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February 2, 2022

Written Testimony of
Jon Berrier, Vice President State Government Affairs, Juul Labs

on

S.B. 45

Before the
Senate Finance Committee
Alaska State Legislature

Co-chairs Bishop and Stedman, and Members of the Senate Finance Committee,

On behalf of Juul Labs, Inc. ("JLI"), thank you for the opportunity to submit testimony regarding S.B. 45. While we are encouraged that S.B. 45 would increase the state's minimum age of purchase to 21, we believe this bill, in its current form, will impede the access for adult smokers to switch to potentially less harmful alternatives. From the original high tax proposal to the problematic amendments, including a flavor ban, we are concerned that this bill would harm the ability of noncombustible alternative products to compete with the most deadly consumer product on the planet - combustible cigarettes. Juul Labs is fully supportive of risk-proportionate regulatory pathways to create a responsible marketplace that combats underage use while preserving adult smokers' chance to transition away from combustible cigarettes. Unfortunately, S.B. 45 will likely lead to significant adverse consequences such as increased or sustained cigarette use, reduced switching to potentially less harmful products, unstable tax revenue, and a proliferation in illicit trade that threatens data-driven measures to combat underage use.

There are already robust federal regulations in place to assess, monitor, and regulate these products.The U.S. Food and Drug Administration ("FDA" or "the Agency") provides extensive federal regulatory oversight of tobacco products, including electronic smoking products. FDA has exercised this authority by issuing guidance related to flavored electronic smoking products that removed all non-tobacco, non-menthol flavored cartridge based products unless and until authorized through a Premarket Tobacco Product Application (PMTA).[1] FDA can also regulate nicotine content and delivery of such products through the PMTA process, and any product receiving authorization continues to be subject to extensive oversight, restrictions, and reporting requirements for as long as they are in the market. The PMTA process is a rigorous, science-based process conducted by career scientists and technical experts, which we believe is the appropriate forum to determine the role electronic smoking

[1] U.S. Food and Drug Administration (2020). Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization (Jan. 2020), available at http://bit.ly/36xpplv.

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products and other innovative products can play to transition and completely switch adult smokers from combustible cigarettes.

FDA has made significant progress in its review of PMTAs, taking action on about 93% of the total timely-submitted applications. As of October 2021, the FDA has issued Marketing Denial Orders for more than 1,181,581 electronic smoking products.[2] Applications for products with the largest market share, such as JUUL, remain under review.

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 to preserve the harm-reduction potential of electronic smoking products, we are focused on listening and building constructive relationships with regulators, policymakers, and other stakeholders.

One of the key tenets to these efforts is our commitment to combat underage use of our products through evidence-based interventions. JLI also supports risk-proportionate regulation for electronic smoking products and other reduced-risk, noncombustible products. Within this framework, JLI believes that the regulatory balance should be weighted in favor of harm reduction, moving adult smokers *away* from the most harmful tobacco and nicotine products (e.g., combustibles) *towards* potentially less harmful noncombustible alternatives. Robust, informed regulation of tobacco and nicotine products and our category will always be appropriate.

Unfortunately, other than the Tobacco 21 provision, S.B. 45 does not reflect risk-proportionate regulation and does not align with FDA's science-based PMTA process. Further, in response to the excessive tax rate established by S.B. 45 - made even more exorbitant when combined with local taxes on electronic smoking products in Anchorage and Wasilla - some adult consumers may seek out cheaper products that can be purchased through illicit markets, which predominantly occur outside of tax regulation. A more prominent illicit market can potentially present additional health and safety risks for adult consumers and undermine underage-prevention measures.

We respectfully request that the provisions other than Tobacco 21 be removed from S.B. 45, the amended Tobacco 21 legislation be subsequently passed, and the Committee instead engage with stakeholders to develop a thoughtful, risk-proportionate tax framework to help transition adult smokers away from combustible cigarettes—the number one cause of preventable death and disease in Alaska and the rest of the country.

[2] U.S. Food and Drug Administration, "PMTA Acceptance Phase Metrics (Data as of: 10/06/2021)," https://www.fda.gov/media/154053/download

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FDA Oversight and Regulatory Framework

In 2009, Congress enacted and President Obama signed 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 electronic smoking products, 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.

FDA has exercised that authority, including by issuing its guidance related to flavored electronic smoking products in January 2020 which removed all non-tobacco, non-menthol flavored cartridge based products until authorized through a PMTA. As it stated, the Agency's decision sought to strike the public health balance by maintaining electronic smoking products as a potential off-ramp for adults using combustible tobacco while ensuring these products do not provide an onramp to those underage. FDA did so after careful consideration of the data and made the decision to continue enforcement discretion as to both tobacco- and menthol-flavored electronic smoking products pending PMTA review.

The Agency can also regulate nicotine content and delivery of any new tobacco product, including electronic smoking products, 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. Any product receiving authorization through the PMTA process continues to be subject to rigorous FDA oversight and post-marketing requirements aimed at reducing youth exposure and access to the products. FDA "may suspend or withdraw a marketing order issued under the PMTA pathway for a variety of reasons if the agency determines the continued marketing of a product is no longer 'appropriate for the protection of the public health,' such as if there is a significant increase in youth initiation."[3]

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

[3] U.S. Food and Drug Administration, "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency," October 12, 2021, https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency

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appropriate for the protection of public health, accounting for both adult current users of tobacco products and nonusers, especially those who are underage.

FDA has made significant progress in its review of PMTAs, taking action on about 93% of the total timely-submitted applications. As of October 2021, the FDA has issued Marketing Denial Orders for more than 1,181,581 electronic smoking products and issued a Marketing Granted Order for a tobacco-flavored electronic smoking product.[4] Applications for products with the largest market share, such as JUUL, remain under review.

Given its scientific expertise and public-health mandate, the FDA is best positioned to assess the role electronic smoking products can play in helping adult smokers move away from combustible cigarettes while also being kept out of the hands of youth.

Excise Taxation and Electronic Smoking Products

Specific to taxes, a risk-proportionate approach to policymaking entails a lower, reduced rate for noncombustible products compared to combustible cigarettes in order to maintain and encourage access for adult smokers, while combating underage access through targeted, evidence-based interventions.

For former and current adult smokers, electronic smoking products compete with cigarettes in the marketplace to provide smokers an off-ramp from combustible use toward a potentially less harmful pathway. Several economic studies conclude that excessive taxes on electronic smoking products can have the unintended consequence of discouraging switching and, as a result, increasing cigarette smoking:

- In a recent study funded by a grant from the National Institute of Health to the National Bureau of Economic Research, the authors estimate that the high excise tax on electronic smoking products in Minnesota deterred 32,400 adult smokers in the state from transitioning away from cigarettes.[5]
- Another recent study published in the *Journal of Risk and Uncertainty* uses two nationally representative public health surveys, the Behavioral Risk Factor Surveillance System and National Health Interview Survey, to estimate that a national tax on electronic smoking

[4] U.S. Food and Drug Administration, "PMTA Acceptance Phase Metrics (Data as of: 10/06/2021)," https://www.fda.gov/media/154053/download; U.S. Food and Drug Administration, "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency," October 12, 2021, https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency.

[5] Saffer, H. et al. E-cigarettes and adult smoking: Evidence from Minnesota. J Risk Uncertain 60, 207–228 (2020). https://doi.org/10.1007/s11166-020-09326-5.

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products equivalent to $1.65 per milliliter of vaping liquid would raise the proportion of adults who smoke cigarettes daily by approximately 1 percentage point, translating to 2.5 million additional adult daily smokers.[6]

Establishing a 75% wholesale tax on electronic smoking products would significantly reduce the excise tax differential between combustible products and electronic smoking products, disincentivize cost-conscious adult smokers who are open to the harm-reduction potential of these products, and introduce additional adverse unintended consequences.

Tobacco 21 Is an Effective, Evidence-Based Intervention to Combat Underage Use of Tobacco and Nicotine Products

JLI remains committed to combating underage use of electronic smoking products, which is unacceptable, by working with states toward full implementation and enforcement of Tobacco 21. JLI is pleased to see this section included in S.B. 45 and is committed to work with key stakeholders in Alaska to achieve implementation throughout the state.

Recent data suggests that, although significant work remains, meaningful progress is being made to combat underage use of electronic smoking products through evidence-based interventions such as Tobacco 21. The latest data from the 2021 National Youth Tobacco Survey showed 7.6% of U.S. middle and high school students reported using electronic smoking products within the past 30 days.[7]

Even with federal Tobacco 21 legislation in effect, it is critical that states align their minimum age of purchase laws to facilitate full implementation and enforcement of Tobacco 21 and to ensure the state's share of grant funding under the Synar Amendment is not reduced. For these reasons, we support Tobacco 21 implementation in Alaska.

Conclusion

Tobacco 21 laws have proven to be an effective, targeted policy to combat underage use of tobacco and electronic smoking products, and we strongly support this aspect of S.B. 45. However, imposing a 75% wholesale excise tax would have adverse effects in Alaska while being an ineffective measure to attempt to address underage use or create a reliable revenue source. Finally, we are concerned that the other provisions of S.B. 45, as outlined above, would introduce additional unintended consequences and not be aligned with the FDA's robust and evidence-based PMTA

[6] Pesko M. et al. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. J Risk Uncertainty J Risk Uncertain 60, 229–258 (2020). https://doi.org/10.1007/s11166-020-09330-9 (2020).

[7] Park-Lee E. et al. Notes from the Field: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387–1389. DOI: http://dx.doi.org/10.15585/mmwr.mm7039a4

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process. As previously stated, we respectfully request that the provisions other than the Tobacco 21 component be removed from S.B. 45, the amended Tobacco 21 legislation be subsequently passed, and the Committee engage with stakeholders to develop a thoughtful, risk-proportionate tax framework for all tobacco and nicotine products.

Sincerely,

Jon Berrier