



**Hearing Before the House Committee on Oversight and Reform
Subcommittee on Economic and Consumer Policy**

July 25, 2019

Chairman, Ranking Member, Distinguished Members of Congress.

My name is James Monsees. Adam Bowen and I founded JUUL Labs, and I now serve as Chief Product Officer.

My colleague Ashley Gould, Chief Administrative Officer of JUUL Labs, and I are grateful for the opportunity to share with this Committee information about our company and to answer your questions.

From the moment we began the journey that would lead to the JUUL system, we were clear in our goal: to help improve the lives of adult smokers. We are proud of the progress we have made toward that goal.

We never wanted any non-nicotine user, and certainly nobody under the legal age of purchase, to ever use JUUL products.

Yet the data clearly show a significant number of underage Americans are using e-cigarettes, including JUUL products.

That is a serious problem. Our company has no higher priority than combatting underage use.

Toward that end, we have taken what we believe to be unprecedented actions to prevent underage use of our products. Going forward, we will continue to take additional steps.

Before detailing those actions, we would like to say a few words about how this company came about.

Adam and I used to smoke. We knew all the risks. Yet we were both on our way to becoming statistics – one of the nearly 500,000 Americans who die each year from the leading cause of preventable death in the world: smoking-related disease. Smoking not only kills half a million Americans each year, it is also the source of \$300 billion in costs – both in direct medical costs and lost productivity.¹

Like the vast majority of adult smokers, we tried to quit – many times. And like most, we failed.

¹ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

The average smoker may try up to thirty times before successfully quitting.² Smokers may try a vast array of products to help them quit. But study after study confirm that success rates are relatively low. For example, traditional nicotine replacement therapies have limited success rates that hover around 3–8%, even when used in conjunction with behavioral support.³

That was certainly the experience we had as smokers. For us, giving up smoking required an alternative that did not exist at the time. We founded JUUL Labs to invent one.

The product we developed holds the promise to do what no previous technology has ever done on a consistent basis: help adult smokers stop smoking combustible cigarettes.

The FDA has put forth a new vision of tobacco harm reduction, rooted in a comprehensive plan for tobacco and nicotine regulation that aims to move smokers down the continuum of risk by transitioning them off combustible cigarettes while providing less harmful nicotine delivery options. We believe we offer that alternative. As FDA has stated, “if we succeed in our overall plan, the public health impact can dwarf anything else we’re able to accomplish in any reasonable stretch of time. It can dwarf the introduction of any new medical technology. Analysis shows that our plan has the potential to drop smoking rates from the current 15 percent to as low as 1.4 percent.”

Harm reduction is not a new or novel concept: it is an established tenet of public health. In 2006, Matt Myers, head of the Campaign for Tobacco Free Kids, reaffirmed the potential of tobacco harm reduction to the New York Times: “The challenge to me is not to eliminate smoking, but the death and disease from smoking. That should be the end goal. If you had a product that addicted 45 million people and killed none of them, I would take that deal. Then you'd have coffee! I have to believe that if the marketplace incentives were such that over time someone could devise a product that would give the same satisfaction as tobacco but didn't kill them, people would flock to it.”⁴ We took inspiration from this statement and believe it still holds true today.

And while further research is required into the long-term health impacts of using JUUL and other vapor products, our product is rooted in harm-reduction principles.

As a vapor product, JUUL does not involve burning tobacco, which is the process that unleashes 7,000 chemicals, at least 250 of which are known to be harmful and at least 69 of which can cause cancer.

In a recent behavioral study undertaken by third-party researchers sponsored by the company, we have seen that more than half of adult smokers who purchase and use JUUL products switch completely from smoking cigarettes within six months and abstain from combustible cigarette use going forward.⁵ Another

² Chaiton M, Diemert L, Cohen JE, et al Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers *BMJ Open* 2016;6:e011045. doi: 10.1136/bmjopen-2016-011045.

³ Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. *Cochrane Database of Systematic Reviews* 2018, Issue 5. Art. No.: CD000146. DOI: 10.1002/14651858.CD000146.pub5.

⁴ <https://www.nytimes.com/2006/06/18/magazine/18tobacco.html>

⁵ Russell et al (2019). Factors associated with past 30-day abstinence from cigarette smoking in a non-probabilistic sample of 15,456 adult established current smokers in the United States who used JUUL vapor products for six months. *Harm Reduction Journal*. *In press*.

study of JUUL users also demonstrates those smokers who exclusively used non-tobacco flavors were 30% more likely to have reported abstinence from combustible cigarette use.⁶ Most importantly, the research has shown that the complete switching rate significantly increases over time.

These studies align with real world experience and the dramatic drop in cigarette sales. Since our product started to gain market share among adult smokers, cigarette sales have declined at an accelerating rate. In 2018, cigarette sales declined at an average of 5 percent year-over-year, the fastest rate of decline in a decade according to IRI data. In 2019, IRI data shows cigarette sales plummeting at more than 8 percent year-over-year through May. To put that in context, every one percent decrease in the smoking rate translates to 125 million packs of cigarettes that are never sold or smoked.

JUUL products contain nicotine concentrations designed to provide adult smokers with a viable alternative to combustible cigarettes. In terms of actual nicotine absorption, our clinical studies have consistently shown that 5% strength JUUL use results in a nicotine uptake similar to, but lower in concentration than, a cigarette.⁷ This familiar nicotine experience was specifically developed to help adult smokers transition from combustible use and, ultimately, eliminate cigarette consumption. As the FDA has stated, nicotine, while addictive, “does not directly cause the estimated 480,000 deaths each year from smoking-related diseases.”⁸

Around the world, a number of public health authorities that have compared cigarettes with vapor products have found a significant difference in the health risks. Public Health England, for example, concluded that “vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders.”⁹ The health authorities of Canada and New Zealand have similarly concluded that e-cigarettes are a less harmful alternative for adults who smoke.¹⁰

These findings are consistent with durably designed and executed scientific studies commissioned by JUUL Labs, which have found that JUUL users show significant reductions in biomarkers of exposure (BOEs) compared to cigarette smokers. For example, in one study, the tested biomarkers were known

⁶ Russell, C., Haseen, F., & McKeganey, N. (2019). Factors associated with past 30-day abstinence from cigarette smoking in a non-probabilistic sample of 15,456 adult established current smokers in the United States who used JUUL vapor products for three months. *Harm reduction journal*, 16(1), 22.

⁷ Wynne C, Waaka DS, Cohen G. Acute Use of Nicotine Salt-based ENDS and Combusted Cigarettes. Poster presented at Society for Research on Nicotine & Tobacco Annual Meeting (2018). Available on [jliscience.com](https://www.jliscience.com).

⁸ Zeller, M. (2018). The future of nicotine regulation: key questions and challenges. *Nicotine and Tobacco Research*, 21(3), 331-332.

⁹ McNeill A, Brose LS, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London, England: Public Health England; 2018.

¹⁰ Health Canada, *Reducing Youth Access and Appeal of Vaping Products: Consultation on Potential Regulatory Measures*, Apr. 2019, <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-reducing-youth-access-appeal-vaping-products-potential-regulatory-measures/consultation-reducing-youth-access-appeal-vaping-products-potential-regulatory-measures-eng.pdf>; New Zealand Ministry of Health, *Website to give Kiwis the facts on vaping*, June 9, 2019, <https://vapingfacts.health.nz/our-position-on-vaping.html>.

carcinogens and toxicants observed from the use of combustible cigarettes, and are widely recognized as contributing to tobacco-related cancers, and heart and lung disease.¹¹

After five days of exclusive JUUL use, the clinical study found a 99.6% relative reduction in aggregate BOEs for the JUUL group versus those smokers who abstained from tobacco use altogether for the same five days. In the cigarette group, the same BOEs increased by an aggregate of 14.4% from baseline. The manuscript of the results of this study are presently under peer-review with a scientific journal.

Separate nonclinical studies of JUUL aerosol show an over 99% average reduction in the levels of key chemicals known to be carcinogens, respiratory toxicants, irritants, sensitizers, and cardiovascular toxicants detected in combustible cigarette smoke.¹²¹³ Similarly, tests of exhaled secondhand vapor from JUUL users demonstrated more than a 99% reduction of carbon monoxide and other toxicants compared to secondhand smoke from combustible cigarettes.¹⁴

These findings do not mean that JUUL products carry no health risk – what they indicate is that JUUL products are showing to be substantially less harmful than cigarettes for adult smokers and we look forward to the continued scientific development in this area. The safest choice any person can make when it comes to nicotine products is to never use them at all. But when compared to cigarettes, the deadliest legal consumer product ever invented, the evidence suggests that vapor products like ours have the potential to present a significantly lower-risk alternative for adult smokers.

Mister Chairman, we realize that the harm-reduction potential of JUUL products hinges on addressing the problem of youth vaping.

For as long as society has placed age restrictions on certain products, underage consumers have tried to access and use them. That has certainly been true for cigarettes. For generations, minors have used cigarettes, many of them becoming life-long smokers and, tragically, many having their lives cut short as a result.

JUUL Labs faces the same challenge of minors seeking to use our products. But unlike traditional cigarettes, we have the chance to break the cycle of underage use.

¹¹ Jay J, Pfaunmiller EL, Huang NJ, Graff D. Changes in Biomarkers of Exposure Associated with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System. Poster presented at Society for Research on Nicotine & Tobacco Annual Meeting (2019). Available on jliscience.com.

¹² Gilman G, Johnson M, Martin A, et al. Characterization of Temperature Regulation and HPHC Profile of a Nicotine Salt-Based ENDS Product. Poster presented at Society for Research on Nicotine & Tobacco Annual Meeting (2018). Available on jliscience.com.

¹³ Gilman G, Johnson M, Martin A, Misra M. HPHC Analysis of Eight Flavors of a Temperature-Regulated Nicotine Salt-Based ENDS Product. Poster presented at the Global Forum on Nicotine Conference (2018). Available on jliscience.com.

¹⁴ Evans B, Heraldez D, Salapatek AM. An Open-Label Clinical Study to Evaluate Selected Constituents in Exhaled Breath and Room Air after the Use of Vapor Products and Conventional Cigarettes under Conditions of Residential, Office and Hospitality Environments. Poster presented at the Global Forum on Nicotine Conference (2019). Available on jliscience.com.

As a technology-based company, we can develop innovative tools to combat underage access. But more importantly, unlike traditional cigarette manufacturers, our company has no incentive to see minors use our products.

We know there is skepticism on this point, but it is simply the truth.

Traditional cigarette companies control a saturated, concentrated global market. Finding new users is their only path to growth. JUUL Labs, on the other hand, has captured just 0.3% of the global market of one billion smokers, the vast majority of whom – 70% – want to quit.¹⁵

Our incentive is to do right by those adult smokers, giving them products that help them achieve their goal of transitioning from cigarettes. It is an astonishing business opportunity and, more importantly, a historic public health opportunity.

Underage use of our products does not advance that goal. It imperils it.

When minors use our product, far from benefiting our business, it causes direct harm. Indeed, the single biggest risk to our company is that unabated growth in underage usage will cause us to lose our ability to reach our true intended market of adult smokers.

That being the case, we have no higher priority than combatting youth vaping. Indeed, we have oriented our entire company around that goal and have taken the most aggressive actions in the industry.

In August 2017, we banned online sales to anyone under the age of 21. In April 2018, we announced our support of Tobacco 21 legislation, which raises the minimum purchasing age for tobacco products, including vapor products like JUUL, to 21. At that time, we had already started working with social media platforms to delete inappropriate posts and listings featuring our products that were published by third-parties unaffiliated with JUUL Labs.

In the Fall of 2018, the CDC and FDA released the results of the National Youth Tobacco Survey (NYTS), which showed an alarming increase in underage e-cigarette use. After discussions with the FDA, in November 2018, we announced an aggressive, comprehensive action plan.

We stepped up our efforts to advocate for Tobacco 21 legislation. In just six months, a dozen states across the country passed such laws and, as a result, well over 50% of the US population is now covered by T21 laws.

We stopped selling non-tobacco and non-menthol-based flavored JUULpods to traditional retail stores, which represented 50% of our revenue at that time. We are now effectively out of the flavored product business in brick-and-mortar retail throughout the U.S. Meanwhile, other manufacturers – including those that illegally sell JUUL-compatible pods – continue to sell their non-traditional flavored products in retail, and in some cases have illegally introduced new products and accelerated their expansion in apparent attempts to take advantage of our exit.

We have continuously enhanced our industry-leading third-party age-verification process online, which limits sales to adults 21+, and added more stringent bulk-purchasing restrictions to limit the amount of

¹⁵ Centers for Disease Control and Prevention. Quitting Smoking Among Adults—United States, 2000–2015. *Morbidity and Mortality Weekly Report* 2017;65(52):1457-6.

product that can be purchased.

We strengthened our retailer compliance program with over 2,000 secret shopper visits per month. Since March of 2019, we have issued almost 500 violations to the FDA for further action.

We shut down our U.S.-based Facebook and Instagram accounts, remaining on Twitter for non-promotional purposes only. And we work constantly to remove inappropriate social media content generated by third-parties. To date, we have helped remove 34,760 social media posts and listings.

We committed to developing technology-based solutions to further restrict underage access and use. We are making progress on our previously announced Bluetooth connected device with our pilot program currently running in Canada.

These far-reaching measures come at the problem from a variety of angles, and taken together, will help reduce access to our products so that even minors who desire to experiment with a product intended for adults cannot easily get their hands on it.

We know this problem won't be solved overnight. And JUUL Labs will not be able to solve it alone. It will require the shared effort of federal, state and local regulators, governments and law enforcement, along with parents, educators, community leaders and industry all working together.

But JUUL Labs is 100 percent committed to doing all we can and we believe our actions to date are important steps in the right direction.

Mister Chairman, we understand that our company must work hard to earn trust. As a company that sells a product that is for adults only and that contains an addictive substance, the bar for trust is appropriately high.

By constantly learning and evolving, and by committing to the shared effort to address underage vaping, we hope to earn the trust of this Committee, Congress, our regulators, our customers and the American public.

As part of that effort, we pledge to be transparent with our stakeholders. As an indication of that approach, for this hearing and efforts underway by certain state AGs, JUUL Labs produced well over 50,000 documents constituting more than 175,000 pages.

Mister Chairman, we believe that our company can help eliminate combustible cigarettes. We know that doing so requires progress in the fight to combat underage vaping. We will pursue both goals with all the resources at our disposal.

We are grateful for the opportunity you have afforded us to discuss these important topics and look forward to answering your questions.