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Altria Client Services

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Division of Dockets Management
Food and Drug Administration
5639 Fishers Lane, Room 1061
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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"), U.S. Smokeless Tobacco Company LLC ("USSTC"), John Middleton Co. ("JMC"), Sherman Group Holdings LLC ("Nat Sherman") and Nu Mark LLC ("Nu Mark"),[1] submits these comments in response to the Food and Drug Administration's ("FDA") proposed collection of information entitled, "Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications" ("the Notice").[2]

According to the Notice, the information FDA proposes to collect "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 conducts its research and ultimately implements new communication and education campaigns about the risks of tobacco use, we urge the Agency to direct resources to 1) develop communications to adult tobacco consumers about the continuum of risk and the relative risks of

[1] PM USA, USSTC, JMC, Nat Sherman, and Nu Mark are wholly-owned subsidiaries of Altria Group, Inc., ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout this letter to refer collectively to PM USA, USSTC, JMC, Nat Sherman and Nu Mark.
[2] FDA invites comments on, among other things, "ways to enhance the quality, utility, and clarity of the information to be collected." 83 Fed. Reg. 6190, 6191 (February 13, 2018).
[3] *Id.*
[4] *Id.*

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different tobacco products along the continuum of risk; and 2) address underage social access to tobacco products.

1. FDA Should Provide Adult Tobacco Consumers With Truthful and Accurate Communications About Reduced Risk Products Because Such Products Could Play an Important Role in Moving Smokers Down the Continuum of Risk.

A strong public health consensus has formed that not all tobacco products present the same risk. Public health authorities, including FDA, agree that there is a continuum of risk among tobacco products, with cigarettes at the highest end of that spectrum. This continuum recognizes that most of the harm caused by tobacco results from the burning of tobacco.

Despite efforts to persuade people to never start or to quit if they do, millions of adults will continue using tobacco products. There are currently about 40 million adult cigarette smokers in the U.S. According to the data from the FDA's Population Assessment of Tobacco and Health ("PATH") study, more than half, or 22 million, of these smokers are interested in satisfying but less harmful nicotine alternatives to cigarettes.[5] For these consumers, appealing reduced-risk products may offer a promising opportunity to reduce the harm associated with tobacco use, particularly cigarette smoking.

On July 28, 2017, FDA announced a new Comprehensive Approach to Nicotine and Tobacco Regulation (the "Comprehensive Plan").[6] In this announcement, FDA recognized, for the first time, "that there's a continuum of risk for nicotine delivery," and "[t]hat continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other."[7] We applaud the Agency for clearly acknowledging – and embracing – the continuum of risk and the importance of regulating the tobacco industry in a way that encourages the development of innovative tobacco products that can reduce the harm associated with smoking.

The Comprehensive Plan places nicotine at the "center of [FDA] regulatory efforts,"[8] and recognizes that different tobacco products present different levels of risk to the user. To that end, the Comprehensive Plan envisions "a world where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them."[9]

Despite recognition by FDA and other public health authorities of a continuum of risk, tobacco consumers remain alarmingly misinformed about the relative risks of different tobacco products. Figure 1 below illustrates the risk perceptions of adult cigarette smokers regarding various products as compared to smoking cigarettes. According to an ALCS Analysis of PATH Wave 1 (September 2013- December 2014), 45% of respondents incorrectly believe that e-cigarettes are

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[5] *"Highlighted Findings From Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study"* Plenary presentation at the 22nd Annual Meeting of the Society for Research on Nicotine & Tobacco (2016), Chicago IL. Wave 1 was conducted September 2013 – December 2014.

[6] More information on FDA's Comprehensive Plan is available at https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm.

[7] Scott Gottlieb, Commissioner, U.S. Food and Drug Administration, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 28, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm.

[8] *Id.*

[9] *Id.*

more harmful or about as harmful as combustible cigarettes.[10,11,12] Further, over 90% of respondents incorrectly believe that smokeless tobacco products are as harmful or more harmful than cigarette smoking.[13,14]

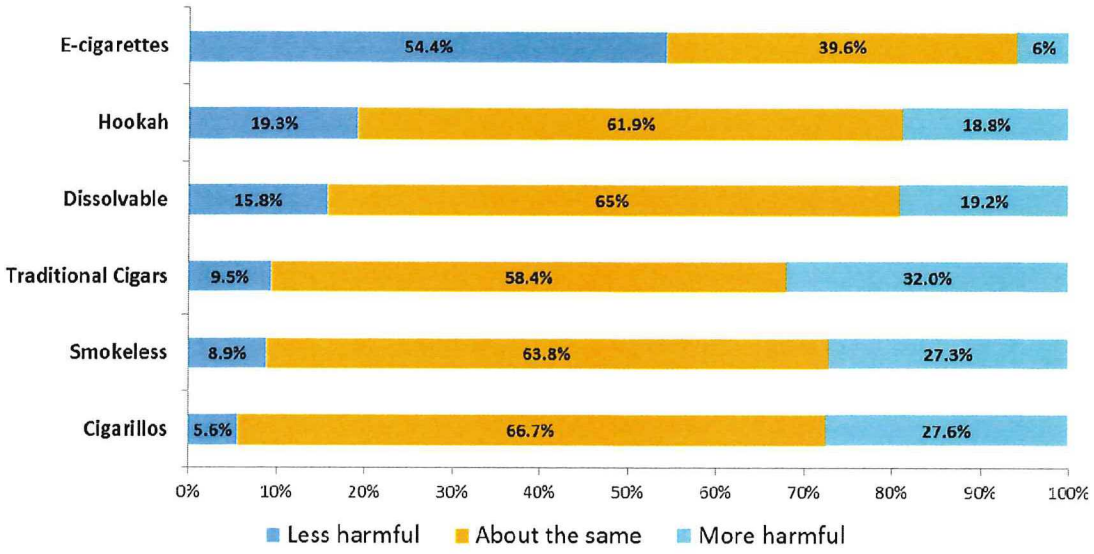

Figure 1. Perceived harmfulness of using [product] compared to smoking cigarettes… (among adult cigarette smokers). Harm Perceptions among Adult Cigarette Smokers (2013/14). ALCS Analysis of PATH Wave 1 (September 2013- December 2014). Adult Public Use File. In PATH, "Don't Know" is not included in the valid response set. Percentages may not sum to 100% due to rounding.

These misperceptions have important consequences. For example, according to data in the 2010-2011 wave of the Tobacco Use Supplement to the Current Population Survey, many long term cigarette smokers tried to quit cigarette smoking by switching to other combustible tobacco products,[15] suggesting lack of awareness of the continuum of risk. Furthermore, some consumers switch from smokeless tobacco to cigarettes in order to quit using smokeless tobacco.

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[10] "The Population Assessment of Tobacco and Health ('PATH') Study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the United States will take part in this study. The PATH Study is the first large research effort undertaken by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) since Congress gave FDA authority to regulate tobacco products in 2009." Additional information is available at https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx.

[11] According to a Report by Public Health England, "Best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes." *E-cigarettes: an evidence update, A report commissioned by Public Health England*, 2015, Public Health England, p. 5, *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

[12] ALCS Analysis of PATH Wave 1 (September 2013- December 2014), Adult Public Use File. In PATH, "Don't Know" is not included in the valid response set. Additional information is available at https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx.

[13] *Id.*

[14] *See* Royal College of Physicians of London, Tobacco Advisory Group of the Royal College of Physicians, *Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit* (London: RCP 2007), p. 18, ("The health risks of smokeless tobacco are considerably lower than those associated with combustible tobacco products as it is largely the combustion process that makes tobacco use so deadly.") *See also* K. Meister, *Helping Smokers Quit: A Role for Smokeless Tobacco?,* American Council on Science and Health (2006) at 5 ("[o]verall, the use of smokeless tobacco confers *only about 2% of the health risks of smoking*," emphasizing that in contrast to cigarette smoking, smokeless tobacco poses no risk of lung cancer or chronic pulmonary diseases and little risk, if any, of other cancers. (Emphasis added)).

[15] Soulakova JN, Crockett LJ. Unassisted Quitting and Smoking Cessation Methods Used in the United States: Analyses of 2010-2011 Tobacco Use Supplement to the Current Population Survey Data. Nicotine Tob. Res. 2016.

For example, Ebbert et al. reported that 9% of smokeless tobacco users attending a smokeless co-treatment program began using combustible products in the next week rather than using smokeless tobacco.[16] Among a sample of male college students, 24% of former smokeless tobacco users reported using cigarettes to cease using smokeless tobacco.[17] Thus, tobacco consumers may make tobacco product use decisions inconsistent with the continuum of risk, likely because they do not understand the relative risks of combustible and non-combustible tobacco products.

Truthful and accurate communications by FDA and other government agencies, combined with FDA-authorized modified risk claims,[18] are critical to correcting consumer misperceptions about the relative risks of tobacco products. These communications could encourage cigarette smokers who will not quit tobacco use to switch to less harmful products. Accordingly, we urge FDA to develop communications to adult tobacco consumers about the continuum of risk and the relative risks of different tobacco products along that continuum.

2. FDA's Communication Campaigns Should Address Social Access Because it is the Primary Source of Tobacco Products for Underage Youth.

According to the Substance Abuse and Mental Health Administration's FFY 2014 Annual Synar Reports on tobacco sales to youth, retailer violation rates declined significantly from 1997 to 2014, from 40.1% to 9.8%.[19] As retailers have tightened controls on underage sales, youth have turned to social sources to access tobacco products. According to an analysis of the Youth Risk Behavior Surveillance System data, youth primarily access cigarettes by borrowing or bumming, giving someone else money to buy, or a person over 18 giving the product.[20] Findings from Wave 1 of the Population Assessment of Tobacco and Health study confirm that underage social access to tobacco products continues to be the issue.[21] Specifically, according to the study, most 15-17 year old current tobacco users usually access tobacco by asking for or someone offering the product, or by giving someone else money to buy it.

Because social sources are the primary way that youth access tobacco products, FDA should assess adult consumer understanding and attitudes toward providing tobacco products to others and test messages and strategies for the intended audiences. Based on those assessments, FDA

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[16] Ebbert JO, Klinkhammer MD, Stevens SR, et al. A survey of characteristics of smokeless tobacco users in a treatment program. Am J Health Behav. 2005;29(1):25-35.

[17] Chakravorty B, Chakravorty S. Cessation related perceptions and behavior of former and current smokeless tobacco users. J Am Coll Health. 1997;46(3):133-138.

[18] The Tobacco Control Act gave FDA a wide range of tools to effectuate the law's central purpose – to reduce the harm associated with tobacco products. One of those tools is Section 911 of the Act, which creates a pathway for manufacturers to pursue the marketing tobacco products with risk reduction or other modified risk claims with sufficient scientific substantiation. *See* 21 U.S.C. § 387k; *see also* Food and Drug Administration, *Perspective: Lessons Learned from the First Review of Modified Risk Tobacco Product (MRTP) Applications, available at* https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533753.htm ("MRTP information may communicate to consumers that the product is less harmful or presents a lower risk of tobacco-related disease than other commercially marketed tobacco products, reduces exposure to a substance, or does not contain or is free of a substance.")

[19] *See* Substance Abuse and Mental Health Services Administration, FFY 2014 Annual Synar Reports Tobacco Sales to Youth. https://store.samhsa.gov/shin/content/SYNAR-15/SYNAR-15.pdf

[20] Altria Client Services analysis of 2015 Youth Risk Behavior Surveillance System data; analysis among high school students under the age of 18 who smoke cigarettes.

[21] *See* A. Hyland K. Conway, N. Borek, et al. *Highlighted Findings from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study*, presented at 2016 Society for Research on Nicotine and Tobacco Plenary, March 2016.

should then develop and research communications educating adults to not provide tobacco products to youth. Ultimately, FDA should launch a national public education campaign to raise awareness of the issue and to encourage adults not to provide tobacco products to youth.

We appreciate the opportunity to provide our input and would be happy to discuss our suggestions in more detail. If you have any questions, please contact me at (804) 335-2879.

Sincerely,