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Written Testimony of
Ashlie Kuehn, State Government Affairs
Juul Labs
concerning
H.F. 904
Before the House Committee on Preventive Health Policy Division
Minnesota House of Representatives

Chair Freiberg, Vice Chair Bierman, and Members of the Committee,

On behalf of Juul Labs, Inc. ("JLI"), thank you for the opportunity to submit testimony regarding H.F. 904, which would prohibit the sale or offer for sale of flavored tobacco and nicotine products in the state.

As JLI strives to reset our company and category in the U.S., we are focused on listening and building constructive relationships with regulators, policymakers, and other stakeholders to advance the harm reduction potential for adult smokers. One of the key tenets of these efforts is our commitment to combat underage use of our products through evidence-based interventions.

JLI also supports risk-proportionate regulation for vapor and other reduced-risk, noncombustible 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, it means robust, informed regulation of tobacco and nicotine products and our category will always be appropriate.

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 - all while combating access to and use of these products by those underage.

For these reasons and those stated in more detail below, we respectfully request that H.F. 904 be put aside, and the Committee instead engage with stakeholders to develop a thoughtful, risk-proportionate regulatory framework for all tobacco and nicotine products.

The Role of Menthol In Vapor and Other Alternative Products

With regard to menthol, it is our bedrock belief that FDA is the body best-positioned to develop and implement policy relating to tobacco products, including on flavors.

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The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), signed by former President Obama, is a comprehensive and thoughtful law that gives FDA expansive authority and oversight 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, the Premarket Tobacco Product Application (PMTA) process, for new tobacco products like vapor. Through the PMTA process, FDA would evaluate and determine, based on the science and evidence, whether the product is "appropriate for the protection of public health."[1] 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 vapor products in January 2020, which removed all flavored cartridge based products other than tobacco and menthol until authorized through a PMTA. As it stated, the Agency's decision sought to strike the public health balance by maintaining vapor 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 vapor products pending PMTA review.

Furthermore, in an environment in which Tobacco 21 is the law of the land and access controls are enforced to combat underage use, we believe menthol-flavored noncombustible products, including vapor, should remain available for adult smokers, particularly those who want to transition away from menthol cigarettes.

Recent data suggests that meaningful progress is being made to combat underage use of vapor products, demonstrating the importance of evidence-based interventions such as Tobacco 21. The 2020 National Youth Tobacco Survey found past 30-day e-cigarette use among high school students decreased 29%, from 27.5% in 2019 to 19.6% in 2020.[2] A recent study analyzing data from the 2020 Monitoring the Future survey found that fruit was the most commonly used flavor at 59%, followed by Mint at 27%, Menthol at 7%, Tobacco at 3%, and Sweet at 2%.[3] Only a minority of JUUL users reported use of menthol or tobacco, the only flavors distributed to

[1] U.S. Food and Drug Administration, "Premarket Tobacco Product Application," https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications.
[2] Wang T. et al. E-cigarette Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1310–1312. DOI: http://dx.doi.org/10.15585/mmwr.mm6937e1.
[3] Miech R. et al. Trends in Use and Perceptions of Nicotine Vaping Among US Youth From 2017 to 2020. JAMA Pediatr. Published online December 15, 2020. doi:10.1001/jamapediatrics.2020.5667.

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retailers since November 2019. While we are encouraged that underage use has declined significantly, significant work remains to reduce underage use of vapor products through evidence-based interventions.

One example to do so involves recent advancements in point-of-sale (POS) technology that allow traditional retail outlets to incorporate new technological tools and update existing sales systems to restrict underage access through automated sales controls. Retailers now can incorporate automated quantity-purchase limits and electronic scanning of government-issued IDs to verify age and ID validity automatically, before completing purchases with consumers.

What is also important in this debate is recognizing the goal of transitioning adult smokers away from combustible cigarettes — the leading cause of preventable death in the U.S. and worldwide. Studies have shown that flavors are important to adult smokers considering alternatives to combustible cigarettes. A recent third-party study by researchers with FDA's Center for Tobacco Products found 41.4% of prior adult menthol smokers reported using menthol or mint-flavored vapor products and 21.3% reported using them exclusively. The authors concluded that, "Menthol cigarette smokers are particularly likely to use menthol/mint-flavored e-cigarettes compared to nonmenthol smokers."[4] To transition and completely switch adult smokers from combustible cigarettes, it is critical that noncombustible alternatives sufficiently appeal to smokers.

Additionally, the removal of menthol-flavored vapor products could have significant negative public health consequences, such as: increased or sustained cigarette use, reduced switching to potentially less harmful products, increased cross-border sales, reduced tax revenues, and increased black market activity. Research developed by JLI found that significantly higher than expected cigarette sales occurred in states that implemented temporary bans on flavored vapor products in the fall of 2019 — 4.6% in Washington and 5% in Rhode Island. Sales of menthol cigarettes were also higher than expected: Actual sales of menthol cigarettes in Washington and Rhode Island were 6.5% and 7.1% higher than predicted.[5]

There is a crucial balance between effectively reaching adult smokers and restricting access and limiting appeal to those underage. This balance and approach are critical to the effort to reduce the harm caused by cigarettes, particularly at a time when the country has recently experienced a rebound of combustible cigarette sales.[6]

Based on its scientific approach and evidence-based analysis, we believe FDA and the PMTA process can strike the appropriate balance to provide adult smokers with less harmful alternatives while limiting initiation among nonusers, including those underage.

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[4] Ibid.

[5] Jian, L., Xu, Y., and Prakash, S. The Impact of Banning ENDS Products on Combustible Cigarette Sales: Initial Evidence from U.S. State-Level Policies. 3rd Scientific Summit on Tobacco Harm Reduction, 2020.

[6] Jennifer Maloney, "Smoking's Long Decline is Over," Wall Street Journal, Jan. 28, 2021, https://www.wsj.com/articles/during-covid-19-lockdowns-people-went-back-to-smoking-11611829803?mod=pls_whats_news_us_business_f.

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Conclusion

We are concerned that H.F. 904 would lead to adverse consequences in Minnesota while being an ineffective way to attempt to address underage use of vapor products. We respectfully request that the Committee put aside the proposed legislation 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. At the very least, we believe any state-level flavor restriction on vapor products should provide an exception for the two traditional flavors, tobacco and menthol, and also provide an exception for any flavored vapor product that receives a market order from FDA after going through the rigorous PMTA process that allows for products to be marketed in the U.S. if they are determined to be appropriate for the protection of public health.

Sincerely,

Ashlie Kuehn