Paige C. Magness
Senior Vice President
Regulatory Affairs

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Division of Dockets Management
Food and Drug Administration
5639 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2018-N-0180 – Comments to Docket on "Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications"

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA), John Middleton Co. ("JMC"), U.S. Smokeless Tobacco Company LLC ("USSTC"), and Helix Innovations LLC ("Helix"),[1] submits these comments in response to the above-referenced docket.[2]

The Food and Drug Administration ("FDA") seeks to collect data that "will serve the primary purpose of providing FDA information about the perceived effectiveness of messages, advertisements, and materials in reaching and successfully communicating with their intended audiences."[3] Using this information, FDA says it "will create and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the risks of tobacco use, how to quit using tobacco products and FDA's role in regulating tobacco."[4]

As FDA continues the important work of collecting quantitative data on tobacco products and communications, we urge the Agency to 1) design and utilize research to help correct deeply entrenched public misperceptions regarding the health effects of nicotine and 2) study the efficacy of messages regarding the relative risks between combustible and non-combustible tobacco products including the "risk cliff" view of tobacco harm reduction.

[1] PM USA, JMC, and USSTC are wholly owned subsidiaries of Altria Group, Inc. ("Altria"). Helix is a majority-owned subsidiary of Altria Enterprises II LLC, which is a wholly owned subsidiary of Altria. PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and JMC manufactures cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, JMC, USSTC, and Helix.
[2] FDA invites comments on, among other things, "ways to enhance the quality, utility, and clarity of the information to be collected." 86 Fed. Reg. 12952, 12953 (March 5, 2021).
[3] *Id.*
[4] *Id.*

Altria Client Services LLC
601 E. Jackson Street
Richmond, Virginia 23219
(804) 335-2353
Paige.C.Magness@altria.com

I. FDA Should Research Means to Address Nicotine Misperceptions That Threaten Harm Reduction

The need to clarify the relative risks between combustible and non-combustible products is driven by deeply entrenched misperceptions regarding the role of nicotine. Although FDA has long recognized that the death and disease that comes from smoking is not directly attributable to nicotine, [5,6] many adult smokers do not understand that "[n]icotine is what addicts and keeps people using tobacco products, but it is not what makes tobacco use so deadly."[7]

For example, a 2016 study analyzing data from the Health Information National Trends Survey found that 73 percent of people "either incorrectly believed that nicotine is the main substance in cigarettes that causes cancer or were unsure about the relationship between nicotine and cancer."[8] This entrenched misperception is not limited to adult smokers. For example, a recent study found that more than 80% of surveyed physicians, one of the stakeholder groups FDA intends to research, "strongly agreed" that nicotine directly contributes to the development of cardiovascular disease, COPD and cancer.[9] These misperceptions among physicians strike at the core of the collection's purpose to inform and educate health professionals about the health risks of tobacco use and present an opportunity to correct physician-held misperceptions about nicotine.

Collectively, these misperceptions could result in smokers rejecting non-combustible alternatives simply because they contain nicotine[10] and demonstrate a clear need for "developing health messages, communication strategies, and public information programs" to correct these misperceptions.[11] Despite a commitment from FDA to "reframe the conversation around nicotine and harm reduction,"[12] adult tobacco consumers and other important stakeholder groups like physicians remain unclear about the role of nicotine in, and the health risks associated with, combustible versus non-combustible tobacco products.

To reframe the conversation, factual information from trusted sources must be made available to adult tobacco consumers and physicians. As discussed at a Tobacco Products Scientific Advisory Committee meeting, well-funded, evidence-based communications campaigns can be effective in correcting nicotine

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[5] Alex Azar and Scott Gottlieb. "We cannot let e-cigarettes become an on-ramp for teenage addiction." *The Washington Post.* October 11, 2018. https://www.washingtonpost.com/opinions/we-cannot-let-e-cigarettes-become-an-on-ramp-for-teenage-addiction/2018/10/11/55ce424e-ccc6-11e8-a360-85875bac0b1f_story.html.

[6] U.S. Department of Health and Human Services (USDHHS). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.

[7] *See*, Nicotine: The Addictive Chemical in Tobacco Products, August 28, 2020. *Available at*, https://www.fda.gov/tobacco-products/health-information/nicotine-addictive-chemical-tobacco-products.

[8] Remarks by Scott Gottlieb, M.D., *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco*. (June 28, 2017). https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.

[9] Steinberg, M.B., Bover Manderski, M.T., Wackowski, O.A. *et al.* Nicotine Risk Misperception Among US Physicians. *J GEN INTERN MED* (2020). https://doi.org/10.1007/s11606-020-06172-8.

[10] "The misperception of the risks of these products results in smokers rejecting them, misperceptions that arise from inaccurate information and sensational media headlines. Public health officials are misinformed by these sources as well, plus they buttress their opposition to tobacco harm reduction products with unsubstantiated fears of youth addiction. These barriers will need to be addressed if tobacco harm reduction is to make the maximum impact on the tobacco endemic." O'Leary, R.; Polosa, R. Tobacco harm reduction in the 21st century. *Drugs and Alcohol Today*. Apr. 20, 2020. DOI 10.1108/DAT-02-2020-0007.

[11] *Id.* at 12593.

[12] Scott Gottlieb, M.D., and Mitch Zeller, J.D., Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine (August 2, 2018), *available at* https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-tobacco-regulation-protect-children-and-families-updates-and-new-initiatives-fda.

misperceptions.[13] Building on its reported success in other targeted communication campaigns,[14] and aligned with FDA's goal of "maximizing the effectiveness of messages and strategies for reaching targeted audience,"[15] we urge FDA to conduct a communications campaign focused on correcting nicotine misperceptions among targeted adult tobacco consumer and physician audiences.

II. FDA Should Study Potential Inclusion of the "Risk Cliff" Concept in Communications with Adult Tobacco Consumers

As FDA contemplates its continued research to communicate with adult tobacco consumers, we urge the Agency to consider an alternative view of the continuum of risk,[16] the "risk cliff" model. Data suggest that the two dimensional "risk cliff" model is a useful description of the relative risk between combustible and non-combustible products,[17,18,19] as the body of evidence indicates a profound risk differential between the product categories as a whole.[20]

In this model, the highest risk products (cigarettes) are presented at the top of a "cliff" and non-combustible products (Smokeless Tobacco, Oral Tobacco-Derived Nicotine, Electronic Nicotine Delivery Systems, Heated Tobacco Products) rest at the foot of the cliff. Figure 1(a) shows the results of a risk analysis of nicotine-containing product categories and Figure 1(b) shows a visualization of a risk cliff model.[21] Importantly, the risk cliff makes clear that non-combustible products are not without risk, as all nicotine-containing products pose risks, including addiction.

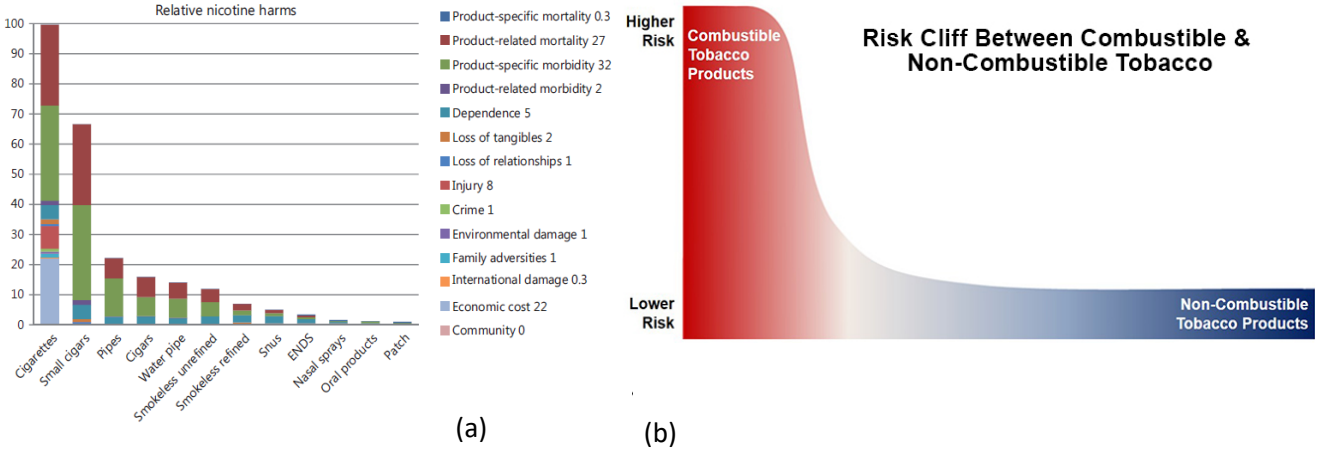

Figure 1: (a) Ranking of relative harm from nicotine-containing products from Nutt et al. (b) Visualization of the same data as a two-dimensional risk cliff

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[13] Presentation by M. Justin Byron, PhD, "Investigating and addressing the perceived risk of nicotine and very low nicotine content cigarettes" (February 14, 2020).
[14] Press Release, FDA launches new, comprehensive campaign to warn kids about the dangers of e-cigarette use as part of agency's Youth Tobacco Prevention Plan, amid evidence of sharply rising use among kids (September 18, 2018). *Available at*, https://web.archive.org/web/20190119201459/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm.
[15] *Id*. at 12954.
[16] As part of the 2017's "Comprehensive Plan for Tobacco and Nicotine Regulation," FDA endorsed the continuum of risk "rang[ing] from combustible cigarettes at one end, to medicinal nicotine products at the other." *See*, Remarks by Scott Gottlieb, M.D., *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (June 28, 2017). *Available at* https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.
[17] Nutt, et. al Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.
[18] Clark, B. Presentation to GTNF: *Risk Continuum or Risk Cliff: Appropriate Evidence for Appropriate Claims*. 2016.
[19] Knowledge.Action.Change. *No Fire No Smoke: Global State of Tobacco Harm Reduction* 2018 https://gsthr.org/report/full-report-online (last accessed 08.13.2020).
[20] *See* Figure 1(a).
[21] Nutt, et. al Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.

The risk cliff approach builds on the linear harm continuum depicted in FDA's communications, providing an easily understandable, and different, description of the relative risk of tobacco products. FDA should research the utility of placing the risk cliff and its combustible/non-combustible comparison at the center of communications to adult smokers.

Conclusion

At Altria, our 10-year vision is to responsibly lead the transition of adult smokers to non-combustible products. With increasing adult smoker demand for potentially reduced risk, non-combustible products, a commitment to innovation, and an appropriate regulatory framework, we have the opportunity to make more progress on reducing the harm caused by combustible cigarettes.

A research-driven, FDA-led communication program can begin to address nicotine misperceptions that thwart adult smoker conversion and advance understanding of the substantial risk differentials between combustible and non-combustible tobacco products.

Thank you for your consideration of our recommendations. Please feel free to contact me if you would like to discuss our ideas further.

Sincerely,