum, online searches for "DIY e-liquid" return millions of results, including videos demonstrating how individuals can formulate their own flavor e-liquids. While

some individuals may make their own flavored e-liquids solely for personal use, others may, and likely will, use this knowledge to establish or expand the manufacture of black-market vapor products. Unlike legal vapor product businesses, the state cannot readily monitor or inspect these illicit manufacturers and one cannot readily determine or verify ingredients in black-market products. As the severe lung illnesses associated with illegal THC "vape carts" demonstrate, products manufactured and sold on the black market without regulatory oversight or safeguards can prove deadly. *See* Siegel Aff. at ¶¶ 9, 12-19.

Similarly, the demographic data associated with the cases of severe respiratory illness suggest that youth are more likely to access products on a black market. *See* Siegel Aff. at ¶ 11. Here, Deputy Commissioner Hutton's affidavit demonstrates that the vast majority of youth users of vapor products already do not obtain the products from traditional sources like brick-and-mortar or online retailers. *See* Hutton Aff. at ¶ 35. This strongly suggests that youth will be willing and able to purchase flavored vapor products via black-market channels, and, unlike legal vapor product businesses, the state cannot quickly and easily sanction or shut down illicit suppliers for selling products to underage individuals. Instead, the State will be forced to attempt to identify and then apprehend these bad actors; however, by the time that is accomplished, potentially contaminated or even deadly black-market products may already be in the hands of youth users.

For these reasons, and those set forth in Petitioners' original memorandum in support of the injunction and petition, the balance of equities favors immediately enjoining the Emergency Rule.

CONCLUSION

For the foregoing reasons, the Court should grant Petitioners' motion for a preliminary injunction and enter an order preliminarily enjoining and preventing Respondents from enforcing the Emergency Rule pending a final determination on the Verified Petition.

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