

Medical Campus
801 Massachusetts Avenue, 4th Floor, Suite 431
Boston, Massachusetts 02118-2605
T 617-638-5160 F 617-638-4483
<http://sph.bu.edu/chs>

October 17, 2019

The Honorable Anna G. Eshoo
Chairwoman, Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Congresswoman Eshoo:

Thank you for the opportunity to testify before your subcommittee on October 16th regarding “Legislation to Reverse the Youth Tobacco Epidemic.” During the hearing, you asked if I could provide documentary support for my statement that the vaping of THC vape cartridges and other off-the-street products have been found to be involved in the respiratory disease outbreak that was discussed at the hearing. The purpose of this letter is to provide that documentation.

The conclusion that the outbreak is related to the vaping of THC vape cartridges and other off-the-street products was reached by the U.S. Food and Drug Administration (FDA) and was communicated publicly in its statement of October 4.¹ This is not just my conclusion; it is the conclusion of the FDA, which is in the best position to evaluate this question because it has the ingredient lists that have been submitted for all legal e-liquids sold by retail stores.

In that statement, the FDA concluded that: *“A majority of the samples tested by the states or by the FDA related to this investigation have been identified as vaping products containing THC. Through this investigation, we have also found most of the patients impacted by these illnesses reported using THC-containing products, suggesting THC vaping products play a role in the outbreak.”*

The FDA then made three recommendations to the public:

- *“Do not use vaping products that contain THC.”*
- *“Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources.”*
- *“Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments.”*

¹ 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. <https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping>.

While the FDA specifically warned the public not to vape THC or any other products obtained off the street, it did not make a recommendation that the public avoid nicotine-based electronic cigarettes sold at retail stores. Certainly, if the FDA believed there was any reasonable chance that this outbreak was related to nicotine-containing e-liquids sold at retail stores, it would have issued such a warning.

The key information that I believe the Committee needs to understand is that 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 busts² 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 every patient provided at least one THC cartridge that 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).³

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

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.

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

² 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>.

³ 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/>.

also induces severe inflammation (as the body's immune cells try to get rid of the oil). This is consistent with the typical radiographic appearance in the cases, which is actually part of the case definition.

In an emergency *MMWR* publication⁴ 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 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."*

In a separate article⁵ 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."*

Former FDA Commissioner Dr. Scott Gottlieb recently wrote⁶ that: *"Reading transcripts, it seems there's too much conflating these tragic lung injuries with store bought brands 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."*

The Massachusetts Department of Public Health reported⁷ that of the 10 confirmed cases in the state, nine of patients admitted to vaping THC cartridges. It is extraordinary in an outbreak

⁴ 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>.

⁵ 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>.

⁶ Scott Gottlieb (@ScottGottliebMD), Twitter (Sept. 26, 2019, 5:57 AM), <https://twitter.com/ScottGottliebMD/status/1177160230616084480>.

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.

In the state of Utah, which conducted the most thorough investigation of its case patients, 94% of outbreak cases⁸ for which products were identified involved the use of THC products. Of the THC products recovered, 89% tested positive for vitamin E acetate.

On the day of the hearing itself, in Texas, it was reported that 93% of case patients who were interviewed admitted to using THC vaping products.⁹

Also on the day of the hearing, in Minnesota, it was reported that: "Of those patients who have been interviewed, nearly all reported vaping illegal THC products."¹⁰

In an outbreak investigation like this one, percentages as high as these cannot be ignored. These numbers are particularly striking in light of the fact that youth are understandably reluctant to publicly admit to THC use, given the potential disciplinary consequences. Moreover, some patients may not even know what is in the cartridges that they are vaping. Furthermore, there are many counterfeit products on the market. Patients may actually think they are vaping nicotine, but the product may be contaminated.

In summary, I agree with the FDA that the most likely explanation for this outbreak is contaminated black market cartridges of THC or counterfeit nicotine e-liquids that are contaminated, not legal nicotine e-liquids that are regulated by the FDA, whose ingredients have been submitted to the FDA, and which are sold at retail stores with packaging that allows the user to know exactly what ingredients are present.

Please understand that I agree with you that the youth vaping epidemic is a serious problem and Congress needs to urgently take action. Also, I believe that every other provision of H.R. 2339 is well-founded and will substantially contribute to reducing the prevalence of youth e-cigarette use

⁷ 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/departments-of-public-health-reports-five-additional-vaping-associated-pulmonary-injury-cases>.

⁸ 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>

⁹ Ackerman T. More local cases of vaping-related illness. *Houston Chronicle*, October 16, 2019. <https://www.houstonchronicle.com/news/health/article/More-local-cases-of-vaping-related-lung-illness-14540066.php>.

¹⁰ Bornhoft W. Vaping injuries kill 2 more Minnesotans. *Minneapolis Patch*, October 16, 2019. <https://patch.com/minnesota/southwestminneapolis/2-more-minnesotans-die-vaping-injuries>.

without having profound negative health consequences for millions of adult ex-smokers. The flavored e-cigarette ban is the only provision in the bill that I believe is problematic.

Finally, I am not suggesting that the Subcommittee should merely amend the bill to omit the flavor provision. Instead, I believe that an even stronger and more effective provision should take its place. Specifically, regulation of the nicotine content of e-cigarettes is the single most effective step you can take to address the problem of youth addiction to e-cigarettes. Representative Krishnamoorthi has introduced a bill (H.R. 4624), also in the Energy and Commerce Committee, that would do exactly this. I encourage the Subcommittee to consider combining the text of H.R. 4624 into H.R. 2339 during the mark-up process.

Please don't hesitate to contact me if I can provide further information.

Sincerely,

A handwritten signature in cursive script that reads "Michael Siegel". The signature is written in dark ink and is positioned above the printed name.

Michael Siegel, MD, MPH
Professor