

**Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

**Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”**

September 25, 2019

**Dr. Joneigh Khaldun, Chief Deputy Director for Health and Chief Medical Executive,
Michigan Department of Health and Human Services**

The Honorable Frank Pallone (D-NJ)

1. States, including yours as the first, have attempted to address youth e-cigarette use by, among other efforts, banning certain flavored e-cigarette products.
 - a. Why is addressing access to flavors so important in addressing the youth epidemic of e-cigarette use?

There is overwhelming evidence that youth initiate use of e-cigarettes because of flavors. Data from recent studies such as the CDC’s population assessment of tobacco and health (PATH) study found that 96.1% of 12-17 year olds who initiated e-cigarette use since the last survey started with a flavored product,¹ 97% of current youth e-cigarette users used a flavored e-cigarette in the past month, and 70.3% say they use e-cigarettes because “they come in flavors I like.”²

- b. Do you believe there should be a nationwide ban on non-tobacco e-cigarette flavors, including mint and menthol?

Youth vaping is a public health emergency and measures such as a flavor ban are necessary to protect the public health. As Chief Medical Executive for the State of Michigan, I found that a public health emergency exists in the State of Michigan regarding youth use of e-cigarettes. That finding formed the basis for emergency rules that prohibited the sale, transport, or distribution of flavored nicotine vapor products in Michigan. Including mint and menthol is important as the CDC National Youth Tobacco 2018 data indicates that menthol or mint was popular among 75.5% of High Schooler e-cigarette users in 2018 and 65.9% in 2019.³

¹ <https://www.fda.gov/media/121384/download> fn. 14-15.

² *Id.* at fn. 17.

³ Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products. September 11, 2019. <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>.

- c. Do you think the measures contained in the emergency rules will do enough to help reverse the trend of youth use rates, or do you need FDA to do more?

Despite the FDA's August 2016 deeming rule, the state of Michigan and other states across the United States have seen a marked increase in youth usage of e-cigarettes. After that rule went into effect, the numbers of high schoolers using e-cigarettes continued to rise significantly, more than doubling from 2016 to 2019. The US Surgeon General identified strategies to combat the epidemic of youth use of e-cigarettes to include removing access to flavors and restricting marketing and advertising for youth. While states are working to reduce youth access to flavored e-cigarettes, FDA action to prohibit flavors would assist and streamline nationwide efforts to reduce the national rates of youth addiction to nicotine through the use of e-cigarettes.⁴

- d. What types of resources has your department had to marshal to respond to both the vaping lung illness investigations as well as in response to youth vaping use?

The Michigan Department of Health and Human Services (MDHHS) Tobacco Section has shifted full time staff from their regular assignments in order to address the youth e-cigarette epidemic. These staff members have committed significant time to reaching out to state level partners to educate them on the youth e-cigarette epidemic. The Tobacco Section team spent many hours vetting existing e-cigarette resources and creating new ones, which were then used to publish a dedicated e-cigarette webpage. This webpage contains sections to educate and assist school staff and administrators, parents, and healthcare professionals. In addition, there has been increased collaboration within the Department in order to maximize efficacy and resources while addressing the e-cigarette epidemic. Numerous staff and managers throughout MDHHS have dedicated considerable time and resources to assist in addressing the e-cigarette epidemic as it relates to their service populations. Additional resources that are necessary for continued response include funding for media campaigns to raise awareness and education and additional staffing to handle statewide education and prevention efforts.

With regard to the response to the outbreak of severe lung injury associated with vaping or e-cigarette use, MDHHS first became aware of the outbreak in early August when it was reported in Wisconsin and Illinois. In anticipation that this outbreak would reach Michigan, MDHHS assigned a masters level epidemiologist and a medical epidemiologist to develop a plan to identify possible injury cases and conduct investigation. The first patient suspected of having this disease was reported in mid-August, and reporting has steadily increased since then with no signs of abatement. (As of 10/24/2019 80 cases have been reported and 43 have met the CDC case definition for "confirmed" or "probable" injury case, including one death). MDHHS

⁴ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

has engaged significant resources since mid-August to develop and maintain the public health surveillance system; review medical records and interviews; ensure communications with the public, local health departments, medical associations, other states agencies, CDC and FDA; and utilize the MDHHS laboratory in processing and shipping of vaping products and clinical specimens to the FDA and CDC. Local health department staff already experienced with infectious disease outbreaks have been trained to collect medical records and conduct interviews of reported patients. The MDHHS epidemiologist and medical epidemiologist have worked almost full time on the investigation most weeks, taking away from other work responsibilities. A senior level public health consultant was brought on to coordinate the response and public communications. This response team has worked closely with the MDHHS Tobacco Control Program to ensure consistent messaging regarding this outbreak. Senior management in MDHHS has been deeply engaged in policy decisions using the surveillance data provided by the outbreak response team and nationally by CDC, aided by the communications, public health administration, legal affairs, and the office of the Director.

- e. To what extent does this youth vaping crisis require additional resources or the development of new approaches to address nicotine addiction among young people?

The Michigan Department of Health and Human Services has responded to the increase in demand for youth vaping resources by partnering with National Jewish Health, one of the nation's largest quitline providers. Funding was provided to develop a new program designed for teens and with teen input. The program is called My Life My Quit (MLMQ) and relies heavily on interactive text and online coaching and uses promising practices. In the four years prior to launch of MLMQ, an average of 23 new youth (under 18) participants were enrolled across the 16 states National Jewish Health serves. Since launch of the MLMQ dedicated youth program there have been an average 81 new participants enrolled per month, mainly related to having a dedicated program that could be promoted directly to youth.

Additional funding is needed to help states and national partners to develop and test youth vaping cessation strategies such as MLMQ in order to move from promising practices to an evidence-based approach. Other points to consider include:

- Raising the minimum legal age of sale of tobacco products, including e-cigarettes, to 21 years of age will help to reduce youth use of tobacco products, prevent youth initiation, and reduce the morbidity and mortality caused by tobacco use.
- Dedicating a portion of each state's Master Settlement Agreement revenue to state tobacco prevention and control programming, including funding to assist youth to quit e-cigarette/tobacco use, will help states to address youth use of tobacco products including e-cigarettes.

The Honorable Diana DeGette (D-CO)

1. According to your testimony, between the years of 2015–2016 and 2017–2018, counties across Michigan witnessed between a 30 percent to 118 percent increase in e-cigarette use among high school students who used an e-cigarette in the past month. What are some of the concerns you have regarding the potential long-term public health consequences of this marked increase in use?

The tobacco industry knows that the younger children are when they first experiment with or begin using tobacco, the more likely they are to become addicted, life- long tobacco users. This early use, which often leads to addiction, can lead to tremendous health implications for these people.⁵

According to the CDC, most e-cigarettes contain nicotine—the addictive drug in regular cigarettes, cigars, and other tobacco products. Nicotine can harm the developing adolescent brain, which continues to develop until about age 25. Using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control, and may increase risk for future addiction to other drugs.⁶

The long term health consequences of the epidemic are still being determined, but are likely to be serious. Young adults who use e-cigarettes are more than four times as likely to begin smoking tobacco cigarettes within 18 months as their peers who do not vape.⁷ As they shift to become users of combustible cigarette, there is a greater potential for increased health consequences ranging from heart disease, stroke, cancer, and asthma among others. Studies of health impact of e-cigarettes have begun to find health consequences of e-cigarettes to include oral, lung, cardiovascular and dermatologic health.⁸ Current adult asthma

⁵ <https://www.tobaccofreekids.org/what-we-do/us/sale-age-21>

⁶ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html.

⁷ Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naïve US Young Adults. *The American Journal of Medicine*. April 2018, Volume 131, Issue 4, Pages 443.e1–443.e9.

⁸ It's Worse Than You Think (Advisory article). January 10, 2019. Scott Froum, DDS, and Alisa Neymark, DDS <https://www.perioimplantadvisory.com/articles/2019/01/vaping-and-oral-health-it-s-worse-than-you-think.html>

⁸ Inflammatory Response and Barrier Dysfunction by Different e-Cigarette Flavoring Chemicals Identified by Gas Chromatography-Mass Spectrometry in e-Liquids and e-Vapors on Human Lung Epithelial Cells and Fibroblasts. *Appl In Vitro Toxicol* 2017;3:28–40.
[doi:10.1089/aivt.2016.0030](https://doi.org/10.1089/aivt.2016.0030)

prevalence is nearly twice as high in e-cig smokers (18.4%) as in non-smokers (10.6%).⁹ Studies have also shown acute effects of e-cigarette use to vasculature and airways.¹⁰

2. Your state was the first to implement a flavored e-cigarette product ban in the country. Why do you believe this and other actions are critical to act swiftly to address the youth epidemic of e-cigarette use?

Michigan was the first state to announce a flavored nicotine vapor ban in the country, but the United States still has a long way to go to protect our children from the dangers associated with vaping and nicotine addiction. E-cigarettes are a much newer product than cigarettes, though they have been around in the United States since approximately 2007. Since the deeming rule went into effect in 2016, the number of high schoolers using e-cigarettes has continued to rise significantly, more than doubling from 2016 to 2019. It is clear that children still have access to e-cigarettes at an alarming rate. According to the U.S. Surgeon General, it is flavors that have fueled the epidemic rise in youth use of e-cigarettes. The Surgeon General identifies removing youth access to flavors and restricting advertising and marketing are effective strategies to address the youth epidemic of e-cigarette use.¹¹ A ban on flavored nicotine vapor products is therefore necessary to protect the public health, safety, and welfare.

The Honorable Brett Guthrie (R-KY)

1. What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?
 - a. For the data that is included in these statistics, how often or how recently does an individual have to have used an e-cigarette to be captured in the data (e.g. in the last 30 days, single-use versus chronic use)?

The National Youth Tobacco Survey reports data from past 30-day use of e-cigarette use as well as use over lifetime.

⁹ Barth O, Anderson B. Michigan Adults with Current Asthma: Symptoms, Management, and Productivity. Michigan BRFSS Surveillance Brief. Vol. 11, No. 2. Lansing, MI: Michigan Department of Health and Human Services, Lifecourse Epidemiology and Genomics Division, December 2018.

¹⁰ Acute Effects of Electronic Cigarette Inhalation on the Vasculature and the Conducting Airways. Cardiovascular Toxicology, pp 1–10. First Online: 08 April 2019. Lukasz Antoniewicz, Amelie Brynedal, Linnea Hedman, Magnus Lundbäck, Jenny A. Bosson
<https://link.springer.com/article/10.1007%2Fs12012-019-09516-x>

¹¹ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

- b. Does the data break out how many are using e-cigarettes for tobacco products (e.g. nicotine) or for THC products?

No. The National Youth Tobacco Survey questions asks whether the electronic cigarettes that were used in the past 30 days consists of flavors such as menthol, mint, clove, spice, candy, fruit, chocolate, or other sweets. It does not directly ask about THC products.

2. How does that data compare to trends regarding youth use of combustible cigarettes?

According to data obtained from the Youth Risk Behavior Survey (1999-2017), the trend of current cigarette smoking among youth had been decreasing from 1999 until 2017 (the last year data is available for Michigan). For tobacco use in general, a decreasing trend was seen over the same period of time until 2015 when it started to trend up again due to e-cigarette use.

The Honorable Michael C. Burgess (R-TX)

1. The state of Michigan has banned the sale of flavored e-cigarettes, Dr. Khaldun, how will the Michigan Department of Health and Human Services regulate and enforce the ban?

The emergency rules are enforced by both state and local law enforcement. Local law enforcement may also get assistance from the Michigan Department of Health and Human Services Tobacco Section.

A person who violates any provision of the rules is guilty of a misdemeanor, punishable by imprisonment for not more than six months, or a fine of not more than \$200, or both, as set forth by MCL [333.2261](#). Fines for selling flavored nicotine vapor products are calculated on a per-item per transaction basis. Retailers, including online retailers, and resellers are subject to the emergency rules.

2. Following the ban in your state, what will Michigan do to monitor the impact a ban could have on smoking cessation for those who utilize e-cigarettes to quit smoking?

The Tobacco Control Program has developed an evaluation plan to monitor and assess the e-cigarette use rate among youth before and after the ban including the youth quit attempts through the My Life My Quit program.

E-cigarette has not been approved by the FDA as a tobacco cessation method therefore cannot be evaluated as such.