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Statement of

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Good morning, Chairman Krishnamoorthi, Ranking Member Cloud, 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 you regarding CDC's investigation into lung disease associated with using e-cigarette or vaping products, and for your continued commitment to supporting CDC's work in protecting public health.

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 September 18, 2019, 38 states and one territory have reported 530 confirmed and probable cases of lung disease associated with e-cigarette use or vaping. Six states (California, Illinois, Indiana, Kansas, Minnesota, and Oregon) have reported the death of a patient who had been hospitalized with lung disease with a history of recent e-cigarette or other vaping product use. As of September 18, there have been seven reported deaths. These tragic deaths reinforce the urgency of efforts by CDC, in coordination with the U.S. Food and Drug Administration (FDA), to identify the cause of this illness and to equip states with the necessary resources to address this emerging public health issue.

As you know, CDC's mission is to protect America from health, safety and security threats. CDC leverages cutting edge science and experience in preparedness and response to effectively protect Americans from public health threats. 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 to enable it to dedicate more resources to this investigation. CDC works directly with state and local health departments as they identify cases, better describe illnesses, and search for causes and risk factors. CDC facilitates information sharing between state health departments and clinicians, analyzes data and conducts investigations, coordinates national communication activities such as updates on the status of the investigation, and provides health messaging tools for states.

Epidemiology Summary

The ongoing investigation into the cause of lung injury associated with e-cigarette or vaping product use is challenging for a variety of reasons. First, the investigation covers a large number of states. Second, the investigation is complicated by the diversity of the e-cigarette or vaping product marketplace, with a multitude of products, a wide array of ingredients, and the intersection with potentially illicit substances such as marijuana. Users do not know what is in their e-cigarette or vape solutions. Moreover, many of the products and substances themselves can be modified by the user. They can be obtained from brick and mortar stores, online retailers, on the street, or through social sources. Our preliminary results are from data collected from dozens of states. In addition, data collection on the products used relies on self-reporting, and interviewees may be hesitant to share information about their use of illicit substances such as marijuana. According to data collected in two states and recently published in the New England Journal of Medicine, most patients (around 80 percent) reported using e-cigarette or vaping product liquids containing tetrahydrocannabinol, or THC (a psychoactive compound of marijuana), and more than half (around 60%) reported using liquids with nicotine, while around 10-20 percent reported using products with nicotine only. No single e-cigarette or vaping product, brand or specific substance has been definitively linked to the outbreak.

CDC has received complete sex and age data on 373 of 530 cases. Nearly three-fourths of cases are male. Two-thirds of cases are 18 to 34 years old. Sixteen percent of cases are under 18 years and 17 percent are 35 years or older. Patients reported use of e-cigarette or other vaping products which could include devices, liquids, refill pods, and/or cartridges. The lung injuries observed in this outbreak does not appear to be due to infection. The pathologic appearance and absence of infectious diagnoses suggests chemical exposure(s). Patients first experienced their symptoms from a few days to several weeks after they most recently used e-cigarette or 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. Investigators have not identified any specific product or compound that is linked to all

cases thus far.

CDC's Collaboration with States

CDC and FDA are working closely with and providing a coordinating function to state and local health officials to investigate these incidents as quickly as possible and aggregate information across states. CDC activated its Emergency Operations Center on September 16. CDC's incident command structure comprises more than 80 staff from across the agency to coordinate activities, develop investigation tools and guidance, and provide assistance to states, public health partners, and clinicians around the nation.

Shortly after Wisconsin first alerted CDC on August 1, 2019, to a cluster of pulmonary illness among young adults that began in July 2019, CDC learned that there also were possible similar cases in Illinois. Wisconsin and Illinois state health departments requested an "Epi Aid," a formal assistance mechanism, from CDC on August 14, and August 16 respectively. Four CDC staff, including two Epidemic Intelligence Service Officers, were deployed to Illinois and Wisconsin on August 20, 2019, to assist with their respective state investigations. Building on the tools that were developed in Wisconsin and Illinois, CDC staff worked with all the states and the Council of State and Territorial Epidemiologists to help develop a standardized surveillance case definition and medical data collection tools to allow for more consistency across the states as they complete their own investigations and verify and classify their cases.

When state investigators learn of suspected cases, they examine the medical records and consult with the clinical care team for each case. Using the standard case definition that has been developed, the state investigators then determine which cases are confirmed and which are probable. In both confirmed and probable cases, the patient recently used an e-cigarette product or vaped, developed a breathing illness, and other common causes of illness were ruled out as the primary cause of the illness. Confirmed and probable cases differ in the certainty with which an infectious cause is ruled out. But because the differences between these definitions are subtle, CDC reports confirmed and probable cases together for simplicity. In addition to approaching the investigation from this clinical perspective, clinicians and public health departments are also

interviewing patients to gather more information about the devices and substances used as well as individual behaviors.

CDC has established a data reporting system which has been made available for states to enter data or to send data to CDC in an effort to describe the outbreak and define causes. CDC also reaches out to state health departments when it receives anecdotal reports of possible cases from clinicians and other sources. The reported information will allow CDC to aggregate and analyze the data across states to provide a better national picture of this emerging health issue.

CDC is coordinating regular multi-state conference calls with health officials, laboratory personnel, and others to exchange information and is leading outreach to state health departments and clinicians, as well as coordinating efforts 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-cigarette or vaping products used, the substances used, any modifications of the products, and where the products and liquids were obtained. This information will be shared with FDA to help FDA assess which of the products fall within FDA's regulatory authority. CDC also developed interim guidance for clinicians and the public in support of the investigation.

Based on CDC's expertise in evaluation of e-cigarette or vaping devices and solutions, additional investigations are in development to help identify the potential chemical cause or causes of lung disease associated with use of e-cigarettes and vaping products. Because of the variety of chemicals that are present in e-cigarettes or vaping liquids and that may be added to e-cigarette or vaping liquids, as well as the diversity of products in circulation, laboratory analyses may be complex. In addition, users can modify the products, and the heating process can also influence the types and amounts of chemicals a user is exposed to. Thus, the identification of the cause or causes for the outbreak may take substantial time and continuing effort.

CDC's Outreach

CDC is the source of public health information on this investigation and ensures that the findings from the investigation, as well as evidence-based interim recommendations, are provided to the public, health care

providers, and others as soon as possible. CDC has communicated to 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 the Morbidity and Mortality Weekly Reports (MMWRs), a summary from clinicians in North Carolina of clinical characteristics and e-cigarette or vaping product use exposures among five identified cases in that state, as well as CDC guidance for public health officials, clinical providers, and the public about prevention, case identification, and reporting.

The New England Journal of Medicine article by authors from the Illinois and Wisconsin health departments in collaboration with CDC authors was also published on September 6. The article summarized the clinical characteristics and e-cigarette or vaping product use exposures among 53 Wisconsin and Illinois cases. Many of the patients, but not all, reported recent use of products containing THC, and some reported using both THC- and nicotine-containing products. Around 10-20 percent of cases report using nicotine-containing products only.

CDC and FDA are working tirelessly to investigate whether the disease may be linked to specific ingredients or contaminants in the devices or substances associated with e-cigarette or vaping product use.

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 rather than electronic reporting and systems that are not interoperable. 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 released interim recommendations for healthcare providers, health departments, and the public, and CDC will continue to provide evidence-based recommendations as we learn more.

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

This outbreak comes in the middle of epidemic-level use of e-cigarettes by young people in the United States and reinforces the need to address the broader e-cigarette epidemic in the United States. Youth are much more likely than adults to use e-cigarettes. In fact, e-cigarettes are the most commonly used tobacco product among youth and their increased use has erased recent progress in reducing overall use of tobacco among youth. Preliminary data from the 2019 National Youth Tobacco Survey show a continued rise in rates of youth e-cigarette use. The data show that in 2019, more than a quarter of high school students were current (past 30 day) e-cigarette users, a substantial increase in e-cigarette use among youth since 2017. E-cigarette use among high school students increased by 77.8 percent from 2017 to 2018, and more than one in four high school students reported current use of any tobacco product. As a result, the U.S. Surgeon General in December 2018 called the use of e-cigarettes among youth an epidemic in the United States.

CDC is engaged in multifaceted 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, including e-cigarettes. CDC and FDA jointly administer the National Youth Tobacco Survey (NYTS), an annual survey to monitor trends in the use of tobacco products among U.S. students in grades 6 through 12. CDC complements its routine surveillance efforts with novel, rapid response monitoring that captures emerging trends concerning e-cigarettes, such as the rise of e-

cigarette sales from 2013 to 2017. 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 also educates the public about the harms of tobacco products, including e-cigarettes. 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 report on e-cigarettes among young people released by the U.S. government. 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, which was the first such advisory on a tobacco related topic released by the Office of the Surgeon General.

Through the National Tobacco Control Program, 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's Efforts to Understand the Harms Associated with Marijuana Use

CDC is working to monitor cannabis use, identify associated health effects, and increase the surveillance capacity of CDC and state/local jurisdictions. The exposure to e-cigarettes or vaping products containing THC in many patients in this outbreak suggests the need to 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 or recreational use. In 2018, an estimated 16 percent of the population age 12 and older reported using marijuana in the past year. The potency of THC in marijuana and the different products available have significantly increased over the last two decades.

CDC Interim Outbreak Recommendations for Providers, States and the Public

CDC has released interim recommendations for healthcare providers, health departments, and the public to supplement its existing e-cigarette and vaping product messaging. As we learn more about this outbreak, CDC will continue to provide evidence-based recommendations. While this investigation is ongoing, CDC recommends that individuals who are concerned about lung disease associated with e-cigarette use or vaping consider refraining from vaping or using e-cigarette products**.** CDC recommends that, regardless of the ongoing investigation, anyone who uses an e-cigarette or vaping products should not buy these products (such as e-cigarettes or vaping products with THC or other cannabinoids) off the street and should not modify or add any substances to these products that are not intended by the manufacturer. In addition, regardless of the ongoing investigation, e-cigarette products should not be used by youth, young adults, pregnant women, or adults who do not currently use tobacco products.

CDC recommends adults who use e-cigarette products or vape because they have quit cigarette smoking should not return to smoking cigarettes. Those who need help quitting tobacco products, including e-cigarettes, should contact their doctor. Adult smokers who are attempting to quit should use evidence-based treatments, including counseling and FDA-approved medications. People who have recently used e-cigarette or vaping products should seek medical attention if they experience symptoms associated with this outbreak, such as

cough, shortness of breath, or chest pain.

CDC will share more information as it becomes available. Updated information 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 prioritizes sharing information with clinical providers, public health departments, toxicologists and laboratories, and the public, to help prevent additional cases and to rapidly identify and treat affected individuals. 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.