

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF ALBANY

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In the Matter of

VAPOR TECHNOLOGY ASSOCIATION, et al.,

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 Department of Health, THE PUBLIC  
HEALTH AND HEALTH PLANNING COUNCIL, and  
NEW YORK STATE POLICE,

Index No. 906514-19

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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**AFFIDAVIT OF DR. MICHAEL SIEGEL**

Michael Siegel, M.D., being duly sworn, hereby deposes and states under penalty of perjury as follows:

1. I am over the age of 18 years and have personal knowledge of the facts and opinions set forth below such that I would be competent to testify as to the same if called.
2. I am a physician and a professor in the Department of Community Health Sciences at the Boston University School of Public Health. For the past 32 years, I have been a tobacco control researcher and anti-tobacco advocate.

3. I have testified in eight (8) different lawsuits against the tobacco industry. I consider myself to be a long-time, committed anti-tobacco researcher and advocate. I have conducted considerable research into tobacco and e-cigarette (including vaping) products.

4. I summarize my educational background as follows:

- a. University of California at Berkeley/UCSF  
General Preventive Medicine Residency Program  
August, 1991 to June, 1993  
M.P.H. completed: May, 1992 (Epidemiology)
- b. Berkshire Medical Center, Pittsfield, MA  
PGY-1 Year in Internal Medicine  
July, 1990 to June, 1991
- c. Yale University School of Medicine  
M.D. completed: May, 1990
- d. Brown University  
B.A., Environmental Studies: May, 1986

5. Affixed hereto as Exhibit 1 is a true and accurate copy of my current curriculum vitae.

6. I am familiar with the New York “flavor ban” Emergency Rule that was adopted and took effect on September 17, 2019, as 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.” I have also had an opportunity to review the affidavit of Brad Hutton, the Deputy Commissioner of the New York State Department of Health that was filed on October 10, 2019, in support of enforcement of the Emergency Rule.

7. I have not received any form of compensation for offering the opinions set forth in this declaration, or my time spent in preparing it. In fact, I have received no compensation from any party to this action or, to my knowledge, from any member of the vapor products or tobacco

industries. I offer these opinions not as a paid advocate, but as a medical and public health professional.

8. Based on all of the data publicly available to date, it is my opinion that there is no reasonable evidence that nicotine-containing vapor products sold in retail stores are causing the observed cases of vaping-associated respiratory illness.

9. Rather, the primary suspected cause of this outbreak of severe, acute respiratory failure which often takes the form of lipoid pneumonia or chemical pneumonitis, is the widespread black market sale of illicit marijuana vape cartridges (or “vape carts”), many of which contain a viscous oil that is used as a thickening agent to help drug dealers obtain a higher price for the THC vape carts they are selling. There were recently two major drug busts<sup>1</sup> which recovered thousands of oil-laden THC vape carts, and testing of THC vape carts provided by numerous case patients in New York State revealed that all of them contained high levels of vitamin E acetate oil, the thickening agent that has recently come into widespread use by illicit drug manufacturers (as well as some legal manufacturers).<sup>2</sup>

10. The application of basic epidemiology principles should tell us that there is no link between nicotine-containing vapor products and the reported cases of severe respiratory illness. Since most nicotine-containing vapor products sold at retail stores have been on the market for at least several years, it does not make sense that we would suddenly see these products causing severe respiratory failure. Moreover, since there are millions of adult nicotine-containing vapor

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<sup>1</sup> Michael Siegel, *Arizona Detectives Bust Illegal THC Vape Cart Operation and Butane Hash Oil Lab*, The Rest of the Story (Oct. 1, 2019, 12:30 PM), <http://tobaccoanalysis.blogspot.com/2019/09/arizona-detectives-bust-illegal-thc.html>.

<sup>2</sup> Sophie Peel, *Leading Oregon Cannabis Extractor Pulls Line of Vape Products off Its Website as Health Questions Swirl*, Willamette Week (Sept. 9, 2019), <https://www.wweek.com/news/state/2019/09/09/leading-oregon-cannabis-extractor-pulls-line-of-vape-products-off-its-website-as-health-questions-swirl/>.

product users, we would be seeing a lot more adult cases of this disease if it were being caused by nicotine-containing vapor products.

11. Based on the demographic data on the confirmed severe respiratory illness cases, the illness is predominantly affecting youth and primarily males. Nicotine-containing vapor products sold by retail stores could not explain this pattern of occurrence. In contrast, the use of black market THC products could. Since adults can legally access cannabis vaping products in states with legalized recreational or medical cannabis, it is primarily going to be youth who use the black market THC oils that are being distributed by drug dealers.

12. The strongest evidence that the primary culprit is black market THC oils is the fact that the most common presentation of the illness is a lipoid pneumonia. This is a disease that is known to be caused by oil inhalation. Virtually all, if not all, nicotine-containing vapor products sold in stores are made with water/alcohol-based e-liquids, which do not cause lipoid pneumonia. In contrast, the THC vape carts that are in wide circulation are loaded with a viscous oil. When this oil is heated and then cools when it reaches the lungs, it solidifies and basically cakes the alveoli and also induces severe inflammation (as the body's immune cells try to get rid of the oil). This explains the typical radiographic appearance in the cases, which is actually part of the case definition.

13. In an emergency *MMWR* publication<sup>3</sup> of September 29, 2019, the CDC reported that of cases in which there was information on the products used, 84% of patients admitted to vaping THC. The CDC also emphasized that there are multiple reasons why many patients might

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<sup>3</sup> Cria G. Perrine et al., *Characteristics of a Multistate Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping—United States, 2019*, CDC, Morbidity & Mortality Weekly Report, (Sept. 27, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e1.htm>.

not report using THC even if they did: *"patients might not always know what substances they use or might be hesitant to reveal use of substances that are not legal in their state."*

14. In a separate article<sup>4</sup> covering patients from Illinois and Wisconsin, the CDC revealed that: *"Use of tetrahydrocannabinol (THC)-containing e-cigarette products, the majority of which were prefilled cartridges obtained from informal sources, was reported by 87% of patients during the 3 months preceding illness."* Importantly, CDC stated that: *"the predominant use of prefilled THC-containing cartridges among patients with lung injury associated with e-cigarette use suggests that they play an important role."* The CDC also reported that: *"In Wisconsin, eight patients initially denied using THC-containing products in interviews, but five (63%) were later found to have used THC through review of medical charts, reinterview, or cross-referencing with friends who were also interviewed as patients."* Finally, the CDC finally provided very specific information about the black market THC vape carts that were used: *"Although no single brand name was reported by all patients, a prefilled THC cartridge sold under the brand name Dank Vapes was reported by 57 (66%) patients. In Wisconsin, two groups of friends (two patients in one group and three in the second group) who became ill after using THC-containing cartridges specifically reported sharing Dank Vapes cartridges. Dank Vapes was the only e-cigarette product reported by one of the patients."*

15. Former FDA Commissioner Dr. Scott Gottlieb recently wrote<sup>5</sup> that: "Reading transcripts, it seems there's too much conflating these tragic lung injuries with store bought brands

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<sup>4</sup> Isaac Ghinai et al., *E-Cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury—Illinois & Wisconsin, April–September 2019*, CDC, Morbidity & Mortality Weekly Report (Sept. 27, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e2.htm>.

<sup>5</sup> Scott Gottlieb (@ScottGottliebMD), Twitter (Sept. 26, 2019, 5:57 AM), <https://twitter.com/ScottGottliebMD/status/1177160230616084480>.

of regulated, legal e-cigs like Juul and NJOY; and far too little blaming THC, CBD, and bootleg nicotine vapes - where so far, the only available hard evidence points.”

16. The Massachusetts Department of Public Health reported<sup>6</sup> that of the 10 confirmed cases in the state, nine of patients admitted to vaping THC cartridges. It is extraordinary in an outbreak investigation to have 90% of cases report a common exposure. This strongly suggests that contaminated THC vape cartridges are the cause of the outbreak. Banning the sale of flavored nicotine-containing vapor products at retail stores will have absolutely no effect on curtailing this outbreak.

17. In the state of Utah, 94% of outbreak cases<sup>7</sup> for which products were identified involved the use of THC products. Of the THC products recovered, 89% tested positive for vitamin E acetate.

18. As confirmed in paragraph 46 of his Deputy Commissioner Hutton’s affidavit, the New York State Department of Health has reported that 85% of outbreak cases in that state were associated with patients who reported the use of THC vaping products.<sup>8</sup>

19. In my opinion, the outbreak of severe, acute respiratory disease should not be conflated with the problem of youth electronic cigarette use. The 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. Furthermore, the Emergency Rule will not help prevent

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<sup>6</sup> Massachusetts Department of Public Health, *Department of Public Health Reports Five Additional Vaping-Associated Pulmonary Injury Cases to US Centers for Disease Control and Prevention* (Sept. 30, 2019), available at <https://www.mass.gov/news/department-of-public-health-reports-five-additional-vaping-associated-pulmonary-injury-cases>.

<sup>7</sup> Utah Department of Health, *Vaping-related Lung Injury, Utah, 2019: Investigation to Date Updated September 30, 2019* (Sept. 30, 2019), available at <https://health.utah.gov/wp-content/uploads/Vaping-Report-for-Public-9-30-Final.pdf>

<sup>8</sup> Affidavit of Deputy Commissioner Brad Hutton, Office of Public Health, ¶ 46.

the outbreak of severe respiratory disease because the overwhelming majority of the cases are due to the use of black market THC products purchased from illicit drug suppliers.

20. Based upon my approximate 32 years of experience, education, research and knowledge of the subject matter relative to underage and adult use of tobacco and nicotine products, it is my expert opinion that the Emergency Rule does not constitute a decision in the interest of public health. Stated differently, the net result of the Emergency Rule will be to harm the public health and the citizens of New York State.

21. The ban on non-tobacco- and non-menthol-flavored nicotine vapor products will cause significant harm to former smokers who currently rely upon these products to remain off cigarettes. An estimated 2.5 million former adult smokers in the United States rely upon e-cigarettes to keep themselves off highly addictive and deadly tobacco burning cigarettes and the overwhelming majority of them rely on non-tobacco flavored e-liquids. The *New England Journal of Medicine* recently published a study finding that e-cigarettes are twice as effective as nicotine patches in helping smokers quit completely.<sup>9</sup> It cannot be overstated that these non-combustible e-cigarette products are literal life-savers for millions of former smokers.

22. In the absence of flavored vapor products, I expect that many former or current adult smokers that also use flavored vapor products will not necessarily switch to tobacco flavored e-liquids, but will instead either return to cigarette smoking or to black market flavored vapor products. The health of ex-smokers who return to cigarette smoking will be severely harmed, and they will be subject to an increased risk of smoking-related disease and death. The health of ex-smokers who turn to the black market for flavored vapor products will be put at great risk because

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<sup>9</sup> Hajek P, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine* 2019; 380:629-637, available at <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>

there is no way to control or regulate black market products and consumers will have no way to know what ingredients are in these products.

23. New York's ban on flavored nicotine vapor products will not help to prevent the outbreak of severe respiratory disease because the overwhelming majority of the cases are due to the use of black market THC products purchased from illicit drug suppliers.

24. The truth of the matter is that, if allowed to be enforced, the Emergency Rule will eliminate the sale of all but tobacco-flavored e-cigarettes in New York State but will allow for the sale of combustible cigarettes to continue unabated. This will result in many former smokers going back to smoking combustible cigarettes – which are undoubtedly far more dangerous than e-cigarettes.<sup>10</sup> According to the American Cancer Society's February 2018 position statement, "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." The statement goes on to observe that, "[b]ased on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes..." Accordingly, the American Cancer Society concludes that, although it is preferable for smokers to quit "cold turkey," those who will not stop smoking cigarettes "should be encouraged to switch to the least harmful form of tobacco product possible," i.e., e-cigarettes or other non-combustible products, because "switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products."

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<sup>10</sup> American Cancer Society Position Statement on Electronic Cigarettes, February, 2018.  
<https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>



Signed under the pains and penalties of perjury this 15th day of October, 2019

Michael Siegel, M.D.

COMMONWEALTH OF MASSACHUSETTS )

COUNTY OF NORFOLK )

Subscribed and sworn to before me this 15<sup>th</sup> day of October, 2019.

Notary Public



JASON HARDIN  
Notary Public  
Commonwealth of Massachusetts  
My Commission Expires Jan. 25, 2024