June 15, 2021

Mr. Mitch Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

RE: Relevance of North Carolina Case Against JUUL to JUUL PMTA

Submitted by e-mail.

Dear Director Zeller:

Multiple state attorneys general have filed lawsuits against JUUL Labs, Inc., (JUUL) alleging violations of state Unfair Trade Practice statutes and other laws, through the design, marketing and sale of JUUL e-cigarettes to attract young people to tobacco use and to deceive consumers. In the case brought by the State of North Carolina, trial is currently set to begin on July 12, 2021. As you know, a Premarket Tobacco Application (PMTA) for various JUUL products is currently pending before FDA, requiring FDA to determine whether the continued sale of these products is "appropriate for the protection of the public health." Because many documents obtained from JUUL during the discovery process are likely to be highly relevant to FDA's consideration of the JUUL PMTA, we urge you to require JUUL to transmit to FDA the documents produced in the discovery process, including any expert reports that may have been developed from a review of such documents.[1] In addition, it has been reported that sanctions have been imposed on JUUL for discovery abuse in the North Carolina litigation, including the deletion of data concerning JUUL's age-verification system and images from JUUL's youth-oriented social media posts.[2] We urge FDA to take this conduct into account in evaluating the JUUL PMTA, particularly in assessing the credibility of any assertions by JUUL that its products will not appeal to youth and that it will institute adequate safeguards against youth access to its products.[3]

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[1] There is no question that FDA has the authority to require JUUL to supplement its PMTA by submitting relevant documents produced in the North Carolina litigation. Under Section 910 of the Food, Drug & Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, (Tobacco Control Act) FDA has the authority to require a PMTA to include "such other information relevant to the subject matter of the application as the Secretary may require." 21 U.S.C. §387j(b)(1)(G).

[2] Virginia Bridges, *Judge's ruling could be 'death penalty' for e-cigarette maker Juul in NC lawsuit*, NEWS & OBSERVER, May 18, 2021, https://www.newsobserver.com/news/business/article251468028.html.

[3] In evaluating the JUUL PMTA, FDA clearly has the authority to consider JUUL's conduct in the North Carolina litigation, given the nature of the material JUUL deleted and its obvious relevance to whether youth will be exposed to JUUL advertising or use JUUL's products. Under Section 910 of the Tobacco Control Act, FDA "shall deny [a PMTA] if, upon the basis of the information submitted to the Secretary as part of the application ***and any other***

The JUUL PMTA

Whether the statutory public health standard is met in a PMTA requires FDA to assess "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product."[4] In turn, this population-wide assessment must take into account, (A) "the increased or decreased likelihood that existing users of tobacco products will stop using such products," and (B) "the increased or decreased likelihood that those who do not use tobacco products will start using such products."[5] As we argued in our April 27, 2021 letter to Acting Commissioner Woodcock, in applying the public health standard to the JUUL PMTA, it is critical that FDA recognize that the JUUL products that are the subject of the company's PMTA have been on the market for several years and that the agency take into account the adverse real-world impact on public health, and particularly the impact on youth initiation, of those products.

Thus, as discussed at length in our April 27 letter, the actual experience with JUUL's products demonstrates the following:

- JUUL e-cigarettes have been primarily responsible for the epidemic of youth e-cigarette use and resulting youth nicotine addiction.

- JUUL marketing of flavored e-cigarettes has been a key factor driving the appeal of those products to youth.

- JUUL products deliver unprecedented levels of nicotine efficiently with minimal irritation, thus causing addiction among substantial numbers of youth, who are particularly vulnerable to the addictive effects of nicotine.

- The sleek, high-tech design of JUUL e-cigarettes, which resemble a USB flash drive and are highly concealable, contributes to the appeal of these products to youth.

- JUUL's marketing and sales strategies, including youth-oriented imagery and themes, with sophisticated use of social media and other marketing avenues calculated to reach young people (e.g. online advertising and sales without adequate age-gating restrictions), represent an intentional effort to target young people and make these highly addictive products appealing to youth.

information before the Secretary with respect to such tobacco product, the Secretary finds that there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (emphasis added). 21 U.S.C. §387j(c)(2)(A).

[4] 21 U.S.C. §387j(c)(4).

[5] 21 U.S.C. §387j(c)(4)(A) and (B).

North Carolina's Case Against JUUL and Its Relevance to the JUUL PMTA

Given the nature of the allegations in North Carolina's case against JUUL, there is little doubt that many documents produced by JUUL in discovery are likely to be highly relevant to FDA's evaluation of the JUUL PMTA (e.g. actual impact of the JUUL products on public health, particularly their impact on youth initiation). The core of the North Carolina case is that "JUUL's actions – designing, marketing, and selling e-cigarettes in ways that it knows will attract minors and deceptively downplaying the potency and danger of the nicotine in its e-cigarettes – are unfair, deceptive, and illegal under North Carolina law."[6] The specific allegations against JUUL include the following: (1) JUUL adopted flavors, and a sleek design that enhanced its concealability, to appeal to young people (Complaint, ¶¶ 28, 29, 38-45; 52-54); (2) JUUL altered the chemistry of its products to deliver highly addictive levels of nicotine while reducing the harshness of the nicotine to appeal to new users, especially young people (Complaint, ¶¶ 46-51); (3) JUUL deceived the public, including minors, about the nicotine potency of its products (Complaint, ¶¶ 96-117); (4) JUUL marketed its e-cigarettes in ways that increased their appeal to youth (Complaint, ¶¶ 55-73); (5) JUUL took a lax approach to age verification for its internet sales and knew that its system was insufficient (Complaint, ¶¶ 74-95); and (6) through its targeting of youth, JUUL has played a central role in fostering the epidemic of e-cigarette use among youth (Complaint, at 3, ¶¶ 118-126). Each of these allegations is plainly relevant to a determination of whether a marketing order allowing the continued sale of these products meets the public health standard. No FDA evaluation of JUUL's PMTA can possibly be sufficient without agency access to the relevant discovery documents produced in the North Carolina case. FDA should require JUUL to provide the agency with the documents produced in discovery, including any expert reports that may have been developed from a review of such documents. In order to avoid allowing JUUL to burden the agency with millions of irrelevant documents, an abuse that has characterized JUUL's conduct in the North Carolina case,[7] FDA should take all steps necessary to obtain, from the North Carolina Attorney General, guidance as to the documents most relevant to the public health impact of JUUL and its marketing practices, including requesting that the Attorney General obtain any relief from protective orders in place in that litigation as necessary to provide FDA with such guidance.

Moreover, the fact that JUUL has been sanctioned by the North Carolina court for deleting material that bears directly on JUUL's targeting of youth in its marketing activities, and on its system for verifying the age of purchasers, is highly relevant to FDA's evaluation of the credibility of any assertions made by JUUL in its PMTA that it will not target youth in its marketing activities and that it will implement age verification systems that effectively prevent access to its products by underaged individuals. Given JUUL's pivotal role in the youth e-cigarette epidemic, as described in detail in our April 27 letter to Acting Commissioner Woodcock, its conduct in the North Carolina case designed to conceal the full scope of its marketing activities to appeal to youth, and the inadequacy of its age verification system, is plainly material to the JUUL PMTA.

[6] Complaint and Motion for Preliminary Injunction, *State of North Carolina v. JUUL Labs, Inc.*, Superior Court No. 19CVS 2885 (May 15, 2019), at 7 (Complaint).
[7] *See* Bridges, *supra* note 2.

In summary, we urge FDA to require JUUL to submit to the agency all relevant documents produced in discovery in the North Carolina litigation, including any expert reports that may have been developed from a review of such documents, and to reach no decision on the JUUL PMTA without taking into account the implications of those documents, and of JUUL's sanctionable conduct in the North Carolina litigation. Without such information and consideration, the agency cannot determine whether the continued sale of JUUL e-cigarettes are "appropriate for the protection of the public health."

Respectfully,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Cc: Acting Commissioner Dr. Janet Woodcock