October 14, 2022

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993-0002

RE: Deficiencies in Final Guidance for Industry on TPPI Studies, FDA-2019-D-4188

By e-mail.

Dear Dr. King:

We wish to again express our appreciation to you and Dr. Califf for the time given us to meet and share our views on the central issues facing the FDA in regulating tobacco products.

We write now because we are concerned that the recently-issued Guidance for Industry "Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies" (TPPI Guidance or Guidance) fails to address the critical importance of studies that provide direct evidence of the potential impacts of new tobacco products and modified risk claims on American youth and adolescents. Although the TPPI Guidance recommends that applicant companies "consider the potential impacts to vulnerable populations," it fails to even mention youth as a "vulnerable population." TPPI Guidance at 20. We request that FDA promptly withdraw the Guidance and remedy this deficiency. This letter is being filed as a comment in the above-referenced Docket.

In our joint comments on FDA's Draft Guidance on TPPI Studies, we discussed in detail the importance of direct evidence of youth perception and intention to support Premarket Tobacco Product Applications (PMTAs) and Modified Risk Tobacco Product Applications (MRTPs).[1] As we explained, the failure to present such data has meant that new tobacco products and reduced risk claims are being authorized even though manufacturers have failed to meet their statutory burden to demonstrate a public health benefit. We also presented the views of established tobacco researchers as to how youth perception evidence could be developed with sufficient protocols and safeguards to ensure its scientific integrity and due protection of study subjects, even if funded by tobacco companies in connection with PMTAs and MRTPs.[2] It is noteworthy that comments on the Draft Guidance consistent with our views were submitted by

[1] Comments of American Academy of Pediatrics, et al., in Docket No. FDA-2019-D-4188 (December 28, 2020), https://www.regulations.gov/comment/FDA-2019-D-4188-0011.
[2] *See* Halpern-Felsher, et al., *The Importance of Including Youth Research in Premarket Tobacco Product and Modified Risk Tobacco Product Applications to the Food and Drug Administration*, 67(3) J. ADOLESCENT HEALTH 331 (2020).

researchers on behalf of the Arnold School of Public Health at the University of South Carolina[3] and by the University of California at San Francisco TCORS.[4]

Over the last several years you and several other Tobacco Products Scientific Advisory Committee (TPSAC) participants have repeatedly emphasized the adverse public health risks that arise from the authorization of new products and modified risk claims with inadequate data about the impact on youth.[5] In the February, 2019 TPSAC meeting, you warned against the hazards of excessive reliance on post-market surveillance, particularly as to youth, citing the example of Juul e-cigarettes as an illustration of a product that caused enormous public health harm long before FDA was able to act to protect kids.[6] We agree with you that our young people can be sufficiently protected against tobacco-related harm only by a rigorous premarket assessment of the risks of new products and claims, which must include youth data. Tobacco companies should no longer be allowed to conduct real-world experiments on youth with new products and reduced risk claims.

As Director of the Center for Tobacco Products (CTP) you are now in the position to ensure that no new tobacco product or modified risk claim is authorized without sufficient direct evidence of its impact on youth. The TPPI Guidance should be promptly withdrawn and CTP should prioritize development of a new Guidance that strongly recommends that applicants submit direct evidence of youth perception and specifies the protocols and safeguards to be used in developing such evidence. CTP should authorize no new tobacco products nor modified risk claims in the absence of such evidence.

Thank you for your consideration of our views.

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[3] Thrasher, et al., Public Comments Submitted to FDA-CTP on Draft of "Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies: Guidance for Industry" (Dec. 21, 2020), at 5-6 (noting that the Draft Guidance "does not address the issue of research with those who are not of legal age to purchase tobacco products," and asserting that although "industry should not be allowed to conduct this research or have access to the databases that result because of the possibility of using these data to design products or labeling that appeal to youth . . . for consumer perception studies, it is possible to establish processes whereby industry funds credible, independent researchers . . . ."

[4] Lempert, et al., Docket No.: FDA-2019-D-4188 (Dec. 21, 2020), at 5 ("TPPI studies should specifically consider youth perceptions as well as adult perceptions, although tobacco companies should not conduct studies on youth directly and should instead follow strict safeguards.").

[5] *See e.g.*, TPSAC meeting on PMI's IQOS MRTPs, January 24-25, 2018, Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2018-tpsac-meeting-materials-and-information; TPSAC Meeting on Reynolds' Camel Snus MRTPs, Sept. 13-14, 2018, Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2018-tpsac-meeting-materials-and-information; TPSAC Meeting on Swedish Match General Snus MRTP Amendment, Feb. 6, 2019, Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2019-tpsac-meeting-materials-and-information; TPSAC Meeting on Altria/US Smokeless Copenhagen Snuff MRTP, Feb. 6, 2019, Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2019-tpsac-meeting-materials-and-information; TPSAC Meeting on 22nd Century VLN Cigarette MRTPs, Feb. 14, 2020 Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/advisory-committee-calendar/february-14-2020-tobacco-products-scientific-advisory-committee-meeting-02142020-02142020.

[6] Transcript and other meeting materials available at https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2019-tpsac-meeting-materials-and-information.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

CC: Dr. Robert Califf, Commissioner, U.S. Food and Drug Administration