



September 25, 2023

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Sent via e-mail

Re: Referral to TPSAC of PMTA for JUUL2

Dear Dr. King:

The undersigned public health and medical organizations write to urge the Food and Drug Administration (FDA) to refer to the Tobacco Products Scientific Advisory Committee (TPSAC) the Premarket Tobacco Product Application (PMTA) recently filed by Juul Labs (JLI) for its “next generation vapor platform,” which the company refers to as JUUL2. We also ask that the JUUL2 PMTA be subjected to the same transparency, and public comment, as would be afforded a Modified Risk Tobacco Product (MRTP) Application referred to TPSAC.

As explained below, this treatment of the JUUL2 PMTA is justified by the unique and deleterious role of prior JUUL products in harming the public health, as well as the implications of the new Bluetooth technology being featured on JUUL2. Given the new and pivotal scientific issues that will be raised by this product, there are substantial advantages to involving TPSAC at the earliest stages of FDA consideration, as well as receiving the input of the public that will be affected by introduction of the product into commerce. Based on the potential introduction of Bluetooth technology and given the past history of JUUL products, our organizations would have serious concerns about the introduction of this product into commerce in the U.S. We urge FDA’s enlistment of TPSAC to more fully explore these issues.

FDA Statutory Authority

Although the Family Smoking Prevention and Tobacco Control Act (TCA) does not require FDA to refer any particular PMTA to TPSAC or to receive public comment on each PMTA, as it does with every MRTP Application,¹ the statute expressly gives the agency the authority to refer any PMTA to TPSAC, with the degree of public disclosure and participation inherent to that referral. Thus, under Section 910(b)(2) of the Food, Drug and Cosmetic Act, as amended by the TCA, FDA may refer a PMTA to TPSAC “for reference and for submission . . . of a report and recommendation respecting the application, together with all underlying data and

¹ 21 USC §387k(e)(f).

the reasons or basis for the recommendation.”² In effect, this provision gives FDA the discretion to use, with respect to PMTAs, the same process of TPSAC referral that is required for MRTTP applications.³ As discussed below, there are strong reasons for FDA to exercise that discretion with respect to the PMTA for JUUL2.

The JUUL2 Application

On July 19, 2023, JLI announced the submission of a PMTA for its “next generation vapor platform,” which it introduced in the U.K. in 2021 as the JUUL2 System.⁴ From the announcement, it is clear that the company is promoting JUUL2 as an advanced technology device. An example of the “new technology” in the device is that it is “Bluetooth-enabled” with “a mobile and web-based app that enables age-verification technology, including device-locking and real-time product information and usage insights for age-verified consumers with industry-leading data-privacy protections.”⁵ The JLI announcement also makes specific claims for the product’s success in the U.K., including that “[o]ver 32% of JUUL2 users have switched completely from combustible cigarettes 6 months after purchasing the product.”⁶

Importance of TPSAC Referral and Transparency

Given JUUL’s leading role in causing the epidemic of youth e-cigarette use and addiction during recent years, as well as the new and unique scientific issues raised by the JUUL2 PMTA, there is ample reason to refer the PMTA to TPSAC and to ensure the maximum possible public transparency and opportunity for public comment.

The uniquely destructive role of JUUL products on public health, and particularly its egregious marketing directed at youth, is a matter of undisputed historical record and a sufficient reason to deny a marketing order to any JUUL product currently on the market.⁷ It is surely instructive that JLI has been a defendant in more than 5,000 lawsuits brought by approximately

² 21 USC §387j(b)(2).

³ The Reagan-Udall Foundation Report *Operational Evaluation of Certain Components of FDA’s Tobacco Program* (“Reagan-Udall Report”) suggests that CTP use TPSAC “for input . . . on major PMTA decisions,” noting that TPSAC referral “gives an additional level of transparency for CTP decision making.” Reagan-Udall Report at 15 (Dec. 2022), https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_Dec.%202022.pdf.

⁴ JLI, *A Technological Solution for Public-Health Problems: Juul Labs Submits the First PMTA for its Next-Generation Platform to Improve Adult-Smoker Switching and Restrict Underage Access* (July 19, 2023), <https://www.juullabs.com/next-generation-platform-pmta/>.

⁵ *Id.*

⁶ *Id.*

⁷ See generally Letter of Public Health and Medical Groups re Premarket Tobacco Product Application for JUUL (Apr. 27, 2021),

https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2021_04_27_Letter-JUUL-PMTA.pdf.

10,000 plaintiffs,⁸ paying an estimated \$3 billion in settlement of those lawsuits.⁹ These included settlements of over \$1 billion reached with 48 states.¹⁰

The skyrocketing rate of youth e-cigarette use that sparked national alarm was fueled by JUUL, which became the most popular e-cigarette during the peak of the youth epidemic. In mid-2016, the dollar sales share for JUUL products was less than 5%, but by the end of 2017, JUUL sales had surpassed all other companies' products, including the e-cigarette brands manufactured by the major tobacco companies.¹¹ At its peak popularity in late 2018 and early 2019, JUUL sales comprised over 70% of the market.¹² JUUL's rise directly coincided with, and was largely responsible for, an unprecedented surge in youth e-cigarette use. According to the National Youth Tobacco Survey (NYTS), high school e-cigarette use increased by 135% from 2017 to 2019 (from 11.7% to 27.5%), leading to an increase of over 3 million middle and high school student e-cigarette users in just two years.¹³ According to the CDC, "The rise in e-cigarette use during 2017-2018 is likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavors that appeal to youths."¹⁴

There is also little doubt that much of JUUL's popularity among young people has been the direct result of a conscious effort to market the product to young consumers. A report by Stanford University researchers found that JUUL's early advertising, which included YouTube videos, launch parties, product sampling events, and the use of "influencers" on social media,

⁸ JLI, *Statement by Juul Labs on Settlement with Minnesota Attorney General* (Apr. 17, 2023), <https://www.juullabs.com/statement-by-juul-labs-on-settlement-with-minnesota-attorney-general/> ("Minnesota settlement statement").

⁹ Christina Jewett & Julie Creswell, *Juul Reaches \$462 Million Settlement with New, York, California and Other States*, N.Y. TIMES (Apr. 12, 2023), <https://www.nytimes.com/2023/04/12/health/juul-vaping-settlement-new-york-california.html#:~:text=49-.Juul%20Reaches%20%24462%20Million%20Settlement%20With%20New%20York%2C%20California%20and,to%20states%2C%20cities%20and%20people.>

¹⁰ Minnesota Settlement Statement, *supra* note 6.

¹¹ Nielsen Total US xAOC/Convenience Database & Wells Fargo Securities, LLC, in Wells Fargo Securities. Tracked data includes mass channel and convenience stores; does not include online sales or sales from tobacco and vape shops.

¹² *Id.*

¹³ Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019*, 68 MMWR 1, 5 (Dec. 6, 2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>; Karen Cullen et al., *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018*, 67 MMWR 1276, 1276 (Nov. 16, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w.

¹⁴ *Id.* at 1277.

was “patently youth-oriented.”¹⁵ Under public pressure and FDA scrutiny, JUUL eventually curbed its youth-directed marketing. But, as then-FDA Commissioner Scott Gottlieb observed, “[Y]ou can’t un-ring the bell and undo what was done since they launched.”¹⁶ Even today, JUUL remains among the most popular e-cigarette brands among youth, with 22% of current middle and high school e-cigarette users reporting JUUL use in the past month.¹⁷

JLI’s history of designing and marketing products especially appealing to youth makes the new technology in JUUL2 especially concerning. The public health risks posed by any Bluetooth-enabled tobacco product are set out in detail in a July 16, 2020 letter to then-Director of CTP Mitch Zeller by the undersigned organizations,¹⁸ incorporated here by reference. These risks include:

- Tobacco companies have unlimited access to user data, raising substantial privacy concerns.
- Tobacco companies have the capacity to utilize user data to prolong and enhance a user’s addiction by controlling nicotine delivery and monitoring usage patterns.
- Gives tobacco companies the capacity to utilize user data for marketing.
- Facilitates social interactions with other users by alerting the presence of other nearby users.
- Creates capacity to add gaming features.

JLI’s PMTA announcement for JUUL2 makes reference to its web-based app that enables “real-time product information and usage insights for age-verified customers.” Thus, JLI, a tobacco company that has played a leading role in creating an epidemic of e-cigarette use and nicotine addiction among youth, whose economic viability depends on sustaining nicotine addiction among its users, would have the capacity to obtain personal health information and information about the use of its products by individual consumers with no legal constraints on how it uses that information. Of course, JLI will have every incentive to use the information to ensure that each consumer’s addiction is sustained. Moreover, the marketing of the device as offering new and innovative technology will no doubt be part of its appeal to young people. Finally, JLI’s claim that its novel technology will “restrict underage access” will need to be closely scrutinized.

¹⁵ ROBERT K. JACKLER ET AL., *JUUL ADVERTISING OVER ITS FIRST THREE YEARS ON THE MARKET* (2019),

http://tobacco.stanford.edu/tobacco_main/publications/JUUL_Marketing_Stanford.pdf

¹⁶ Deanna Paul, *North Carolina sues JUUL, setting up a fresh legal fight for the embattled e-cigarette company*, WASH. POST (May 15, 2019),

https://www.washingtonpost.com/health/2019/05/15/north-carolina-sues-juul-setting-up-fresh-legal-fight-embattled-e-cigarette-company/?noredirect=on&utm_term=.b49e601ae199.

¹⁷ Maria Cooper et al., *E-Cigarette Use Among Middle and High School Students—United States, 2022*, 71 MMWR 1283, 1283 (Oct. 7, 2022),

<https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

¹⁸https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2020_07_16-Letter-to-FDA-re-Bluetooth-Technology-in-Tobacco-Products.pdf.

Therefore, it is apparent that the JUUL2 PMTA will present FDA with new and unique scientific questions of great importance in determining whether JLI has demonstrated that its product produces a net public health benefit, as required by the TCA. We urge FDA to refer this PMTA to TPSAC for a report and recommendation and to ensure the same degree of transparency and public participation that would occur with respect to referrals of MRTPs to TPSAC.

Respectfully submitted,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Parents Against Vaping e-cigarettes (PAVe)
Truth Initiative