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Statement of

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Good morning, Chairwoman DeLauro, Ranking Member Cole, and members of the Subcommittee. I am Dr. Anne Schuchat, the Principal Deputy Director of the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify before the Committee regarding CDC's investigation into lung injury associated with using e-cigarettes or other vaping products, and for your continued commitment to support CDC's work to protect Americans.

Introduction

On August 1, 2019, Wisconsin first alerted CDC to a cluster of pulmonary illness among young adults that began in July 2019. As of October 8, 2019, 1,299 lung injury cases associated with use of e-cigarettes or other vaping products have been reported to CDC from 49 states, DC and the U.S. Virgin Islands. Among 1,043 patients with data on age and sex, 70 percent of patients are male and 80 percent of patients are under 35 years old. The median age of cases was 24 years, with a range of 13 to 75; 15 percent of patients are below the age of 18 and 39 percent are between the ages of 18 and 24. This lung condition is serious, and we continue to learn of additional individuals who have become sick or who have died as a result of this outbreak. As of October 8, 2019, 26 deaths have been reported to CDC from 21 states, and we know that additional deaths are under investigation by states. These tragic deaths reinforce the urgency of efforts by CDC, in coordination with the U.S. Food and Drug Administration (FDA), state health departments, and others to identify the cause of this illness, provide recommendations to the public, and equip states with the necessary resources to address this emerging public health issue. The country is facing a new public health crisis with these lung injuries. The appearance of the lung injuries and the absence of infectious diagnoses suggests chemical exposure(s), and not an infectious disease. Patients first experienced their symptoms from a few days to several weeks after they most recently used e-cigarettes or other vaping products. Most patients reported a gradual onset of difficulty breathing, shortness of breath, or chest pain before hospitalization. Some patients reported mild to moderate gastrointestinal illness, sometimes preceding respiratory symptoms. Some patients have reported other symptoms, such as fatigue, fever, and weight loss.

CDC's mission is to protect the health, safety, and security of Americans. To accomplish this, CDC

leverages cutting edge science and dedicated experience in preparedness and response. Consistent with what we do for other emergency investigations, CDC implemented an incident command structure in August and, on September 16, activated its Emergency Operations Center. This enables CDC to dedicate more staff and resources to this investigation. To date, over 100 CDC staff have been working on this response. CDC continues to work directly with FDA, other Federal partners and with state and local health departments to identify affected individuals, characterize the extent of illness, and search for causes and risk factors of individuals suffering or dying from these lung injuries. We are also coordinating with international partners, including health officials in Canada and the United Kingdom. CDC has worked with different partners to: facilitate sharing of information about the illnesses, behaviors and use of e-cigarettes or other vaping products between state health departments and clinicians; analyze and link data to assist in investigations; conduct laboratory testing; coordinate national communication activities such as updates on the status of the investigation; provide public health and clinical recommendations; and provide health messaging tools for states, healthcare providers and the public.

Epidemiology Summary

The ongoing investigation into the cause of lung injury associated with use of e-cigarettes or other vaping products is challenging for a variety of reasons. First, the investigation spans almost all states and the U.S. Virgin Islands. Second, the investigation is complicated by the diversity of the e-cigarettes or other vaping products in the marketplace. There is a multitude of products, a wide array of ingredients, and an intersection with other substances such as marijuana. Third, people using these products do not know what is in the liquid solutions, and chemicals within the solutions may change when aerosolized in the e-cigarette or other vaping device. Moreover, many of the products and substances themselves can be modified by the distributor or the user. E-cigarettes or other vaping products and the liquid solutions and pods can be obtained from brick and mortar stores, online retailers, on the street, or through social sources. In addition, information about the use of e-cigarettes or other vaping products relies largely on self-report, and interviewees may be hesitant to share information about their use of substances such as marijuana.

The latest national findings suggest products containing tetrahydrocannabinol (THC), the main psychoactive compound of marijuana, are linked to a large percentage of the cases and may play a substantial role in the outbreak. Based on information from 573 patients who provided information on the substances they used in the three months prior to symptom onset, 76 percent reported using products containing THC, including 32 percent who reported exclusively using THC-containing products. Overall, 58 percent reported using nicotine-containing products, including 13 percent who reported exclusively using nicotine-containing products. Based on these findings, we believe THC-containing products may contain chemicals or components that are contributing to this outbreak, and that most of these products appear to be obtained from informal sources like friends and family off the street. However, because nicotine-containing products have been reported to be used, either alone or in conjunction with THC-containing products, we cannot exclude the possibility that nicotine-containing products may have a role. No one product, brand, chemical, or additive has been determined to be the cause of these lung injuries.

CDC's Collaboration with States

CDC's incident command structure comprises more than 100 staff from across the agency and in the field to coordinate activities, develop investigation tools and recommendations, and provide assistance to states, public health partners, and clinicians around the nation. As of October 1, 2019, CDC has deployed 15 field staff to 6 states at the request of the state health departments to assist in investigating these lung injuries. These staff members are in addition to the Epidemic Intelligence Service Officers and Career Epidemiology Field Officers who are already stationed in the state health departments. CDC also activated the Laboratory Response Network for Chemical Threats, which is a network of CDC, state, and local public health labs that provide critical lab testing support to the programs and providers who are responding to this outbreak.

CDC is coordinating regular multi-state conference calls with FDA, health officials, laboratory personnel, and others to exchange information. CDC is leading outreach to state health departments and clinicians, and working with FDA to gather information on devices or substances used, to help build a more comprehensive picture of these incidents. CDC is gathering reports of the types and brands of e-cigarettes or other vaping

products used, the substances used, any modifications of the products, and where the products and liquids were obtained. CDC also developed interim guidance for clinicians and the public in support of the investigation.

Additional laboratory investigations are underway to help identify the potential chemical cause or causes of lung injury associated with use of e-cigarettes and vaping products. Because of the variety of chemicals that are present in e-cigarette or other vaping product liquids and that may be added to these liquids, as well as the diversity of products in circulation, laboratory analyses may be complex. Thus, the identification of the cause or causes for the outbreak may take substantial time and continuing effort. CDC is also testing clinical samples from patients to identify whether any substances in vaping fluids are also found in the lungs or body fluids. Insufficient follow-up time has accrued to determine whether there will be long term consequences from lung damage in surviving patients.

CDC's Outreach

CDC ensures that the findings from the investigation are provided to the public, health care providers, and others as soon as possible. These findings are then translated into evidence-based recommendations. CDC communicates regularly with consumers, clinicians, and public health professionals through scientific publications, web products, social media, traditional media, and other channels.

On August 16, 2019, CDC released a Clinician Outreach and Communication Activity (COCA) Clinical Action Alert describing this investigation and asking providers to report possible cases to their state health departments. CDC released a Health Alert Network (HAN) Health Advisory on August 30, 2019, with specific recommendations for clinicians, health officials, and the public. On September 6, 2019, CDC released additional information through several reports in the Morbidity and Mortality Weekly Report (MMWR), including a summary from clinicians in North Carolina of clinical characteristics and e-cigarette or other vaping product use exposures among five cases in that state, as well as CDC guidance for public health officials, clinical providers, and the public about prevention, case identification, and reporting. On September 19, 2019, CDC conducted a follow-up COCA call with more than 2,500 clinicians in attendance, where we reviewed clinical features reported among cases, and provided CDC's recommendations for clinicians.

On September 27th, 2019, CDC released two additional MMWRs, one providing the first national comprehensive data on characteristics of cases reported to CDC, and the other presenting data from Wisconsin and Illinois investigators. Additional data from both states found that nearly all (96 percent) THC-containing products reported were packaged, prefilled cartridges, and 89 percent were primarily acquired from informal sources such as friends, family members, illicit dealers, or off the street. In contrast, 77 percent of nicotine-containing products were sold as prefilled cartridges, and 83 percent were obtained from commercial vendors. We do not know at this time whether the products reported by cases in Illinois and Wisconsin are also being reported by cases in geographically remote parts of the country, and this is a key issue for further investigation.

Challenges

This investigation has posed a number of challenges. First, most public health data collection and reporting systems are antiquated and fragmented, making it challenging to assure timely, actionable information while continuing to safeguard patient privacy. This investigation is emblematic of a challenge to all our work that requires rapid collection and analysis of public health data but is often reliant on paper-based systems and fax machines. Second, the nature of the investigation includes inherent challenges, as reports of use of illicit drugs may complicate data collection from patients. State laws vary regarding THC and cannabis use, which may make standardized and consistent data collection challenging. Finally, the e-cigarette and vaping marketplace is wide and diverse, with a multitude of substances that can be used with the devices. This can complicate toxicology testing (when there are a limited number of samples) and the interpretation of results (when there are many chemicals and substances that may be found across a wide variety of products).

Despite these challenges, CDC has taken positive steps to address the current crisis while also addressing the ongoing epidemic of e-cigarette use.

CDC's Efforts to Address the Epidemic of E-cigarettes

This outbreak comes at a time of epidemic-levels of e-cigarette use by young people in the United States. E-cigarettes have been the most commonly used tobacco product among youth since 2014, and their significantly increased use has erased earlier progress in reducing overall tobacco product use among youth.

Notably, e-cigarette use among high school students increased by 77.8 percent from 2017 to 2018. Additionally, preliminary data from the 2019 National Youth Tobacco Survey (NYTS) demonstrate that more than a quarter of high school students reported e-cigarette use within the past 30 days.

Flavors are one of many factors associated with youth use of tobacco. Specifically, flavors can increase the appeal of tobacco products to youth, promote youth initiation of tobacco products, and result in lifelong tobacco product use. Recent data published earlier this month by FDA and CDC from the NYTS found that in 2018, 67.8 percent of high school students who reported using e-cigarettes within the past 30 days used flavored e-cigarettes. These data also indicated that during 2014 to 2018, current use of flavored e-cigarettes increased among high school students.

CDC is engaged in multi-faceted efforts to prevent and reduce use of all tobacco products, including e-cigarettes, among young people. In collaboration with our partners and other Federal agencies, CDC collects data and conducts research on youth use of tobacco products. For example, CDC and FDA jointly administer the National Youth Tobacco Survey, an annual survey to monitor national trends in the use of tobacco products among U.S. students in grades 6 through 12. This survey has been essential in identifying the extent and scope of the current youth e-cigarette epidemic in this country. CDC also complements its routine surveillance efforts with novel, rapid response monitoring that captures emerging trends concerning e-cigarettes, including through the use of sales data to monitor sub-annual changes in the U.S. e-cigarette marketplace. In addition, the Tobacco Laboratory in CDC's Environmental Health Laboratory provides critical laboratory science, including measuring harmful and addictive constituents in e-cigarette solutions and aerosol, and measuring chemicals in the blood and urine of people who use e-cigarettes or are exposed to secondhand aerosol.

CDC has been at the forefront of this issue for many years. In 2013, CDC published a report highlighting a doubling in youth e-cigarettes use during 2011-2012, which initiated our efforts to warn the public, and others, about the health risks of e-cigarette use among U.S. youth. Since then, CDC has continued those efforts. For example, in 2016, CDC collaborated with the Surgeon General to release a Surgeon General's report entitled "*E-Cigarette Use Among Youth and Young Adults.*" This was the first comprehensive federal report on e-cigarettes

among young people. Since then, CDC has continued to promote the findings of the report to educate parents, influencers of youth, and youth themselves. In response to compelling data about the sales and increased market share of JUUL, reports of widespread teen use of this and similar products, and mounting public concerns, CDC launched a partner initiative to expand the reach of CDC public health warnings. CDC developed plain-language infographics and social media posts for public health organizations and consumer audiences about e-cigarettes and has conducted back-to-school social media campaigns. CDC was the primary federal agency that assisted the Office of the Surgeon General in writing and launching a December 2018 e-cigarette advisory to bring awareness to relevant audiences (teachers, parents, clinicians) about e-cigarette use by young people. CDC also developed promotional materials to support the release of the advisory.

CDC provides funding and technical support to all 50 states, the District of Columbia, 8 U.S. territories, 12 tribal support organizations, and 8 national networks representing priority populations, which are essential for coordinating the public health response to prevent tobacco initiation among youth and young adults, promote quitting among youth and adults, eliminate secondhand exposure to smoke and e-cigarette emissions, and identify and eliminate tobacco-related disparities. With funding from CDC, state and territorial health departments have taken a number of approaches to reduce youth access and exposure to e-cigarettes, including preparing nicotine health advisories and tobacco-free school toolkits, conducting surveillance of tobacco product use among youth, and creating and disseminating evidence-based educational materials to the public through social media and other mechanisms. CDC has ongoing work to prevent and reduce tobacco use, including e-cigarettes.

CDC's Efforts to Understand the Harms Associated with Marijuana Use

The exposure to vaping products containing THC in most patients in this outbreak underscores the need to better understand the health effects of increasing marijuana use in the United States and the changing marketplace as states continue to pursue legalization of marijuana for medical and nonmedical purposes. According to the 2018 National Survey on Drug Use and Health, more than 43 million (16 percent) Americans age 12 years or older reported using marijuana in the past year. Marijuana use among youth and young adults is

particularly concerning given the potential risks to the developing brain. In 2018, one in eight 12 to 17 year-olds and one in three 18 to 25 year-olds reported marijuana use. Prolonged heavy marijuana use has been associated with health effects, and health effects have also been documented in young people.

CDC data indicate that many youth who use e-cigarettes also report using marijuana in vaping devices; for example, data from the 2016 National Youth Tobacco Survey found that one-third of U.S. youth who use e-cigarettes reported using marijuana in vaping products, including approximately one-quarter of middle school users.

CDC conducts limited surveillance, monitoring, technical assistance, and public education related to marijuana. For example, questions regarding marijuana use have been developed for inclusion in the Youth Risk Behavior Survey (YRBS) and are being asked in a limited number of states through the Behavioral Risk Factor Surveillance System (BRFSS) and the Pregnancy Risk Assessment Monitoring System (PRAMS). In addition, CDC is providing informal technical assistance to state, local, tribal, and territorial officials when requested, with a focus on preventing harms, particularly in vulnerable populations such as youth, young adults, and pregnant women. CDC's marijuana webpage (<https://www.cdc.gov/marijuana/>) provides information on health effects, data and statistics, and offers resources and tools for the public. Finally, CDC collaborates with other federal agencies on scientific workgroups to address emerging issues and work toward consensus on indicators and measures to monitor marijuana use and health effects.

CDC Interim Outbreak Recommendations for Providers, States and the Public

CDC continues to refine recommendations based on emerging data. At this time, FDA and CDC have not identified the cause or causes of the lung injuries in these cases and the only commonality between all cases is that patients report the use of e-cigarettes or other vaping products. As noted previously, there may be more than one cause of this outbreak, and many different substances and product sources are still under investigation. To date, national and state data suggest that products containing THC, particularly those obtained off the street or from other informal sources (e.g., friends, family members, illicit dealers), are linked to most of the cases, and play a major role in the outbreak. 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. CDC recommends that persons do not use vaping products that contain tetrahydrocannabinol (THC). At present, CDC recommends persons consider refraining from using e-cigarettes or vaping products that contain nicotine. Regardless of the investigation, e-cigarettes or other vaping products should never be used by youths, young adults, or women who are pregnant. CDC will continue to refine recommendations based on the data emerging from this complex outbreak. Updated information and recommendations related to this investigation is available at <https://www.cdc.gov/lunginjury>.

Conclusion

CDC's foundation of public health work, including direct relations to state and local governments, is essential to the nation's ability to respond to expected, unexpected, and unimaginable threats. CDC provides the majority of its funding to state and local communities to support public health. CDC shares critical information with clinical providers, public health departments, laboratories, and the public, to help prevent additional cases and to rapidly identify and treat affected individuals. We are fully committed to collecting data on this issue as quickly as possible and using this science to inform evidence-based recommendations to protect the American public from this health risk. CDC is working around the clock, together with state and local health officials and FDA to identify the cause or causes of this outbreak and will continue to keep Congress up to date on our progress in this rapidly evolving investigation.