Juul Labs®

Braden Ainsworth
Utah Department of Health
Disease Control and
Prevention, Health
Promotion

JUUL Labs, Inc.
1000 F Street NW
Suite 800
Washington D.C. 20004

On behalf of Juul Labs, Inc. (“JLI” or “the Company”), thank you for the opportunity today to submit comments regarding the proposed amendments to Utah Administration Rule R384-415.

JLI’s mission is to transition the world’s billion adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products.

To succeed in that mission and preserve the harm-reduction potential of vapor products, we are focused on listening and building constructive relationships with regulators, policymakers, and other stakeholders as we strive to reset the vapor category in the U.S. and earn a license to operate in society. And we must continue to address underage use of tobacco and nicotine products through evidence-based tobacco-control strategies, focused on restricting access and limiting appeal of these products.

The Company also supports risk-proportionate regulation for vapor and other noncombustible alternative products. Such a policy framework, at its core, applies the most stringent regulations to the riskiest products (e.g., combustible cigarettes) and encourages current adult users to migrate to potentially less harmful alternatives (e.g., vapor products). To be clear, risk-proportionate regulation does not mean a “lenient” approach to noncombustible alternatives. It certainly does not mean an unregulated marketplace. Rather, robust, informed regulation of tobacco and nicotine products and our category will always be appropriate.

Within this framework, and at the very least, JLI believes that noncombustible alternatives, like vapor products, must be able to compete with combustible cigarettes—especially on nicotine delivery. The regulatory balance should be weighted in favor of harm reduction. That is, to establish public policy that moves

adult smokers *away* from the most harmful tobacco and nicotine products (e.g., combustibles) *towards* potentially less harmful noncombustible alternatives.

The proposed amendments to Utah Administration Rule R384-415 would prohibit retailers from selling closed system containers that exceed 3% nicotine by weight per container or that exceed a 36 mg/mL concentration of nicotine. Yet combustible cigarettes—the most lethal consumer product marketed and most effective nicotine delivery system— would remain untouched by the regulation.

However it is nicotine *delivery*, not content, that is the most important factor to measure, and one that is not contemplated by Utah Administration Rule R384-415. As discussed below, providing a similar nicotine delivery effect and experience to combustible cigarettes is critical to satisfy and completely switch adult smokers to potentially less harmful alternatives.

Critically, the U.S. Food and Drug Administration ("FDA" or "the Agency") provides extensive federal regulatory oversight of tobacco products, including vapor, and can regulate nicotine content and delivery of such products through the Premarket Tobacco Product Application (PMTA) process or by establishing a tobacco product standard. We respect the PMTA process and believe it is the appropriate science-based forum to determine the role vapor and other innovative products can play to transition and completely switch adult smokers from combustible cigarettes.

For these reasons and those stated in more detail below, we respectfully request that the Department put aside the proposed rule and engage with stakeholders to develop a thoughtful, evidence-based regulatory approach that: (1) maintains access to potentially less harmful alternatives for adult smokers; (2) aligns with FDA's review process and determinations regarding how vapor products will be available in the U.S. marketplace; and (3) addresses underage use through tailored measures to restrict access and limit appeal.

Role of Nicotine

"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."[1]
—Scott Gottlieb, M.D., and Mitchell Zeller, J.D.

As a number of public health authorities observed, nicotine is not the primary cause of the harms associated with smoking combustible cigarettes—the only legal consumer product that, when used as intended, will kill half of all long-term users.[2] Nicotine is addictive and is the chemical that gets and keeps adult smokers using combustible cigarettes. But it is the burning of tobacco, inhalation of smoke, and release of other chemical compounds and toxicants that are primarily to blame for tobacco-related death and disease.

In July 2017, FDA announced its Comprehensive Plan for Tobacco and Nicotine Regulation, which initiated a multi-year roadmap to shift the trajectory of tobacco-related death and disease. A key foundation of FDA's Comprehensive Plan is that nicotine is delivered on a continuum of risk and that combustible cigarettes, which deliver nicotine through the inhalation of smoke, present the greatest health risks. FDA's plan envisions a regulatory agenda that seeks to move adult smokers, who do not quit nicotine, down the continuum of risk to potentially less harmful alternative products while delivering satisfying levels of nicotine.

Misperceptions about nicotine remain prevalent. Findings from the Population Assessment of Tobacco and Health (PATH) study in 2016 showed that 80% of respondents incorrectly believed that nicotine is the chemical in cigarettes that

[1] Gottlieb, S. & Zeller, M. (2017). A Nicotine-Focused Framework for Public Health. *N. Engl. J. Med.*, 377 (12) (2017), pp. 1111-1114. doi: 10.1056/NEJMp1707409
[2] Gottlieb, S. (2017). Protecting American Families: Comprehensive Approach to Nicotine and Tobacco [Speech]. Available at: https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017

causes most of the cancer from smoking.[3]

Naturally, these misperceptions negatively impact switching: an additional study has found that adult smokers who were considering switching to a potentially less harmful product—in this case a vapor product—were three times more likely to switch if they properly placed the product on the risk perception scale.[4]

The Company's position is that nicotine is addictive and can be harmful. If you do not use nicotine, do not start. If you smoke cigarettes, the best public health option is to quit. But those adult smokers who have not successfully quit should completely switch to potentially less harmful noncombustible alternatives.

The JUUL System

To transition adult smokers from combustible cigarettes and switch them completely, an alternative product must be sufficiently appealing, provide a competitive nicotine experience to combustible cigarettes, and be lower in toxicity and harm.[5] These products must be able to pull smokers away from the cigarettes they have used for years, if not decades.

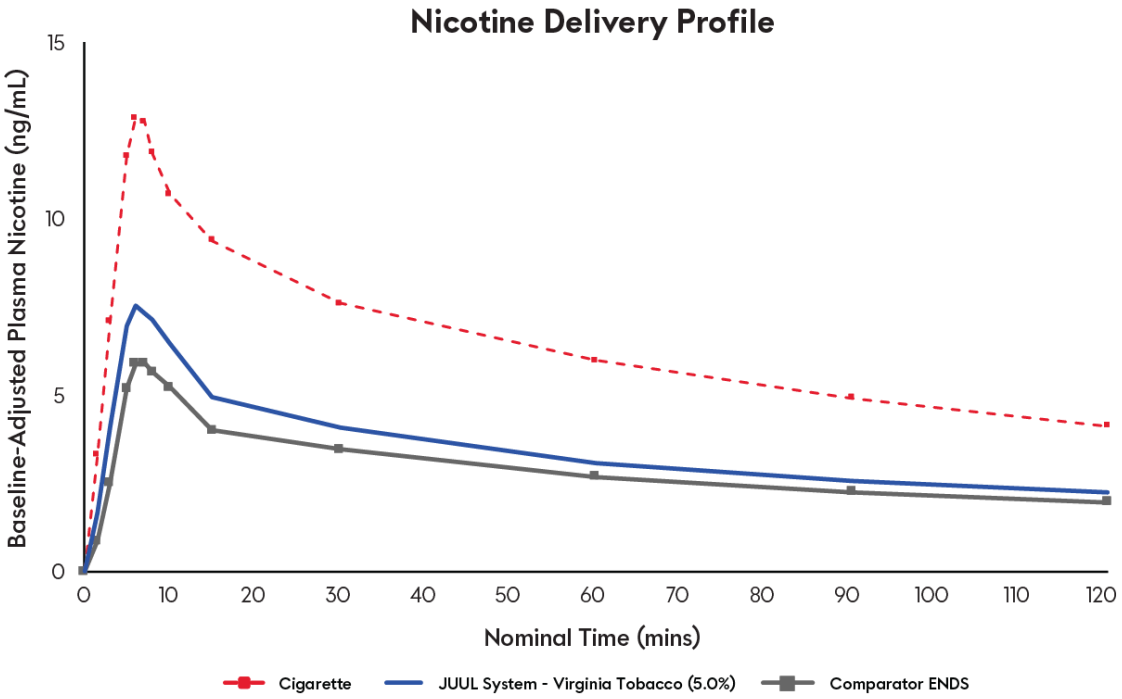
Our clinical studies have shown that the JUUL System at approximately 59 mg/ml (5.0% by weight) nicotine concentration delivers nicotine at levels that can compete with combustible cigarettes.[6]

[3] Johnson, S. E. (2016). What the public knows and believes about nicotine: Insights from recent quantitative and qualitative evidence. FDA Center for Tobacco Products presentation about PATH survey data. Paper presented at the 22nd Annual Meeting
of the Society for Research on Nicotine and Tobacco, Chicago, IL

[4] Persoskie, A., O'Brien, E. K., & Poonai, K. (2019). Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users. Addiction (Abingdon, England), 114(12), 2197–2205. https://doi.org/10.1111/add.14730

[5] Abrams, D. B., Glasser, A.M., Pearson, J. L., Villanti, A. C., Collins, L. K., Niaura, R. S. (2018). Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annual Review of Public Health* 2018 39:1, 193-213. https://doi.org/10.1146/annurev-publhealth-040617-013849

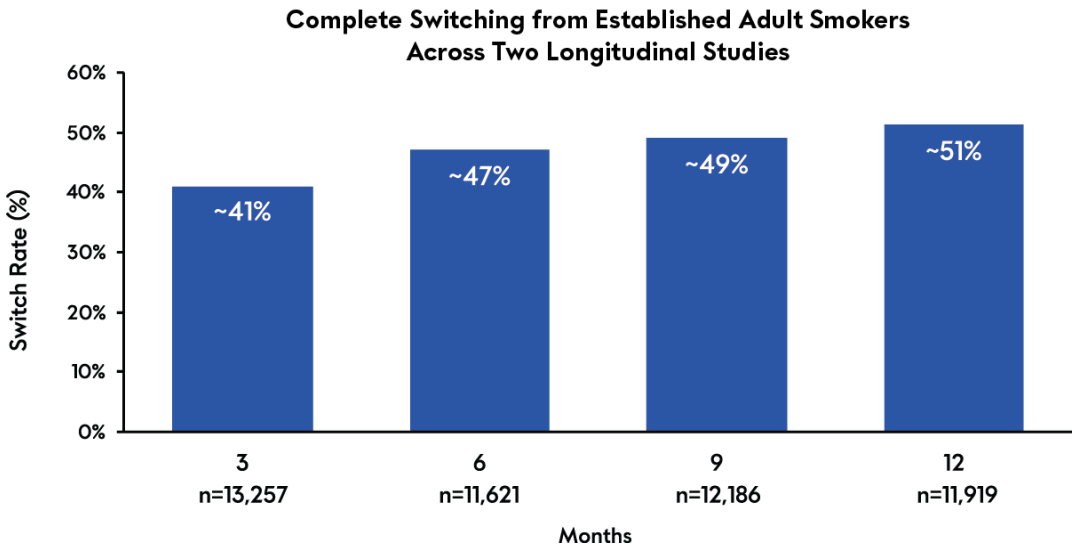
[6] Goldenson, N. I., Buchhalter, A. R., Augustson, E. M., Rubinstein, M. L., Henningfield, J. E. (2020). Abuse liability assessment of the JUUL system in four flavors relative to combustible cigarette, nicotine gum and a comparator electronic nicotine delivery system among adult smokers, *Drug and Alcohol Dependence*, 2020, 108395, ISSN 0376-8716. https://doi.org/10.1016/j.drugalcdep.2020.108395.



The maximum and total nicotine exposure for the JUUL system is lower than a cigarette and on par with other tested vapor products.

Our longitudinal behavioral studies demonstrate that adult smokers find the JUUL System to be a satisfying nicotine alternative and are able to transition off of cigarettes at unprecedented rates.[7] Nearly half of respondent adult smokers in these studies fully switched from combustible cigarettes 6 months after use. That number increases over time, up to approximately 51% at 12 months. Complete switching is defined as no cigarette smoking in the past 30 days — not even a puff.

[7] Goldenson, N., Le, G., Augustson, E. (2020). Switching Away from Cigarettes Among Adult Smokers who Purchased the JUUL System: 12-Month Follow-Up Results from Two Large Longitudinal Studies. Presented at 3rd Scientific Summit on Tobacco Harm Reduction 2020. Available at: https://www.juullabsscience.com/wp-content/uploads/sites/8/2020/09/Switching-Away-from-Cigarettes-Among-Adult-Smokers-who-Purchased-the-JUUL-System-12-Month-Follow-Up-Results-from-Two-Large-Longitudinal-Studies.pdf



FDA Oversight and Regulatory Framework

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), providing FDA jurisdiction and extensive authority over tobacco products. Among other requirements, tobacco product manufacturers are required to register and list their products with FDA; submit health information about their products; disclose ingredients; and report on harmful and potentially harmful constituents (HPHCs) in their products. Critically, the Tobacco Control Act created a premarket-review process for new tobacco products, like vapor, through which FDA would evaluate and determine, based on the science and evidence, whether the product is appropriate for the protection of public health. FDA also has authority to issue product standards, or specific requirements or restrictions for certain tobacco products, if appropriate for the protection of public health.

The Agency can regulate nicotine content and delivery of any new tobacco product, including vapor, through the PMTA process or by setting limits on nicotine levels across tobacco products or on a class of products if determined to be appropriate for the protection of public health.

In July 2020, JLI submitted its PMTAs for the JUUL System to FDA, as well as

proactive, data-driven measures to address underage use of our products. We believe our robust submission will help inform the FDA's science-based decision on whether the continued marketing of the JUUL System is appropriate for the protection of public health, accounting for both adult current users of tobacco products and nonusers, especially those who are underage.

As FDA reviews the scientific evidence in this area and associated PMTA submissions, they have the authority and expertise to deny applications for vapor products that they determine are not "appropriate for the protection of public health."

As mentioned, we respectfully request that the Department put aside the proposed rule and engage with stakeholders to develop a thoughtful, evidence-based regulatory approach that: (1) maintains access to potentially less harmful alternatives for adult smokers; (2) aligns with FDA's review process and determinations regarding how vapor products will be available in the U.S. marketplace; and (3) addresses underage use through tailored measures to restrict access and limit appeal.

Sincerely,

Kenton Stanhope
Sr. Manager, Government Affairs