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Statement of

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Introduction

Good morning, Chairman Alexander, Ranking Member Murray, and members of the Committee. 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.

On August 1, 2019, Wisconsin first alerted CDC to a cluster of pulmonary injury among young adults that began in July 2019. Since that date, CDC has been putting its scientific expertise to use across epidemiologic, laboratory, and clinical realms to address this public health crisis. CDC's response efforts are committed to: identify and define the risk factors and the sources for e-cigarettes or other vaping product use associated lung injury (EVALI); detect and track confirmed and probable cases in the United States; communicate actionable recommendations to state, local, and clinical audiences; and establish laboratory procedures to assist with public health investigations and patient care. Throughout this investigation, CDC has been partnering with colleagues at the U.S. Food and Drug Administration (FDA), state and local health departments, and other public health and clinical stakeholders to gain a comprehensive understanding of EVALI and the potential cause or causes.

As of November 5, 2019, there are 2051 confirmed and probable cases of EVALI reported by 49 states, Washington, D.C., and the U.S. Virgin Islands. 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. This lung condition is serious. As of November 5, 2019, 39 EVALI deaths have been confirmed in 24 states and Washington, D.C., and we know that additional deaths remain under investigation by states. These tragic deaths reinforce the urgency of CDC's efforts, in close coordination with others, to identify the cause of this illness, provide recommendations to the public on how to prevent further illnesses and deaths from occurring, and to assist states to address this public health outbreak.

EVALI presents our nation with a new public health crisis. And as the nation's health protection agency, CDC is leveraging its cutting-edge science and expertise in public health preparedness to quickly and nimbly respond. As we do for other emergency investigations, CDC implemented an incident management structure in August 2019 and, on September 16, 2019, activated its Emergency Operations Center. Doing so has allowed CDC to dedicate more staff and resources to this investigation. To date, approximately 300 CDC staff have been engaged in response efforts, including CDC staff who have been deployed to assist state health departments in investigating lung injuries within their jurisdictions. We also have stood up an international team that is maintaining communication with our international public health partners.

CDC is working 24/7 with FDA and state and local health officials to get at the root cause or causes of these lung injuries. CDC is in continuous discussions with states to determine ongoing and additional needs to assist in gathering data and information to monitor and identify what is leading to these lung injuries. CDC is collaborating with a wide range of partners to: facilitate sharing of information about the illnesses, and 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 information to states, healthcare providers, and the public.

Summary of the Epidemiology

In responding to public health emergencies, CDC's first steps are to understand what is happening, establish where it is happening, and collect as rapidly as feasible relevant data to inform our next steps. For this response in particular, we are aggregating data from our epidemiologic investigation with findings from our laboratory testing of clinical and product samples, in collaboration with FDA, to help identify who is most at risk and the specific substances or ingredients that may be causing these lung injuries.

The ongoing investigation into the cause or causes of EVALI is challenging for many reasons. First, the investigation spans almost all states and the U.S. Virgin Islands. Second, EVALI is a diagnosis of exclusion since, at present, no specific test or marker exists for its diagnosis in a patient. Third, this investigation is complicated by the diversity of the e-cigarettes or other vaping products in the marketplace. There are hundreds of products, and thousands of e-liquids used by people who use e-cigarettes or other vaping products. Fourth, people using these products may not know the ingredients in the liquid solutions, and chemicals may change when aerosolized in the e-cigarettes or other vaping products. Moreover, many of the products and substances themselves can be modified by the distributer or the user. They can be obtained from brick and mortar stores, online retailers, on the street, through the internet, or through social sources. In addition, information about the use of e-cigarettes or other vaping products relies largely on self-reporting, and interviewees may be hesitant to share information about their use of substances such as THC.

National data suggest that THC-containing products are playing an important role in this outbreak. Previously published reports from Illinois, Utah, and Wisconsin suggest that patients typically obtained their THC-containing vaping products through informal sources, such as friends or illicit in-person and online dealers, although local and regional differences in illicit THC supply and production seem to exist. CDC has regularly collected and shared information about the outbreak. On October 28, 2019, a report published in CDC's Morbidity and Mortality Weekly Report (MMWR) provided information on 867 EVALI patients with available data on substances used. Of these, 86% reported any use of THC-containing products in the three months preceding symptom onset, and 64% reported any use of nicotine-containing products in that period. For the same period, 52% reported use of both THC-containing products and nicotine-containing products, 34% reported exclusive use of THC-containing products, and 11% reported exclusive use of nicotine-containing products. Two percent of patients reported no use of THC- or nicotine-containing products in that period.

This outbreak continues to disproportionately affect persons under the age of 35, highlighting the need to communicate the dangers of using e-cigarettes or other vaping products among youth and young adults, irrespective of the substances they are using in these products. In addition to the risk of severe lung injury, use of these products is also dangerous to young people because THC and nicotine both can have lasting adverse effects on brain development.

CDC's Collaboration with States

CDC staff from across the agency currently are involved in the response to coordinate activities, develop resources, and provide assistance to states, public health partners, and clinicians around the nation. In addition to those working on this response from agency headquarters, CDC staff also have been present

on the ground within different states. As of November 2, 2019, CDC has deployed a total of 22 staff to eight states to assist state health departments, at their request, 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 laboratories that provide critical laboratory testing support to the programs and providers who are responding to this outbreak.

CDC is providing scientific expertise to assist state and local public health jurisdictions. To enhance collection and analysis of data about the products, ingredients, and compounds that may be responsible for this outbreak, early on CDC worked with states and the Council of State and Territorial Epidemiologists (CSTE) to develop a uniform report form for states to use to collect data on cases, and our agency has been partnering with states to compile those data. Again collaborating with states and CSTE, CDC recently revised the national data collection instrument to provide a more streamlined means for states to collect and report their data. CDC continues to work closely with states to explore additional quantitative and qualitative studies to increase our understanding of this outbreak and product use behaviors among EVALI patients.

CDC's provision of assistance to states likewise extends to process improvements for sharing and analyzing case-associated data. For instance, CDC has implemented a data integration and management platform called DCIPHER (Data Collation and Integration for Public Health Event Response) for use in this outbreak response. This platform enables states to directly enter or import and view their data. In October 2019, CDC began piloting the use of DCIPHER with a subset of states and, as of November 2019, this platform is now available for use across all states.

CDC also is leading outreach to states in collaboration with FDA to gather information on case-associated devices and substances 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.

In October 2019, CDC expanded its laboratory testing in support of the lung injury outbreak to conduct analyses of aerosol emissions from case-associated e-cigarettes and other vaping products. Aerosol emissions testing will be conducted by CDC's Division of Laboratory Sciences, which will apply its over decade-long experience characterizing e-cigarette aerosol emissions to products associated with this outbreak. CDC's aerosol emissions testing complements FDA's testing of the case-associated e-liquids. When combined with epidemiologic and clinical laboratory data, the results found by testing case-associated product samples may provide insight into the nature of the chemical exposure or exposures contributing to EVALI.

In addition, CDC continues to offer testing of states' pathologic specimens, including lung biopsy or autopsy specimens, associated with patients, as well as testing of bronchoalveolar lavage fluid (BAL), and any blood or urine samples that are paired with BAL fluid. CDC also expanded its laboratory testing to include cannabinoids, including THC, in case-associated urine samples. CDC developed and published clear guidance documents to assist public health laboratories, healthcare providers, pathologists, and others with specimen collection, storage, and submission to CDC for testing, which is posted on our website.

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

are complex. Thus, despite CDC's enhanced laboratory capacity to assist in this outbreak, the identification of the cause or causes for EVALI may take considerable time and continuing effort.

CDC's Outreach

CDC ensures that the findings from the investigation are provided in a timely manner to the public, healthcare providers, and others. 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. As of November 1, 2019, CDC has hosted seven national media telebriefings on the outbreak, joined by colleagues from the FDA and selected state health department investigators.

Throughout this investigation, CDC has been dedicated to providing guidance and targeted communications to healthcare providers. 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 of EVALI to their state health departments. This was followed by 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 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 October 25, 2019, CDC published a factsheet for healthcare providers regarding evaluating and caring for patients with suspected EVALI.

CDC's Lung Injury website houses information specifically for healthcare providers that is updated on a continual basis. For instance, we recently included information for healthcare providers that specifically relates to influenza. As noted on our website, during flu season, CDC recommends that healthcare providers should consider flu in all patients with suspected EVALI. We also note that antivirals should be considered in accordance with established guidelines and that decisions on initiation or discontinuation of treatment should be based on specific clinical features and, when appropriate, in consultation with specialists.

Challenges

Despite all momentum gained and promising work underway across CDC, this investigation has posed a number of challenges. Public health runs on data. Protecting America's health requires reliable and up-to-date information to prevent, detect, and respond to health threats. 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 our agency's overall work, which requires rapid collection and analysis of public health data but is often reliant on paper-based systems and fax machines.

Timely surveillance, particularly concerning newly emerging and rapidly evolving forms of tobacco products and cannabis use other than smoking (e.g., vaping, dabbing, edibles), in the United States is nascent. Although there have been contributory efforts to improve surveillance in recent years, this

outbreak, against a background of limited estimates of baseline rates of use and use behaviors related to THC use in e-cigarettes or other vaping products highlights that data collection and analysis efforts have not kept up, either technologically or with the changing landscape of e-cigarette or other vaping product use. Another inherent challenge of this investigation is the complication introduced by the reporting of potentially illicit drug use from patients. State laws vary regarding THC and cannabis use, which may make standardized and consistent data collection challenging.

Finally, the marketplace for e-cigarettes or other vaping products is wide and diverse, with a multitude of substances that can be used with the devices. This can complicate toxicology testing and the interpretation of results. Despite these challenges, CDC has taken positive steps to address the EVALI outbreak while also continuing to address the ongoing epidemic of e-cigarette use by youth in our nation.

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

The EVALI 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 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 NYTS, 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 United States 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 youth, aged 12 to 17 years, and one in three aged 18 to 25 years reported marijuana use. Prolonged heavy marijuana use has been associated with a broad range of health effects, and health effects have also been documented in young people, in particular those that initiated marijuana use at an early age.

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 have ever used an e-cigarette or other vaping product reported using marijuana in an e-cigarette or other vaping product, including approximately one-quarter of middle school users.

CDC conducts limited surveillance, monitoring, technical assistance, and public education related to marijuana. For example, a small number of questions regarding marijuana use are included 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 (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 data and scientific findings emerging from this complex outbreak. To date, no single compound or ingredient has emerged as the cause of EVALI, and there may be more than one cause. Because most EVALI patients report using THC-containing products before the onset of symptoms, CDC recommends that persons should not use e-cigarette, or vaping, products that contain THC. Persons should not buy any type of e-cigarettes or other vaping products, particularly those containing THC, off the street and should not modify or add any substances to e-cigarettes or other vaping products that are not intended by the manufacturer, including products purchased through retail establishments. In addition, because the specific compound or ingredient causing lung injury is not yet known, and while the investigation continues, persons should consider refraining from use of all e-cigarettes or other vaping products. Regardless of this investigation, e-cigarettes or other vaping products should never be used by youths, young adults, or women who are pregnant. Adults who are using e-cigarettes or other vaping products to quit smoking should not return to smoking; they should weigh all risks and benefits, and consider using FDA-approved medications. Updated information and recommendations related to this investigation are available at www.cdc.gov/lunginjury.

Conclusion

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