Gregory B. Wilson
Vice President
Regulatory Affairs

April 27, 2020

Via Electronic Submission

Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS–D74
Atlanta, GA 30329

Re: Docket No. CDC-2020-0018 (85 Fed. Reg. 10,694 February 25, 2020) – Comments on Proposed Data Collections Submitted for Public Comment and Recommendations, Message Testing for Tobacco Communication Activities ("MTTCA")

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

We support the Centers for Disease Control and Prevention's ("CDC") request to extend Message Testing for Tobacco Communication Activities' ("MTTCA") clearance to include testing of messages on heated tobacco products.[3] As we stated in recent comments on the 2021-2023 National Youth Tobacco Surveys[4] ("NYTS"), we support a comprehensive approach to tobacco product category research and communication development, including expansion of the tools to cover new tobacco product categories.

Also, given MTTCA's goal to support campaigns to "increase public awareness of the health consequences of tobacco use…" coupled with the wide dissemination of MTTCA-developed

[1] PM USA is a 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. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products and Helix manufactures oral tobacco-derived nicotine products, including *on!* ® nicotine pouches. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA and Helix.
[2] 85 Fed. Reg. 10,694 (February 25, 2020).
[3] *Id*.
[4] *See*, ALCS Comments to NYTS 2021-2023, dated March 27, 2020. Available at, https://www.regulations.gov/document?D=CDC-2019-0117-0005.

Altria Client Services LLC
2325 Bells Road
Richmond, Virginia 23234
(804) 335-2034
Gregory.B.Wilson@altria.com

messages via television, radio, print, out-of-home, and digital formats,[5] we encourage CDC to develop and deliver messages that address deep public misperceptions about nicotine, which are undermining progress in tobacco harm reduction.

I. CDC and FDA Should Incorporate the MTTCA's Heated Tobacco Products Insights in Future Communications Campaigns

A key component of FDA's Comprehensive Plan is to "account for the role of all noncombustible products,"[6] facilitated by "[policy] changes that will move addicted smokers down that continuum of risk to these less harmful products."[7] To advance this harm reduction goal, adult tobacco consumers must receive truthful and accurate messages about potentially reduced risk products, including heated tobacco products. In order for these communications to be most effective, they should come directly from trusted public health authorities, such as CDC and FDA. In fact, because tobacco manufacturers are barred from making reduced risk claims outside of an authorized Modified Risk Tobacco Product Application ("MRTPA"), CDC and FDA's roles as trusted communicators are critical to advancing FDA's Comprehensive Plan. Individuals look to the public health community for direction when assessing risks and must trust that the provided information reflects science and evidence for it to be well-received, accepted, and implemented.

As we urged in recent comments on the NYTS 2021-2023 surveys, CDC must keep pace with changes in the market to ensure its efforts to reduce the harm caused by tobacco remain as effective as possible.[8] Timely incorporation of new tobacco product categories into research and surveys will increase the efficacy of federal public health efforts.

In April 2019, FDA authorized, as appropriate for the protection of public health, the first heated tobacco product for sale in the U.S., the IQOS® device and three HeatSticks® variants.[9] CDC should test messages that reflect FDA's scientific evaluation that found the aerosol produced by IQOS® contains fewer toxic chemicals than cigarette smoke, with many of the toxins present at lower levels than in cigarette smoke.[10] Beginning with such baseline facts will facilitate accurate collection of information about adult smokers' attitudes and perceptions toward heated tobacco products. CDC and FDA can then use this information to develop appropriate and effective relative risk communications to adult tobacco consumers. Such truthful and accurate

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[5] 85 Fed. Reg. at 10,694.
[6] *See* Speech by Scott Gottlieb, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (July 28, 2017), *available at* https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.
[7] *Id*.
[8] *See*, ALCS Comments to NYTS 2021-2023.
[9] IQOS® is an electronic device that heats tobacco in HeatSticks® and produces a nicotine-containing tobacco aerosol without combustion. FDA authorized for sale IQOS® and three HeatSticks variants, Marlboro HeatSticks®, Marlboro Smooth Menthol HeatSticks®, and Marlboro Fresh Menthol HeatSticks®, through the Premarket Tobacco Product Application ("PMTA") pathway.
[10] *See*, "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway," April 30, 2019. *Available at*, https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

communications could help facilitate the transition of adult tobacco consumers down the continuum of risk.[11]

Beyond heated tobacco products, we encourage CDC to similarly prioritize capturing data and developing communication plans for other potentially reduced risk products, such as smokeless tobacco, and nascent product categories, including oral tobacco-derived nicotine products, such as *on!*® nicotine pouches.

II. Expanded Message Testing Could Be Used to Inform a Communications Campaign to Correct Nicotine Misperceptions and Bolster Tobacco Harm Reduction Efforts

Additional MTTCA message testing on nicotine could inform a campaign designed to dispel entrenched public misperceptions of nicotine's health effects, which undermine harm reduction efforts. While nicotine is addictive, it is the exposure to smoke – not nicotine – that causes most tobacco-related disease. Tobacco harm reduction requires that adult smokers who do not quit should be able to get nicotine from non-combustible products towards the lowest end of the continuum of risk. In fact, when FDA announced its Comprehensive Plan in 2017, then-FDA Commissioner Gottlieb stated FDA policy should be used as a vehicle to "move addicted smokers down that continuum of risk to these less harmful [innovative] products."[12] Further, Gottlieb stated "A centerpiece of this comprehensive regulatory plan is acknowledging that nicotine, while highly addictive, is delivered through products on a continuum of risk. And it's the delivery mechanism – not the nicotine itself – that is truly the issue at-hand."[13]

Persistent misperceptions regarding the role of nicotine and the relative risks of different tobacco products prove to be a significant obstacle to adult smokers choosing products that present potential reduced harm as compared to combustible cigarettes. For example, a 2016 study found "Most people (73%) either incorrectly believed that nicotine is the main substance in cigarettes that causes cancer or were unsure about the relationship between nicotine and cancer."[14] Potentially reduced harm products will have limited success in transitioning adult smokers until these misperceptions are corrected.

CDC and FDA are uniquely positioned to lead a campaign (utilizing CDC's MTTCA-developed messages) to correct deeply entrenched misperceptions about the role of nicotine in smoking-related disease. CDC and FDA have a track record of executing mass communication campaigns and have published results that appear to show the success of such campaigns.[15] FDA's "The

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[11] Philip Morris International ("PMI") awaits an FDA decision on its pending MRTPAs for IQOS® and HeatSticks.® If authorized, PMI will be able to communicate reduced harm messages directly to adult tobacco consumers. PMI submitted its MRTPAs for IQOS® and HeatSticks® in December 2016. FDA filed the MRTPAs for scientific review in May 2017.

[12] *See*, Scott Gottlieb, M.D., July 28, 2017 Remarks.

[13] *See*, Remarks by Scott Gottlieb, M.D., *Remarks on the Regulation of Nicotine* (October 17, 2017), *available at* https://www.fda.gov/news-events/speeches-fda-officials/remarks-regulation-nicotine-10192017.

[14] *Id.*

[15] 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*

Real Cost" campaign, for instance, reportedly "prevented an estimated 350,000 teens ages 11 to 18 from initiating smoking between 2014 and 2016," by utilizing a paid media strategy.[16] In addition, a 2019 study supports the notion that targeted communication campaigns may be useful in addressing the widespread misperceptions regarding nicotine.[17] As discussed in a recent meeting of the Tobacco Products Scientific Advisory Committee ("TPSAC"), broad-reach, well-funded, evidence-based communications campaigns can be effective in correcting nicotine misperceptions.[18]

CDC and FDA should leverage learnings from the MTTCA to build a comprehensive campaign to correct misperceptions about nicotine in order to advance tobacco harm reduction and achieve one the primary goals of FDA's 2017 Comprehensive Plan – to help adult cigarette smokers switch to potentially less harmful forms of nicotine delivery.[19]

Conclusion

We appreciate the opportunity to comment on CDC's request to expand MTTCA message testing to include heated tobacco products and to offer our suggestions on how MTTCA can be leveraged to help correct persistent nicotine misperceptions. Both actions would help advance tobacco harm reduction. Please let us know if you have any questions or would like to discuss any of our ideas further.

Sincerely,

https://web.archive.org/web/20190119201459/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm.

[16] *See*, The Real Cost Campaign, *available at* https://www.fda.gov/real-cost-campaign.

[17] Villanti, A. C., West, J. C., Mays, D., Donny, E. C., Cappella, J. N., & Strasser, A. A. (2019). Impact of Brief Nicotine Messaging on Nicotine-Related Beliefs in a U.S. Sample. *American Journal of Preventive Medicine*, 57(4), e135-e142. doi:10.1016/j.amepre.2019.05.015.

[18] Presentation by M. Justin Byron, PhD, *"Investigating and addressing the perceived risk of nicotine and very low nicotine content cigarettes*" (February 14, 2020).

[19] *See*, Scott Gottlieb, M.D., July 28, 2017 Remarks.