SUPREME COURT STATE OF NEW YORK
COUNTY OF ALBANY

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In the Matter of the Application 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 the New York State Department of Health, THE PUBLIC HEALTH AND HEALTH PLANNING COUNCIL, and NEW YORK STATE POLICE,
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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DECISION, ORDER & JUDGMENT
Index No.: 906514-19

APPEARANCES:

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Cholakis, AJSC

This litigation is a combined CPLR Article 78 proceeding and declaratory judgment action. Petitioners seek, *inter alia*, to enjoin the enforcement of an emergency regulation adopted by respondent Public Health and Health Planning Council (the Council) at the request and with

the approval of the Commissioner of the Department of Health, respondent Zucker (the Commissioner) pursuant to Public Health Law § 225(1) and (4). Before the Court at present is a motion by petitioners for a preliminary injunction against enforcement of the emergency regulation.

Background

The emergency regulation at issue, 10 NYCRR § 9-3, prohibits the manufacture, possession and sale of certain flavored "electronic liquids" in New York. "Electronic liquids" or "e-liquids" are liquids that are designed to be heated and converted to ærosol form in "electronic cigarettes" or "e-cigarettes." These handheld devices allow a user to inhale or "vape" the ærosol product.

While "vaping" products have only been readily available in the United States for a little more than a decade, the frequency of their use has increased almost exponentially in recent years. E-liquids containing nicotine, for example, are vaped in lieu of smoking traditional cigarettes. This practice has become popular in part because there is evidence to suggest there are fewer health risks associated with vaping than with smoking. In addition, many believe that the transition from traditional cigarettes to vaping can assist smokers in breaking their dependence on nicotine.

Not all e-liquids contain nicotine, of course, and many other compounds, such as THC, the active ingredient in marijuana, can be added to the glycol base. In addition, a seemingly limitless number of flavoring agents are available for incorporation into e-liquids. Fruit flavors, candy flavors and artificial "designer" flavors of e-liquids can be purchased. E-liquids are also available with tobacco flavoring and menthol flavoring, as are e-liquids with no flavoring additives at all.

New York has seen a proliferation of manufacturers, distributors and retail sellers of e-liquids and other vaping products. Petitioners allege – and respondents, at this stage of the litigation, do not deny – that the vaping industry in New York has generated over a billion dollars in gross income in the past year. Unfortunately, however, despite the law prohibiting the sale of vaping products to individuals less than 21 years of age (prior to November 13, 2019, 18 years of

age), an alarming number of underage youngsters in New York are vaping. Of grave concern is the fear that this practice will reverse the hard-won recent trend toward reduced nicotine addiction among our youth. It is widely believed that the vast array of fruit- and candy-flavored e-liquids are at the root of the attraction of vaping to the young.

Recently, there have been a significant number of individuals hospitalized nationwide (and several dozen who have died) due to pulmonary illnesses attributed to vaping. The precise etiology of these illnesses has not been determined. There is some evidence tending to suggest that commercially available e-liquids are not the source of the noxious ingredient or ingredients responsible for these illnesses. The Center for Disease Control has found a potential connection between vitamin E acetate, a compound added to orally ingestible marijuana, and vaping-related lung disease. (Vitamin E acetate is not an ingredient in commercially available e-liquids, according to petitioners.) The investigation is ongoing, and there are certainly sound reasons for a government response to this evolving situation.

On September 15, 2019, respondent Governor Andrew Cuomo announced that he was initiating executive action to ban the sale of flavored e-cigarettes and related products in New York (https://www.governor.ny.gov/news/governor-cuomo-announces-emergency-executive-action-ban-sale-flavored-e-cigarettes). The following day, the Commissioner and the Council announced their intent to promulgate emergency regulations to implement the ban. What followed was a single day of public comment and the immediate issuance of the emergency regulation at the heart of this litigation.

Of particular significance in the emergency regulation is that the ban applies to flavored e-liquids regardless of "whether the liquid contains nicotine or not" (10 NYCRR § 9-2.1[b]). Additionally, the ban does *not* apply to e-liquids that are tobacco flavored, menthol flavored, or flavorless (§ 9-3.1[b]). It is also worth noting that, in its Regulatory Impact Statement, the Council wrote, "The alternative to the proposed regulation is to wait for the FDA to regulate in this area . . . ," without any mention of legislation as an alternative to the proposed regulation.

Shortly after the adoption of the emergency regulation, petitioners commenced the present litigation. Petitioner Vapor Technology Association (VTA) is a trade association comprised of some 800 member businesses in the vaping industry. Petitioner Benevolent

Eliquids, Inc. (Benevolent) is a VTA member and a New York corporation engaged in the manufacture and distribution of e-liquids. Petitioner Perfection Vapes, Inc. (Perfection) is a New York corporation engaged in the retail sale of e-liquids.

By Order to Show Cause dated September 27, 2019 (Connolly, AJSC), Supreme Court initially denied petitioner's application for a temporary restraining order (TRO). A TRO was later granted upon review by the Appellate Division, Third Judicial Department by Decision and Order dated October 3, 2019. This TRO remains in effect pending the determination of the present motion.

Discussion

As respondents' counsel correctly points out, the burden on a party seeking a preliminary injunction is a high one. Such relief is issued sparingly, (*Kuttner v Cuomo*, 147 AD2d 215, 218 [3d Dept 1989]), and only upon clear and convincing evidence in the record (*County of Suffolk v Givens*, 106 AD3d 943, 944 [2d Dept 2013], citing *Apa Security, Inc. v Apa,* 37 AD3d 502, 503 [2d Dept 2007]).[1] The three-part test applicable to motions for preliminary injunctions is a familiar one: first, will the moving party likely suffer irreparable harm if the preliminary injunction is not granted? Second, is there a likelihood of success on the merits of the petition? And finally, does a balancing of the equities favor the moving party? (*see Doe v Axelrod*, 73 NY2d 748, 748 [1988], citing *Grant Co. v Srogi*, 52 NY2d 596, 617 [1981]).

Petitioners assert that the regulation at issue, if enforced, would render it impossible for their businesses to continue operation in New York. In support of this contention, petitioners have submitted affidavits of a number of vaping business owners which indicate that about 90% of the e-liquids they currently sell fall within the definition of the banned flavored products. By way of one example, the owner of one of VTA's member companies states, "Of the e-liquid products that we have distributed to vape shops in the state of New York since January 1, 2018,

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[1] The clear and convincing standard has neither been expressly adopted nor repudiated by either the Court of Appeals or the Appellate Division, Third Department. This Court is therefore bound by the holding of these Second Department cases (*see Mountain View Coach Lines, Inc. v Storms*, 102 AD2d 663, 664 [2d Dept 1984], cited with approval in *People v Turner*, 5 NY3d 476, 482 [2005]).

some 90 percent are products that would qualify as 'flavored e-liquid' under Section 9-3.1 of the emergency flavor ban regulation. Of the remainder, 3 percent are menthol-flavored e-liquid products and 7 percent are tobacco-flavored e-liquid products" (Affidavit of Jonathan Glauser at para 7).

Respondents do not dispute the factual assertion that 90% of the e-liquids currently sold by petitioners fall within the definition of those products banned by the emergency regulation. Instead, respondents assume that the unavailability of the banned flavored e-liquids will simply cause a commensurate increase in the demand for those e-liquids not subject to the ban. They contend that

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

(Memorandum of Law in Opposition at p 4). Yet here respondents are the ones engaging in speculation. There is no evidence in the record to support the inference that once flavored e-liquids are banned, the consumers of vaping products will simply switch to tobacco, menthol, or flavorless e-liquids. In fact, if this argument were valid, the ban would not have any impact on the number of cases of New Yorkers succumbing to pulmonary disease from vaping, since the net amount of e-liquids consumed would not have decreased.

Moreover, respondents' argument is expressly premised on "the highly addictive nature of [petitioners'] product." This ignores the fact that the emergency regulation bans flavored e-

liquids whether or not they contain nicotine (10 NYCRR § 9-2.1[b]). There is no evidence in the record to suggest that flavored e-liquids that do not contain nicotine are in any way addictive. It is therefore purely speculative to conclude that consumers who currently prefer flavored e-liquids that do not contain nicotine would simply convert to the consumption of those few types of e-liquids not banned by the emergency regulation, particularly where the only flavors remaining (tobacco and menthol) are reminiscent of nicotine-containing combustible cigarettes.

Even the Regulatory Impact Statement concedes, "The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products." The very goal of the emergency regulation is to reduce the attraction of vaping to younger consumers. If that goal is to be met, a necessary result would be the decline in the total amount of e-liquid sold. As 90% of the flavored e-liquids currently sold would be removed from the New York market by the emergency regulation, the ineluctable conclusion is that petitioners would, in fact, suffer irreparable harm if the ban were to be enforced.

The second question to be considered is the likelihood of petitioners' success on the merits of the litigation. The central issue on this motion is whether the Council, an administrative agency, overstepped the bounds of its lawfully delegated authority in enacting the emergency regulation. The determination of this issue requires an analysis of both constitutional and statutory standards.

We begin by recognizing, "The concept of separation of powers is the bedrock of the system of government adopted by this State in establishing three coordinate and coequal branches of government, each charged with performing particular functions" (*Matter of NYC C.L.A.S.H., Inc, v New York State Office of Parks, Recreation & Historic Preservation,* 27 NY3d 174, 178 [2016], quoting *Matter of Soares v Carter*, 25 NY3d 1011, 1013 [2015]). The "constitutional principle of separation of powers . . . requires that the legislature make the critical policy decisions, while the executive branch's responsibility is to implement those policies" (*Greater New York Taxi Ass'n v NYC Taxi and Limousine Comm'n*, 25 NY3d 600, 609 [2015]). In the present case, the Council overstepped its authority in adopting the emergency regulation, as the regulation creates out of whole cloth the very policy it seeks to implement.

The core element of the emergency regulation appears, on its face, quite simple: "It 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." Yet "flavored e-liquid" is defined in the emergency regulation as "any e-liquid with a distinguishable taste or aroma, *other than the taste or aroma of tobacco or menthol*" (10 NYCRR § 9-3.1[b] [*emphasis added*]). In other words, tobacco-flavored e-liquid is not a "flavored e-liquid," nor is menthol-flavored e-liquid a "flavored e-liquid" as the term is defined in the emergency regulation. Thus, the Council here has not simply acted to ban flavored e-liquids, it has also chosen to create a "carve-out" for tobacco- and menthol-flavored e-liquids.

One of the natural questions that arise at this juncture is whether tobacco- and menthol-flavored e-liquids have somehow been eliminated from the list of substances shown to cause the spate of pulmonary diseases that prompted the adoption of the emergency regulation. Yet the record developed on this motion shows no evidence to support such a conclusion. Rather, there appears to be a policy decision implicit in this carve-out: that the risks of contracting pulmonary disease by vaping tobacco- or menthol-flavored e-liquids are outweighed by some other, unstated factor. This implies that the Council has encroached on the legislative prerogative of policy-making.

Nor is the "carve-out" for menthol-flavored e-liquids rationally related to the goal of discouraging youth from becoming involved with vaping. Respondents' own survey results show that nearly one-fifth of the young persons who vape prefer menthol-flavored e-liquids (Regulatory Impact Statement at p 6). This apparent paradox can only be resolved by inferring, again, the existence of an underlying policy reason for the carve-out for menthol-flavored e-liquids.

It is settled law that the enabling statute here, Public Health Law § 225, is a valid delegation of regulatory authority (*Matter of Boreali v Axelrod*, 71 NY2d 1, 14 [1987]). Equally settled, however, is the principle that this law "cannot be construed to encompass the policy-making activity at issue here without running afoul of the constitutional separation of powers doctrine" (*Id.*). The Council's decision to exempt tobacco- and menthol-flavored e-liquids from the strictures of the emergency regulation evinces an intent to "construct[ ] a regulatory scheme .

. . based solely upon economic and social concerns" by "weigh[ing] the goal of promoting health against its social cost and . . . reach[ing] a suitable compromise" (*Id.* at 12).

Equally indicative of a violation of the separation of powers doctrine is that the Council "did not merely fill in the details of broad legislation describing the over-all policies to be implemented" but instead "wrote on a clean slate, creating its own comprehensive set of rules without benefit of legislative guidance" (*Id.* at 13). The emergency regulation is less an effort at filling in the blanks left by broad legislation and more an attempt to set a State policy strictly limiting the availability of vaping products in New York. This is action reserved constitutionally to the Legislature and not to the executive branch (nor, for that matter, to the judiciary).

The parallels between the present case and *Matter of New York Statewide Coalition of Hispanic Chambers of Commerce v New York City Department of Health and Mental Hygiene,* (23 NY3d 681 [2014]), are striking. In *Matter of Statewide Coalition*, the New York City Board of Health, in an effort to stem childhood obesity, adopted a regulation prohibiting the sale of sugary drinks in containers larger than 16 ounces. The Court of Appeals held that the Board of Health, an administrative body, had encroached on the legislative powers reserved exclusively to the New York City Council by the city charter. The Court stated, "By choosing between public policy ends . . . the Board of Health engaged in law-making beyond its regulatory authority" (23 NY3d at 699). Likewise, in the present case, the Council appears to have exceeded the scope of its authority by having adopted an emergency regulation that embodies the policy-based trade-off between the competing ends of limiting the attraction of vaping products to minors and allowing former or current combustible cigarette smokers the option to continue to consume tobacco- and menthol-flavored eliquids.

Some latitude may be accorded an administrative agency in areas where scientific or other specialized knowledge is required for action (*see e.g. Chiropractic Assn of NY v Hilleboe,* 12 NY2d 109 [1962]). A regulation requiring that the operators of X-ray equipment be licensed professionals, for example, may be adopted without the need for specific legislative authorization (*Id.*). Here, however, the record is devoid of any specialized expertise having been necessary in the crafting of the emergency regulation. The carve-outs discussed earlier were not incorporated into the emergency regulation because scientists or medical professionals had determined that

tobacco- and menthol-flavored e-liquids were not harmful. Rather, the emergency regulation is a statement of public policy and not the product of biomedical research. Accordingly, the deference for administrative action in highly technical areas is not available to respondents here.

In addition to the separation of powers issue, petitioners raise the question of whether the Council's resort to emergency regulation in this case ran afoul of the State Administrative Procedure Act. There is no dispute that the Council did not follow the notice and public comment periods applicable to regulatory action in general, but instead utilized the truncated procedures of emergency rulemaking. Here, whether petitioners are likely to succeed on the merits of their petition is not nearly as clear as with the separation of powers issue. The spate of illnesses and deaths attributable to pulmonary disease brought on by vaping has only recently come into public consciousness, though vaping has existed in its current form for more than a decade. And the significant rise in teenage use of vaping materials has only recently reached the point where, according to respondent's evidence, one in four high school students has engaged in the activity. Accordingly, it is not nearly so clear at this stage of the proceeding that the Council acted arbitrarily and capriciously when it opted to follow emergency procedures in lieu of those ordinarily employed in adopting regulations (*Cf. Board of Visitors of Marcy Psychiatric Ctr v Coughlin*, 60 NY2d 14, 20 [1983]).

Finally, in determining whether to grant a preliminary injunction, the Court must balance the equities on both sides of the controversy. Denying the preliminary injunction would likely result in the shuttering of petitioners' businesses in New York. It could also, as petitioners contend, result in a number of smokers' returning to the use of much more harmful combustible cigarettes. On the other hand, granting the preliminary injunction would maintain the status quo pending the ultimate determination of this controversy. This could potentially expose members of the public to the risk of contracting the pulmonary illnesses attributed to vaping.

Maintaining the status quo, however, would not in any way prevent or even hinder the Legislature from taking further action. As noted earlier, only a few days ago the minimum age of persons to whom vaping products may legally be sold increased in New York from 18 to 21. The Legislature could opt to await the passage of some period of time to gauge whether this legislation is sufficient in itself to stem the increase in vaping among teenagers. As more

information becomes available regarding the causes of vaping-related pulmonary disease, informed decisions can be made regarding the ultimate question of whether some or all vaping products should be banned.[2] This Court's determination of the present motion would have no direct impact upon such an exercise of legislative prerogative.

In all, then, the balancing of the equities tips in favor of petitioners. A preliminary injunction would stave off the shuttering of their businesses. Meanwhile, the granting of the preliminary injunction would not hamper government action through constitutionally appropriate legislative channels.

Of course, nothing in this Decision, Order and Judgment should be read as in any way trivializing the concern that the availability of flavored e-liquids may well be contributing to the spread of nicotine addiction among our youth. Rather, this Court's holding on the present motion is limited to the recognition that there is a likelihood that petitioners will ultimately succeed in proving that the emergency regulation is an impermissible administrative transgression into territory that is reserved to our Legislature by the State Constitution. For this reason, as well as the other considerations discussed above, the Court is constrained to grant the present motion and issue a preliminary injunction.

For the reasons stated above, it is

ORDERED and ADJUDGED that petitioners' motion for preliminary injunction is granted; and it is further

ORDERED and ADJUDGED that respondents are in all respects enjoined from enforcement of the Emergency Regulation discussed *supra* pending further Order of this Court.

This shall constitute the Decision, Order and Judgment of the Court. Counsel for petitioners are directed to serve a copy of this order with notice of entry upon respondents'

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[2] The record developed thus far seems to suggest that the vast majority of individuals suffering from vaping-related pulmonary illness had vaped THC-laced e-liquids that contained vitamin E acetate. This substance, not found in commercially available e-liquids, is harmless when swallowed but toxic when drawn into the lungs.

counsel within five (5) days after this Decision, Order and Judgment is uploaded on NYSCEF. Petitioners are not relieved from the applicable provisions of 22 NYCRR § 202.55-bb relating to filing, entry, and notice of entry.

SO ORDERED and ADJUDGED.
ENTER.

Dated: January 8, 2020
Albany, New York

C Cholakis

Catherine Cholakis
Acting Supreme Court Justice

Papers Considered:

Order to Show Cause (Connolly, AJSC) dated September 27, 2019; Supporting Affirmation of Emergency of Richard A. De Palma, Esq. dated September 24, 2019;

Notice of Petition dated September 24, 2019; Verified Petition dated September 24, 2019; Affirmation in Support of Richard A. De Palma, Esq. dated September 24, 2019; Annexed Exhibits A-I; Affidavit in Support of Anthony L. Abboud dated September 23, 2019; Annexed Exhibits 1-3; Affidavit in Support of John Dunham dated September 23, 2019; Affidavit in Support of M. Jonathan Glauser dated September 23, 2019; Affidavit in Support of Victor Canastraro dated September 23, 2019;

Memorandum of Law in Support of Petition and Motion for Injunctive Relief dated September 24, 2019;

Affidavit of Michelle Troyer (electronically filed as Appendix 1) dated September 30, 2019;

Affidavit of Jeffrey Barry (electronically filed as Appendix 2) dated September 30, 2019;

Affidavit of Michael Bowers (electronically filed as Appendix 3) dated September 30, 2019;

Supplemental Affidavit of M. Jonathan Glauser (electronically filed as Appendix 4) dated September 30, 2019;

Press Release dated May 11, 2015 (electronically filed as Appendix 5);

Affirmation of Justin L. Engel, Esq. dated October 20, 2015 (electronically filed as Appendix 6);

Memorandum of Law in Opposition to Motion for Preliminary Injunction dated October 10, 2019;

Affidavit of Brad Hutton dated October 10, 2019; Annexed Exhibit A; Footnoted Sources (provided independently of NYSCEF);

Reply Affirmation of Richard A. De Palma, Esq. in further Support of Application for Preliminary Injunction dated October 16, 2019; Annexed Exhibits A and B;

Affidavit of Michael Siegel, M.D. dated October 15, 2019; Annexed Exhibit A;

Second Supplemental Affidavit of M. Jonathan Glauser dated October 16, 2019;

Reply Memorandum of Law in Support of Motion for Preliminary Injunction dated October 16 2019;