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February 25, 2021

Submitted via email

Mr. Mitch Zeller, J.D.
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Ave.
Document Control Center
Building 71, Room G335
Silver Spring, MD 20993-0002

Re: FDA-20-SSN-CTP-Campaigns-Program; RFP_FDA-SOL-1230974

Dear Director Zeller:

I write regarding the Center for Tobacco Products' ("CTP" or "Center") plans for an expansive new public education campaign supported by "a full range of communication activities...to target both national and niche audiences."¹ The Center's ambitious approach includes "placing annual media buys in excess of \$100 million."² The Tobacco Control Act placed the Food and Drug Administration ("FDA" or "Agency") at the center of the government's tobacco harm reduction efforts. Altria fully supports the application of CTP's communication campaign experience toward reducing the harm caused by tobacco.

Through this comprehensive communication effort, CTP should commit resources and expertise to correct the deeply entrenched public misperceptions regarding the health risks of nicotine. Left unaddressed, these widespread nicotine misperceptions could discourage adult smokers from switching to non-combustible tobacco products that may present lower health risk as compared to combustible cigarettes.

¹ See, CTP Public Education Campaign, Notice ID: RFP-FDA-SOL-120974. Available at, https://beta.sam.gov/opp/f8de5ce0ee76498a80a6500e3bf1f280/view?keywords=%22FDA%E2%80%99s%20Center%20for%20Tobacco%20Products%22&sort=-relevance&index=&is_active=true&page=1.

² *Id.*, at Amend1_RFP_FDA-SOL-1230974. Available at, https://beta.sam.gov/api/prod/ops/v3/opportunities/resources/files/80b25c228d54479fae5a52016354855e/download?api_key=null&status=archived&token=.

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Incorporating this important issue into CTP’s communication programs would:

- be consistent with the project’s goal “to reduce the public health burden of tobacco use” and “educate the public about the dangers of tobacco use”³;
- support the Agency’s goal to “foster a public dialogue to re-shape our country’s relationship with nicotine”⁴; and
- advance the “communication of scientific facts”⁵ prioritized by the Biden Administration.

As FDA and CTP recognize, nicotine is not directly responsible for the death and disease caused by smoking. Yet, these data illustrate the daunting scope of the public misperception of this fact:

- A 2016 study analyzing data from the Health Information National Trends Survey found “[m]ost 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.”⁶
- A recent study found that more than 80% of surveyed physicians “strongly agreed” that nicotine directly contributes to the development of cardiovascular disease, COPD and cancer.⁷

A recent presentation at a Tobacco Products Scientific Advisory Committee meeting addressed this opportunity by indicating that “[b]road reach, well-funded campaigns can be effective” at correcting nicotine misperceptions.⁸ Altria believes that the federal government, led by the FDA and executed by CTP, is best positioned with both the resources and expertise to deliver this campaign. CTP has a track record of executing such campaigns, along with published results demonstrating the success of past efforts.⁹

Accordingly, through prior comments, we have shared our perspective that foundational Agency research and communication activities could be directed toward correcting nicotine

³ *Id.*

⁴ Remarks by Scott Gottlieb, M.D., On pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels, March 18, 2018. Available at, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking>.

⁵ See, Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, January 27, 2021. Available at, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>.

⁶ 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>.

⁷ 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>.

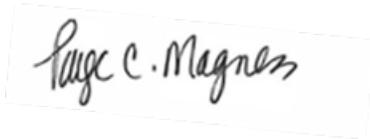
⁸ Presentation by M. Justin Byron, PhD, “*Investigating and addressing the perceived risk of nicotine and very low nicotine content cigarettes*” (February 14, 2020).

⁹ See, The Real Cost Campaign, available at <https://www.fda.gov/real-cost-campaign>.

misperceptions, including the Message Testing for Tobacco Communication Activities program¹⁰ and in qualitative research to guide educational and public information programs.¹¹

By committing resources to correct nicotine misperceptions, CTP can help adult tobacco consumers make informed decisions based on science and evidence. We appreciate your consideration of our suggestion to align the campaign's overall communication goal with this important public health opportunity. Please let us know if you have any questions or would like to discuss this further.

Sincerely,

A handwritten signature in cursive script that reads "Paige C. Magness". The signature is enclosed in a thin, light-colored rectangular border.

¹⁰ See, Altria Comments to Docket No. CDC-20202-0018, dated April 27, 2020. Available at, <https://www.regulations.gov/document?D=CDC-2020-0018-0003>.

¹¹ See, Altria Comments to Docket No. FDA-2014-N-0987 (85 Fed. Reg. 60,999 September 29, 2020). Available at, <https://www.regulations.gov/document?D=FDA-2014-N-0987-0018>.