Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Sounding the Alarm: The Public Health Threats of E-Cigarettes"

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The Honorable Frank Pallone (D-NJ)

1. **Your testimony mentioned a range of recommendations to address youth vaping use, including curbing marketing to youth, increasing the legal age of tobacco sales to persons aged 21 and over, and reducing youth access to flavored tobacco products. Why isn't one approach—such raising the age of sale to 21—enough to address the youth e-cigarette epidemic?**

   Lessons learned from the comprehensive approach to tobacco control of combustible cigarettes can be applied to the approach to e-cigarette use. Comprehensive strategies that combine policies to **decrease access to** (e.g., raise the age of sale to 21, price increases) with those that **reduce demand and appeal for** (e.g., curbing marketing to youth) and **acceptability o**f (e.g., smoke free policies, social messaging) e-cigarettes, as well as with those to **promote effective cessation** for people currently using tobacco products, when implemented with robust enforcement and adequate funding, have been found to be most effective.

   The CDC Best Practices for Comprehensive Tobacco Control Programs (https://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm) state "individual components are most effective when they work together to produce the synergistic effects of a comprehensive tobacco control program." Similarly, the Community Preventive Services Task Force (CPSTF) recommend comprehensive tobacco control programs based on strong evidence of effectiveness in reducing tobacco use and secondhand smoke exposure. Further, the Office of the Surgeon General, the American Academy of Pediatrics, and the Association of State and Territorial Health Officers (ASTHO) have released recommendations for federal and state policies to decrease both youth demand for and access to e-cigarettes and promote effective cessation for people currently using tobacco products. There is overall consensus to consider some type of policies within each recommended domain described in the written testimony.

   In addition, according to FDA, 96.1 percent of youth who initiated e-cigarette use did so with a flavored e-cigarette product. Therefore, restricting the sale of flavored e-cigarette products

would be a particularly key component of a comprehensive policy strategy to reduce youth e-cigarette use.

Specific to consideration of raising the age of sale of tobacco products to 21, the American Heart Association, American Cancer Society Cancer Acton Network and the American Lung Association agree that a strong tobacco minimum legal sales age of 21 policy (Tobacco 21) should include the following robust provisions:

- Define tobacco products to include current and future tobacco products, including e-cigarettes;
- Prohibit the sale of tobacco products to persons under the age of 21;
- Require the tobacco retailer or their employee to verify the age of the purchaser prior to the sale;
- Require tobacco retailers to post signs stating that sales to persons under the age of 21 are prohibited;
- Designate an enforcement agency and establish a clear enforcement protocol;
- Create a tobacco retail licensing program if the jurisdiction has the authority to do so under state law,
- Dedicate funding to fully cover enforcement costs, either through licensing fees or as a provision in a state statute or local ordinance;
- Provide authority for the state, county, or municipality to inspect tobacco retailers for compliance with Tobacco 21 and a mandated minimum number of annual compliance checks for every tobacco retail establishment;
- Provide penalties focused on the tobacco retailer or licensee rather than the youth purchaser or non-management employee. This would mean eliminating Purchase, Use, and Possession penalties where they exist in current tobacco sales laws or policies;
- Establish a civil penalty structure for violations rather than a criminal penalty structure to avoid unintended consequences that disproportionately impact marginalized communities and undermine the public health benefits of the policy, and
- Where state legislation is pursued, ensure that local jurisdictions have the authority to enact more stringent regulations for tobacco products than state or federal law.
- No exemption for military

Restriction to internet sales would complement the protective effects of restrictions on sales to youth in retail settings.

2. Your testimony highlighted emerging research from the University of North Carolina that suggests the use of e-cigarettes may lead to higher risks of emphysema, a form of chronic lung disease.

a. What are some of the gaps in research that we still have regarding the long-term use of e-cigarettes?

As the Honorable Congressman Pallone points out, unregulated e-cigarette use, products and ingredients have been rapidly evolving since introduction to the market and little is known about

long-term use. In addition, because tobacco-related disease often presents itself decades after initiation, we will not fully understand the health consequences of e-cigarette use for some time.

In preparing our response to your follow up questions, we consulted our research colleagues at the University of North Carolina in Chapel Hill (UNC). Their input is included below as well as recommendations from our public health content experts. Areas of future research could include:

Larger population-based studies

The published studies from UNC were based on a limited sample of participants and are cross-sectional (i.e., at one point in time). The UNC researchers recommend repeating them on a larger scale that fully reflects the ethnic diversity of North Carolina and other states. The researchers also recommend additional longitudinal studies that follow cohorts of e-cigarette users over time to understand the longer term effects on exposure to e-cigarettes and ensure the findings are consistent and reproducible. Further, the researchers recommend studies to understand whether and to what extent vaping/e-cig induced health effects are reversible. These additional studies are feasible. For example, the links between elevated proteases and emphysema, bronchiectasis and lung cancer metastasis are well-established and measuring lung protease levels is fairly easy to do. Therefore, studies can be designed and implemented to assess the impact of vaping on protease levels in the population at large.

Investigating effects on organs other than lungs

In addition to lung effects, people may be experiencing vaping-associated health manifestations in other organs that need further exploration. For example, many patients are presenting with gastrointestinal symptoms prior to showing lung effects as part of the outbreak of the acute pulmonary illness. It is unknown if this has been happening in the past or is now just being uncovered as part of the outbreak and warrants further research.

Acute Outbreak of E-cigarette or vaping product use-associating lung injury (EVALI)

The CDC, FDA and state departments of health have mobilized to monitor and investigate the cases associated with acute outbreak of e-cigarette or vaping product use-associating lung injury (EVALI). CDC is tracking relapse and readmissions to the hospital and expanding the scope of its investigation to include lab tests of the heated vapor emitted from e-cigarettes, lung cells, and other substances—such as vitamin E acetate—found in e-cigarettes. They also have examined autopsy specimens, blood, lung biopsies, and urine. While we have learned a great deal to-date, CDC and FDA report that they “have not identified the cause or causes of the lung injuries in these cases, and the only commonality among all cases is that patients report the use of e-cigarette, or vaping, products. No one compound or ingredient has emerged as the cause of these illnesses to date; and it may be that there is more than one cause of this outbreak. Many different substances and product sources are still under investigation.” While, THC does seem to play a role in the majority of cases of EVALI, more research needs to be done to further identify the cause or causes of the pulmonary injury.

Further, as EVALI symptoms are beginning to be characterized, investigations should not be focusing solely on cases that require hospitalizations or intensive care treatment, but should also examine what symptoms of health problems may be occurring in individuals without hospitalizations. This would give us information on the extent of risk or harm to the population.

Cessation

Further research is needed on if e-cigarettes are an effective smoking cessation modality and on effective youth cessation programs and treatments.

Applied Public Health Research

One of the core functions of public health is Assessment, including collecting and analyzing information about health problems. This in turn informs Policy Development which, when enforced and linked to strong program services helps to Assure population health.

Tobacco use patterns and other drug use patterns are in a time of rapid transition in North Carolina and the U.S. as new and emerging products reach the marketplaces, which include both brick and mortar and digital marketplaces, and as new and emerging forms of social media promote use of these products.

Further study, including public health monitoring and tracking can inform policy development and strategies that minimize or eliminate harms. Systems such as the Youth Risk Behavior Survey, the more in-depth Youth Tobacco Survey, the Behavioral Risk Factor Surveillance System are critical resources for monitoring and tracking state and national trends in tobacco use, perceptions and knowledge. These systems have suffered, and new investments are needed such that state and local public health can more rapidly adjust and monitor health trends for the purpose of preventing population health problems through evidence-based policy development and implementation

Other applied research that could be helpful include:

Content of e-cigarettes: Currently, e-cigarette products do not have consistent labels with ingredients, including nicotine levels. Evidence-based methods to assess content of e-cigarettes including nicotine levels would be helpful to inform research on health effects of chemicals in e-cigarette vapor as well as guiding proper dosing for nicotine replacement therapy for tobacco use treatment.

Pricing interventions: There is robust data from health economists for pricing strategies that are effective in preventing combustible tobacco use among young people and helping people who

smoke combustibles to quit. There is a need for evidence for pricing interventions to deter young people from starting to use e-cigarettes.

Mass Media: NC is impressed with the Rescue Agency's peer crowd mass media approach in effectively preventing combustible tobacco initiation. It would be helpful to have community-level research to find evidence to determine if their newest "peer crowd" approach to e-cigarette prevention using mass media is also effective in preventing e-cigarette use or vaping among teens.

b. What role do you believe the federal government should play in supporting such research?

The federal government should have a role in funding, supporting, and understanding the long-term impact of e-cigarettes on the lung and other organs of the body at various levels ranging from epidemiological to biochemical.

The EVALI outbreak indicates that THC use (either by itself or as dual use) contributes to this disease. However, because of the classification of THC as a class 1 controlled substance, the ability to systematically study the toxicity and health effect of THC products in the lab is severely limiting. The federal government could facilitate research related to THC.

Epidemiological services have historically invested time and resources in the diagnosis and investigation of communicable disease outbreaks and the health impacts of acute environmental hazards and events. More investment is needed for diagnosing and investigating tobacco use and other substance use and the relation to chronic disease conditions in order to inform policy and program development. Further, more investment in monitoring systems, such as the Youth Risk Behavior Survey, is needed.

A new code within the 10th version of the International Statistical Classification of Diseases and Related Health Problems version (ICD-10) for vaping/e-cigarette would allow health care providers to document vaping/e-cigarette use in medical history, which could be crucial to understanding health effects about which we currently do not know. The new ICD-10 could also be used for tracking data on use of e-cigarettes/vaping devices.

The Honorable Diana DeGette (D-CO)

1. **In your testimony, you noted that e-cigarette products "are available in thousands of kid-friendly flavors including candy, fruit, bubble gum, cotton candy, graham cracker, mint and menthol and some have packaging that mimic kid-friendly products like Lucky Charms cereal." Are young people using e-cigarettes today likely to be the young people who would have smoked traditional cigarettes regardless of the availability of e-cigarettes?**

It is difficult to say definitively and there are many factors that would have to be considered that are not included in the population-level data we have. However, we have indications that youth

who are using e-cigarettes may not have used combustible cigarettes, if e-cigarettes were not available.

In North Carolina, we observed more than a decade of decline of combustible cigarette use among teens before introduction of e-cigarettes to the market. Once e-cigarettes became available, however, we saw a rapid change in the prevalence of use. From 1999-2017, we have seen a decline in the use of combustibles tobacco use in high schoolers from 31% to historic low of 8.9%, but e-cigarette use increased 894% since 2011. If e-cigarettes were just a replacement for youth who would ordinarily be using combustible cigarettes, we would not have expected to see such a dramatic change in our prevalence rates of youth use of tobacco products.

In addition, we have questions to gauge susceptibility and intention to use in our North Carolina Youth Tobacco Survey (NCYTS). More teens are susceptible or considering e-cigarettes than combustible. In addition, adolescents who use e-cigarettes appear to have fewer social and behavioral risk factors than conventional cigarette users. Further, according to a 2015 report from the National Health Interview Survey, 40 percent of young adults who use e-cigarettes every day or some days were never smokers before trying e-cigarettes.

Further, flavors that appeal to youth are playing a role in youth initiation of e-cigarettes. For the most part, these flavors are not available in combustible cigarettes. Per the North Carolina Youth Tobacco Survey (NCYTS) the main reasons NC students report using e-cigarettes are because a friend or family member uses them and because they were available in flavors. According to the FDA, 96.1 percent of youth who initiated e-cigarette use did so with a flavored e-cigarette product. A 2016-2017 FDA study showed nearly all (97%) current youth e-cigarette users had used a flavored e-cigarette in the past month and that 70% of youth users do so "because they come in flavors I like." The 2018 National Youth Tobacco Survey reports 68% of high school students currently use e-cigarettes of any flavor and 51% currently use menthol or mint flavored cigarettes.

For combustible cigarettes, the only flavor legally available is menthol. In addition, JUUL, the most widely sold e-cigarette product in the United States, contains nicotine salts, which CDC has found allows high nicotine levels to be inhaled more easily and with less irritation than other tobacco products. For these reasons, e-cigarette use may be more appealing to youth than combustible cigarettes, as evidenced by recent increasing youth rates of overall tobacco product use following years of decline.

Further concerning is the data from the Surgeon General's Report 2016 that youth initiation of e-cigarettes can often lead to using traditional tobacco products in the future.

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?**

The data trends in North Carolina delineate the challenges we face as public health officials in addressing the alarming trends of youth vaping. The 2017 North Carolina Youth Tobacco Survey (NCYTS) found that although combustible cigarette smoking was the lowest ever recorded among high school students at 8.9%, e-cigarette use increased 894% since 2011. E-cigarettes have become the most commonly used tobacco product among youth in North Carolina, with 16.9% of high school students currently using them, and with even more (23.3%) saying they plan to use them in the next year. Further, adolescents and young adults who have used e-cigarettes are more likely to report using traditional cigarettes at follow-up compared with those who had not.

Like in North Carolina, youth e-cigarette use is increasing across the country. The 2018 National Youth Tobacco Survey saw a 78% increase in high school e-cigarette use between 2017 and 2018. The 2019 Monitoring the Future survey revealed similar results, with youth e-cigarette use more than doubling between 2017 and 2019 among 8th, 10th and 12th grade students nationwide. The increase from 2017-2018 was the largest ever recorded in the survey's 43-year history for any single substance.

Based on this data, we believe that the 2017 NC Youth Tobacco Survey data underrepresents the scale of the youth e-cigarette use epidemic in North Carolina. Currently, our Division of Public Health is working with the NC Department of Public Instruction and randomly selected schools across the state to conduct the 2019 NC Youth Tobacco Survey. We expect to have the survey results in early 2020. Ninety percent of adults that report using tobacco products reported starting before the age of 18. That is why this trend in youth use is incredibly concerning.

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 prevalence data that was presented from the National Youth Tobacco Survey and the North Carolina Youth Tobacco Survey was current use, meaning use in the past 30 days. This is a standard measure of regular youth use used by CDC and other national youth tobacco surveys.

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

In North Carolina 9.6% of all high school students had ever vaped cannabis in 2017. This increased by grade, ranging from 4.7% of all 9th grade students to 15.5% of all 12th grade students. Among all high students who had used an e-cigarette in the past 30 days, 29.3% had ever vaped cannabis. Among all high school students who had smoked a cigarette in the past 30 days, 32.2% had ever vaped cannabis.

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

Cigarette smoking has been consistently decreasing in North Carolina since the North Carolina Youth Tobacco Survey began in 1999. Between 1999 and 2017 high school cigarette use decreased 71%, from 31.6% to 8.9%, and middle school cigarette use decreased 83%, from 15% to 2.5%.

While the 2017 North Carolina Youth Tobacco Survey (NCYTS) found that although combustible cigarette smoking was the lowest ever recorded among high school students at 8.9%, e-cigarette use increased 894% since 2011. E-cigarettes have become the most commonly used tobacco product among youth in North Carolina, with 16.9% of high school students currently using them, and with even more (23.3%) saying they plan to use them in the next year. Further, adolescents and young adults who have used e-cigarettes are more likely to report using traditional cigarettes at follow-up compared with those who had not.

This survey also asks some evidence-based questions that gauge susceptibility – intention to use. More teens are susceptible or considering e-cigarettes than combustible cigarettes.