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. Monica Bharel, Commissioner, Massachusetts Department of Public Health

The Honorable Frank Pallone (D-NJ)

1. Earlier this month, you mandated that possible cases of unexplained, vaping-associated pulmonary disease be reported to the Massachusetts Department of Public Health. What have been some of the challenges in identifying confirmed and probable cases of lung illnesses associated with vaping in your state?

   On September 11, as more cases of vaping-related pulmonary disease were being seen nationwide, I used my authority under state regulations to require reporting of this emergent condition. We thought it was very important to establish the legal framework for healthcare providers to report cases and suspected cases so that we could get a better sense of the overall burden of disease in Massachusetts.

   While we are seeing high levels of compliance among clinicians, there are significant challenges to obtaining the data we need to identify cases. There are multiple steps and each is dependent on the participation of several partners.

   First, patients with symptoms consistent with vaping-associated injury must present for medical care and be evaluated. The range of symptoms is wide and may not be considered severe enough (or may be confused with pre-existing conditions) by a given individual to warrant medical care. Clinicians in turn need to have a high degree of suspicion and investigate respiratory illnesses in the context of asking patients questions about vape product use.

   Second, to meet the case definitions, clinicians must order the appropriate tests (blood oxygen levels, chest X-ray, CT scan, infectious disease panels). Clinicians also must observe the current reporting regulations and fax an intake form to DPH with basic information about a suspected case. Next, DPH reviews these forms, excludes those that do not meet the case definition, and refers the remainder for follow-up. Follow-up entails requesting and reviewing the patient's medical record and determining whether to assign a case to the probable or confirmed categories or deciding to exclude a case. In some instances, further information may be sought from the reporting provider, including clinical specimens for possible testing by the CDC.

   Each confirmed and probable case is then contacted by DPH epidemiologists and asked if they would agree to an interview. While an interview is not necessary to determine if they are a case, in some instances information from the patient will result in the exclusion of a report from the case group (e.g.,

if a patient indicates no recent vape product use). The primary goal of the interview is to gain additional information about the products and devices used and how recently and frequently they were used. Patients are also asked to hold any remaining product for possible submission to the FDA for testing.

We rely on clinicians to suspect a vaping-associated case, collect sufficient information about the suspect case, and make an initial report. Since we do not know yet the total number of these injuries we are unable to determine at this time the completeness of this reporting, though it is required under public health regulations. We rely on the clinician's health care institution to submit requested medical records, and while this may take some time, DPH has seen a high level of compliance with these requests. Review of medical records is conducted by multiple clinical staff at DPH resulting in new case determinations on a weekly basis. We rely on patients to respond to our interview requests and agree to provide information over the phone. Again, we are seeing a high level of compliance and DPH is not wholly dependent on these interviews to make case determinations.

2. Vaping products were also recently banned in Massachusetts for all ages.

a) Is this an indication that raising the minimum age is not enough to combat rising rates of youth use?

The purpose of the temporary ban is to take a pause on sales so that we can learn what is making people sick and figure out how to regulate these products to protect the health of all of our residents. Increasing the minimum age is an important and effective part of reducing youth exposure to vaping by restricting their access. Policies that raise the minimum age to 21 reduce youth access to these products, but as with every other public health intervention, raising the age is most effective when complemented by other supportive policies, such as flavor restrictions, pricing strategies, and careful permitting to moderate density. This ban gives us a pause while we learn more about how to keep both Massachusetts youth and adults safe from harm.

b) In addition to the temporary ban, what other recommendation has Massachusetts considered or implemented?

Prevention: Massachusetts has 161 cities and towns with a flavored product restriction in place, covering approximately 67% of the population, to help reduce both exposure and addiction. A growing number of communities are expanding restrictions to include mint and menthol, and many others are working to cap permits to reduce density and limit youth exposure. Our award-winning statewide vaping education campaign helps parents identify vaping products and dangers, and provides guidance for speaking with their children around this topic. Another vaping prevention campaign created with youth speaks directly to young people about how nicotine harms the adolescent body, and offers ways to take local action in fighting industry influence in their communities. Massachusetts has also included vaping in our smoke-free workplace laws, and is the first state to have banned the sale of tobacco products in pharmacies.

Youth Cessation: Our state has worked with the Truth Initiative and our Massachusetts Smokers' Helpline vendor, National Jewish Health, to provide resources to support youth with cessation. In addition, we have plans to work with school nurses to increase referrals to both of these programs. Adult Cessation: In addition to creating a standing order for FDA-approved, over-the-counter nicotine replacement therapy (NRT) products such as gum, lozenges, and patches, Massachusetts has also increased support to the Massachusetts Smokers' Helpline, and the amount of available NRT from four weeks to eight weeks. There are no co-pays for nicotine replacement therapies for Medicaid and the state's employees and retirees and their dependents and survivors and participating municipalities, known as the Group Insurance Commission (GIC).

The Honorable Diana DeGette (D-CO)

1. In your testimony you state that "working in tandem with the federal government is critical to combatting this epidemic." What successes have you had in working with the federal government to address e-cigarette use, and where is there room for improvement?

Successes: We cannot combat this epidemic on our own and we welcome the support of our federal partners, with whom we already work closely.. For example, in collaboration with the FDA, our local health departments educate retailers and conduct regular compliance checks. Our FDA inspectors conduct retail inspections to enforce federal tobacco regulations statewide and combined, there are close to 15,000 inspections each year. We successfully collaborate with national efforts around cessation through the CDC's Tips from Former Smokers campaign. Massachusetts regularly works to complement this campaign by running it locally, and we see the results from this effort with increased calls to our Smokers' Helpline from many adults in our state seeking support to quit using nicotine.

I would also mention that Massachusetts follows the Synar Amendment, enacting and enforcing federal and state laws that prohibit the sale or distribution of tobacco products to individuals under the age of 18, conducting random, unannounced inspections to ensure compliance with the federal law. We consider this a shared success, because it represents federal commitment for creating policies that create healthy conditions, thereby empowering Massachusetts to implement this policy locally, resulting in lower sales violation rates in our state.

Where we could use some assistance: We look to our federal partners for help when it comes to advertising, regulating, funding, and enforcement. One way to ensure that we are identifying risks on e-cigarettes and any potential new nicotine products, is to strengthen the collaboration and resources around funding research on the ingredients in e-cigarettes and how this influences health outcomes, so that people can make informed choices, and states can implement stronger laws and regulations based on additional evidence.

Massachusetts encourages our federal partners to create restrictions for advertising around e-cigarettes, at a minimum, mirroring what exists now for combustible cigarettes. Massachusetts

encourages the U.S. Food and Drug Administration (FDA) to ban flavored e-cigarettes, including mint and menthol. Massachusetts also request that the FDA be assertive in holding retailers and manufacturers for sales and marketing efforts that target youth.

2. Public health officials have worked to develop effective strategies for combatting youth use of traditional combustible cigarettes. Your state of Massachusetts has led successful campaigns to reduce youth tobacco use, such as the 84 Movement. To what extent does this youth vaping crisis require additional resources or the development of new approaches?

We know that changing the conditions in which people live is one of the most impactful ways we can help people make healthy choices. One of the reasons the 84 Movement is so successful is that the youth involved educate their peers and adults on the dangers of the tobacco industry and they work to create change locally and statewide.

Additional resources would allow the Commonwealth to continue our youth education campaign, and increase partnerships with our local coalitions, local boards of health, and schools to specifically target the youth population.

On a federal level, increased funding for research on these products, their ingredients, and the links between ingredients and health outcomes would provide all public health departments with the tools and data needed to regulate and provide appropriate resources.

The Honorable Brett Guthrie (R-KY)

What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?

First, I'm proud that Massachusetts has made significant progress in curbing youth and adult tobacco use over the past two decades. In 1996, the youth smoking rate was 36.7%. Today, the youth smoking rate is 6.4%. Our adult smoking rate is also low, with just under 14% of adults using combustible tobacco products. Our low smoking rates are a result of years of hard work with many local and regional partners.

In terms of the data, based on 2017 Youth Risk Behavior Survey (YRBS) data, Massachusetts has one of the lowest youth smoking rates, and yet highest youth vaping rates in the country. 2017 data show that 20% of high school youth vaped in the past 30 days, and one in 10 middle school youth tried vaping.

While 2019 statewide data is not yet available, school surveys conducted by local schools and districts across the state show youth vaping rates as high as 33% for current use and over 50% for ever use. These data were collected before the emergence of JUUL, so it is possible that newer data will show a greater increase in youth vaping due to JUUL's recent rise in popularity.

In addition, current use of e-cigarettes is higher among students in grade 12 (25.9%) than any other age group. Current e-cigarette use among grade 12 students is more than triple the rate of e-cigarette use among 18-24 year olds (7.8%), who have the highest e-cigarette use rate of all adult age groups (ages 18+) *(adult data from 2017 MA Behavioral Risk Factor Surveillance System (BRFSS), youth data from 2017 MA YRBS).*

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)?

Data collected in Massachusetts captures "ever users" (youth who have ever tried an e-cigarette), as well as "current users" (youth who have used an e-cigarette in the past 30 days).

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

This state-level data will be available when the 2019 Youth Health Survey results are released. Once the 2019 data are released, we can report the prevalence of youth who currently use marijuana in a vape product. That said, we know that dual use of vape products and marijuana is high. In 2017, among high school students who used vape products in the past 30 days, 2 in 3 (64.1%) reported also using marijuana in the past 30 days (MA YRBS)

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

In 2017, use of e-cigarettes was three times higher than use of cigarettes (20.1% vs 6.4%) (MA YRBS).

<u>The Honorable Michael C. Burgess (R-TX)</u>

1. The state of Massachusetts Department of Public Health has engaged in a public information campaign about youth use of e-cigarettes, what is the state doing to expand on the research of youth vaping?

When youth rates of e-cigarette use began to skyrocket, we knew public information campaigns would be absolutely critical to increasing both general awareness and to alerting youth – and adults – to the dangers. In July 2018 we started by launching a campaign aimed at educating parents, school staff, and other youth influencers about vaping products and more recently launched a youth campaign, directly informed by youth input and feedback.

Massachusetts is seeking to fill gaps in the data, which includes supplementing existing surveillance systems with additional primary data collection efforts in youth and adults as well as leveraging clinical systems as a means of monitoring vaping use and related adverse events. These new means of data collection are either in the exploratory phases or already being developed, and we will continue to explore feasibility in the coming months.

The Massachusetts Tobacco Cessation and Prevention Program (MTCP) is engaged in research to evaluate the impact of point-of-sale tobacco control policies which aim to protect youth from the tobacco and vaping industries.

In fact, we published our most recent study this month. DPH evaluated the short-term impact of a partial flavor restriction policy and found that in one Massachusetts community, within six months, both flavored and non-flavored tobacco use decreased among high school youth. In comparison, flavored and non-flavored tobacco use *increased* among high school youth in a similar Massachusetts community without the policy during the same time period *(Kingsley M, Setodji CM, Pane JD, Shadel WG, Song G, Robertson J, Kephart L, Henley P, Ursprung S. American Journal of Preventive Medicine. Short-Term Impact of a Flavored Tobacco Restriction: Changes in Youth Tobacco Use in a Massachusetts Community).*

We are also currently examining the additive impact of passing multiple point-of-sale tobacco control policies on youth tobacco use and other tobacco-related behaviors.

2. How is your state addressing the differences between nicotine and THC e-cigarettes?

Our Massachusetts Tobacco Control Program is solely focused on tobacco and nicotine. Since the legalization of marijuana for consumers in Massachusetts, THC e-cigarettes have been under the purview of an independent state Cannabis Control Commission, which is overseen by 5 Commissioners, consisting of one appointee each from the Governor, Treasurer and Attorney General, and two members agreed upon by the majority of those three constitutional officers. Our roles converge when it comes to underage prevention and we work together to ensure the safety and health of young people – whether we are restricting access to combustible cigarettes or THC e-cigarettes.

In addition, The Massachusetts Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences interviews patients who present with vaping-related pulmonary illnesses and collects data around THC use for the CDC. Our Bureau of Substance Addiction Services also champions primary prevention efforts around marijuana.