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Hearing on "Vaping in American: E-Cigarette Manufacturers' Impact on Public Health"
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Chair DeGette, Chairman Pallone, Ranking Members Guthrie and Walden, other Distinguished Subcommittee Members:

Thank you for convening today's hearing.

My name is K.C. Crosthwaite and I am CEO of JUUL Labs, a position I assumed when I joined the company about four months ago.

At JUUL Labs, our thousands of U.S. employees are committed to helping adult smokers transition away from combustible cigarettes, while combatting the serious problem of underage use.

As we look at the vapor category, it is helpful to begin by noting the significant changes that have taken place in a relatively short period.

At the start of 2019, most Americans lived in states where the legal age of purchase was just 18. Vapor products were available in a wide array of flavors. There was low awareness of black-market vapor products. And the deadline for PMTA submissions to the FDA was uncertain.

In contrast, today, 21+ is the law of the land thanks to many of you on this Committee. Under FDA guidance, pod-based products are now available in only Tobacco and Menthol, flavors that can be found in currently available cigarettes. Congress, the FDA and the President have raised the alarm on black-market products. And the PMTA deadline of May 2020 is rapidly approaching.

At JUUL Labs, we recognize the importance of these steps.

Over the past few years, trust in our company and category has eroded. We know some of our past actions have contributed to that erosion, and we are committed to taking concrete action to re-earn trust.

Upon joining the company, I directed a comprehensive review of our policies and practices. Out of that review we halted our broadcast, print and digital product advertising. We voluntarily restricted the sale of flavors other than Tobacco and Menthol. And we restructured our company to allocate significant resources toward technologies aimed at combatting underage usage and conducting the research required to support our PMTA submission.

Clearly, we still have a very long way to go. Underage use rates remain unacceptably high.

But we believe that this challenge can and must be met. It threatens the entire harm reduction opportunity represented by vapor products. And that opportunity is too important to lose.

Combustible cigarettes remain the leading cause of preventable death in our country and worldwide.

More than 34 million Americans still smoke. Each year, nearly half a million Americans die from smoking-related diseases – 1 person every minute. The economic costs exceed $300 billion.

To be clear, anyone who doesn't use nicotine, shouldn't start. Anyone who smokes should quit. For those who cannot or will not quit, less harmful alternatives, like vapor products, should be available.

As the FDA noted in 2017, "[N]icotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes." The FDA stated its intent to encourage, "development of innovative tobacco products that may be less dangerous than cigarettes."

JUUL products are one example of this type of innovation.

Our products are not risk-free. But research indicates that vapor products are substantially lower-risk than cigarettes and that many, if not most, adult smokers who try JUUL products are able to successfully transition completely off of cigarettes to our products.

For example, in 2015, Public Health England, an executive agency of the Department of Health and Social Care in the U.K., first issued its report on the science and public-health effects of e-cigarettes and found that "using [e-cigarettes] is around 95% safer than smoking." Moreover, "[e]ncouraging smokers who cannot or do not want to stop smoking to switch to [e-cigarettes] could help reduce smoking related disease." Public Health England has continued to reaffirm this statistic over the years, based on a broad review of available science.

In 2016, the Royal College of Physicians (U.K.) issued a report entitled Nicotine Without the Smoke in which it surveyed the potential of harm reduction to address the death and disease of tobacco smoking. As the report noted, smoking combustible cigarettes "contributes to more social inequalities in health, and to overall death and disability, than any other avoidable cause." The Royal College of Physicians recommended that for adult smokers who do not respond to traditional methods for cessation, effective tobacco-control policy should promote harm-reduction alternatives, such as e-cigarettes and other novel nicotine products that deliver the addictive chemical but without the smoke. In conclusion, "[a]lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure."

In 2017, the U.S. FDA outlined its own comprehensive plan for tobacco and nicotine policy. The plan initially had two key objectives: (i) to reduce the nicotine levels in combustible cigarettes to levels that minimize their addictiveness; and (ii) to encourage the development and broader use of innovative noncombustible nicotine products as less harmful alternatives. As both then-Commissioner Gottlieb and Director Zeller noted: "Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year. The FDA's approach to reducing the devastating toll of tobacco use must be rooted in this foundational understanding: other chemical compounds in tobacco, and in the smoke created by combustion, are primarily to blame for such health harms." Thus, a critical tool would be to foster innovation in less harmful products which delivered nicotine without the burning of tobacco.

In 2018, the National Academies of Sciences, Engineering and Medicine (NASEM) (U.S.) released its report on the health effects of e-cigarettes. While the crux of the report focuses on recommendations for further research, NASEM determined "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes." NASEM's balanced approach recognizes the likely public-health benefit for adult smokers, while guarding against the potential for initiation and use among those underage.

In addition to the work of major public health bodies, independent institutional researchers have also assessed the health impacts of vapor products. This original research includes toxicological and clinical assessments of the potential reduced exposure and/or risk to the individual user compared to smoking combustible cigarettes, as well as studies on the ability of vapor products to transition adult smokers from combustible use.

In peer-reviewed literature published in the Annals of Internal Medicine, Shahab, et al. assessed exposure to nicotine, tobacco-related carcinogens, and toxins among smokers of combustible cigarettes only, former smokers with long-term e-cigarette use only, and former smokers with long-term nicotine replacement therapy (NRT) use only, long-term dual users of both combustible cigarettes and e-cigarettes, and long-term users of both combustible cigarettes and NRTs. The researchers found that long-term users of both e-cigarettes only and NRTs only demonstrated substantially lower levels of known tobacco-related carcinogens and toxins compared to users of combustible cigarettes.

In Nicotine & Research, Goniewicz, et al. assessed changes in nicotine metabolites and seventeen biomarkers of exposure (BOEs) relating to tobacco smoke in the urine samples of twenty smokers. Samples were collected before and after switching to an e-cigarette for two weeks. Biomarkers consisted of thirteen major carcinogens and toxicants in cigarette smoke. After two weeks of e-cigarette use, study subjects presented a substantial reduction in exposure to selected carcinogens and toxicants, while nicotine exposure remained unchanged. According to the researchers, "[t]hese findings suggest that e-cigarettes may effectively reduce exposure to toxic and carcinogenic substances among smokers who switched to these products."

In addition to this independent research, our company also has developed a robust regulatory science program to assess the population health impact of JUUL products and, critically, support our PMTA for FDA's scientific review. Our scientific research program includes three core areas: (i) nonclinical research; (ii) clinical research; and (iii) behavioral research.

Our nonclinical research examines the JUUL e-liquid and aerosol through various analytical, chemistry, and toxicological assessments in laboratory settings. This includes evaluating the presence of harmful and potentially harmful constituents (HPHCs) found in the smoke of combustible cigarettes compared to the aerosol of JUUL products. FDA has identified these HPHCs as chemicals or chemical compounds in tobacco products or tobacco smoke that cause or could cause harm to smokers and nonsmokers.

JUUL product aerosol analyses show substantial, or approximately 99%, reductions in several HPHCs, including, but not limited to carcinogens such as formaldehyde, NNN and NNK, compared to combustible cigarette smoke. Among other product features, the JUUL system's temperature-regulation control, which maintains an average heating temperature below 300°C, aerosolizes the e-liquid formulation and minimizes the formation of toxic chemicals.

Our clinical research program examines the impact of JUUL products on human health. Research areas include pharmacokinetic studies (i.e., the rate and level of nicotine absorption in the body), topography studies (i.e., individual use and puff patterns), second-hand exposure studies (i.e., the potential second-hand aerosol exposure in real-world settings), and biomarker-of-exposure (BOE) studies (i.e., the exposure to chemicals tied to potential harm in the body).

In one published clinical study, we examined changes, relative to baseline, in primary urine and blood biomarkers of exposure (BOEs) in 90 adult smokers. The selected short-term BOEs were linked to carcinogens and toxicants observed in the use of combustible cigarettes. Study subjects were randomized into six groups and, over five days, used JUUL products, abstained from tobacco use, or continued use of their usual brand of combustible cigarettes. The study found that all eight non-nicotine urine BOEs were reduced by an aggregate of 85.3% in the abstinence group compared to an 85% aggregate reduction in the JUUL product group. This represented a 99.6% relative reduction in aggregate BOEs for the JUUL product group. In the cigarette group, the same BOEs increased by an aggregate of 14.4%.

Alongside the research indicating that vapor products, including JUUL products, may be lower down the risk continuum from cigarettes, there is also substantial and growing evidence that vapor products generally and JUUL products in particular are more successful than products previously brought to market to help adult smokers transition away from cigarettes.

In the New England Journal of Medicine (NEJM), Hajek, et. al. conducted a randomized controlled trial involving adult smokers to assess the efficacy of NRTs and e-cigarettes in

smoking abstinence. A total of 886 participants were randomized into one of two arms (NRT or e-cigarette) and underwent evaluation for one year, with biological validations to assess compliance. The rate of one-year abstinence was 18.0% in the e-cigarette group and 9.9% in the NRT group.

Our company's own behavioral research similarly finds significant switch rates from combustible cigarettes among adult smokers. Our behavioral research program includes real-world assessments of JUUL product use, such as complete switching from combustible cigarettes to JUUL products and, for adult smokers that are still transitioning from combustible use, significant reductions in the number of cigarettes consumed.

We have developed data and analysis on over 70,000 survey participants who have used JUUL products. Based on published research, approximately 50% of survey respondents who were adult smokers fully switched from combustible cigarettes to JUUL products at 6 months after first use. That number increases over time, up to approximately 55% at 12 months. This reflects that, for many smokers, the period of dual use — or using both cigarettes and JUUL products — is part of the transition from combustible use.

One critical component to understanding the impact of JUUL products in helping adult smokers transition away from cigarettes is the nicotine experience our products provide, which we believe is one important factor in an adult smoker's effort to stop smoking. Our pharmacokinetic studies demonstrate that JUUL products deliver nicotine at levels sufficient enough to compete with combustible cigarettes, but at consistently lower concentrations on average than cigarettes. Providing a similar nicotine effect and experience to cigarettes is critical to facilitate a smoker's transition from combustible use.

We will provide all our research findings from over 100 studies – toxicological, clinical, behavioral - to the FDA through the PMTA process.

That process, which we 100 percent support, is a science and evidence-based review that will evaluate the harm reduction potential of our products, along with the ability to prevent youth usage.

Importantly, if authorized by the FDA, our products will be marketed under strict oversight, subject to the comprehensive regulatory powers invested in the agency by Congress.

Chair DeGette, Ranking Member Guthrie, other members of the Subcommittee, my company is working hard to listen to our stakeholders in the hope of making progress together toward the twin goals of helping more adults switch away from cigarettes, while combatting underage use.

My hope is today's panel can be another step along that path.

I thank you for the opportunity and look forward to answering your questions.