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Altria Client Services

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Via Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-3552 (83 Fed. Reg. 48,625, September 26, 2018)— Comments on "Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings"

Altria Client Services ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and Sherman Group Holdings LLC and its subsidiaries ("Nat Sherman"),[1] submits these comments to the Food and Drug Administration's ("FDA" or the "Agency") above-captioned docket entitled "Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings" ("Notice").

Altria, on behalf of its tobacco operating companies, actively supported the passage of the Tobacco Control Act[2] ("TCA" or the "Act") because we believed that a national regulatory framework could contribute to resolving many of the complex issues that surround tobacco products. We also believe that regulation could create guidelines for accurate and scientifically grounded communications about tobacco products to adult tobacco consumers and could provide smokers with accurate risk information. We support a single, consistent public health message on the role of cigarette smoking in the development of disease in smokers, and on smoking and addiction.

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[1] PM USA and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). PM USA manufactures cigarettes and Nat Sherman manufactures cigarettes, cigars, and pipe tobacco. 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 Nat Sherman.

[2] Public Law 111-31, 123 Stat. 1776, June 22, 2009. Codified at 21 U.S.C. § 301.

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The Notice invites comments on, among other things, "ways to enhance the quality, utility, and clarity of the information to be collected" as part of FDA's research into graphic warnings.[3,4] We believe there are ways FDA can more effectively meet the Notice's stated objective of collecting data regarding exposure to the graphic health warnings relative to the text-only Surgeon General's warnings.[5] Our suggestions are as follows:

Study Design & Methodology

- A new graphic alone would be expected to increase noticeability, but may not impact understanding. If FDA is introducing both new graphics and new warning statements simultaneously, a different study design should be considered to assess whether exposure to the graphic warning "would promote greater public understanding."[6] Graphic warnings should be compared relative to the new text-only warning statement, not the current, familiar text-only Surgeon General's warnings. Within this study there should be test conditions where the new information shown as a text only warning statement would serve as the internal controls for whether the pictorial aspects "provide new information, increase self-reported learning, or change beliefs about the negative health consequences of cigarette smoking."[7]

- Certain demographic (e.g., age, socioeconomic status) and other (e.g., nicotine dependence among smokers) factors may impact whether "the warning was perceived to be a fact or an opinion"[8] and "if the warning made [participants] think about the health risks of cigarette smoking."[9] Potential moderating factors should be thoroughly evaluated during the course of this study.

- When developing this study, FDA should consider previous research which has shown that use of graphical warnings can produce an opposite effect to the desired outcome, consistent with behavioral theory (i.e., exposure to aversive stimuli can produce an avoidance reaction).[10]

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[3] The Act amended the Federal Cigarette Labeling and Advertising Act to require the Secretary of Health and Human Services to issue regulations for "Graphic Label Statements." *See* TCA § 201. A federal court found that the resulting regulations, issued the Food and Drug, violated the First Amendment. The research described in this Notice is intended to support a new rulemaking concerning Section 201's graphic warning requirements. *See* (76 Fed. Reg. 36,628, Jun. 22, 2011). *See also R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F. Supp. 2d 36, 53 (D.D.C. 2011). *See also R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 845 F. Supp. 2d 266, 277 (D.D.C. 2012).

[4] 83 Fed. Reg. 48,626 (Sept. 26, 2018).

[5] *Id.* at 48,627.

[6] *Id.* at 48,626.

[7] *Id.* at 48,627.

[8] *Id.*

[9] *Id.*

[10] Hall, M. G., Sheeran, P., Noar, S. M., Ribisl, K. M., Bach, L. E., & Brewer, N. T. (2016). Reactance to Health Warnings Scale: Development and Validation. Ann Behav Med, 50(5), 736-750. doi:10.1007/s12160-016-9799-3, Hardcastle, S. J., Chan, D. C., Caudwell, K. M., Sultan, S., Cranwell, J., Chatzisarantis, N. L., & Hagger, M. S. (2016). Larger and More Prominent Graphic Health Warnings on Plain-Packaged Tobacco Products and Avoidant Responses in Current Smokers: a Qualitative Study. Int J Behav Med, 23(1), 94-101. doi:10.1007/s12529-015-9487-x, Moodie, C., Bauld, L., Ford, A., & Mackintosh, A. M. (2014). Young women smokers' response to using plain

- There is ample research indicating that the general public already believes that cigarette smoking is extremely harmful,[11] which would suggest that exposure to graphical warnings will not meaningfully increase risk perceptions. An analysis conducted by ALCS on PATH Waves 1 (2013-2014), 2 (2014-2015), and 3 (2015-2016) data[12] shows that at least 90% of all adult respondents in each wave believe that cigarettes are at least "very harmful" to health. The study design should include pre/post measures of risk perceptions to evaluate whether the graphic warnings meaningfully increase likely pre-existing high levels of incoming risk perceptions.

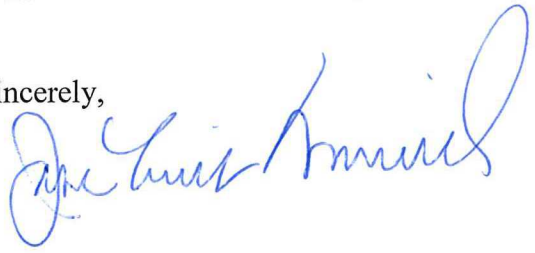
Outcomes Measurement

- FDA should consider assessing comprehension of the new warnings objectively (i.e., evaluating recall of specific content, evaluating comprehension of disease risk) rather than participants indicating only that they learned (i.e., "self-reported learning from the warning"[13]). FDA should prioritize measuring the impact of the warning on behavior (e.g., quit intentions among cigarette smokers, initiation intentions among non-users) over concepts such as the evaluating whether the warning is "informative"[14] and "grabbed…attention."[15]

- FDA has not shared the self-report scales used to measure the primary outcomes, making it impossible for ALCS to determine the validity, reliability, and sensitivity of the self-report scales.

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

Sincerely,



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cigarette packaging: qualitative findings from a naturalistic study. BMC Public Health, 14, 812. doi:10.1186/1471-2458-14-812

[11] Foundation for a Smoke-Free World. (2018). The State of Smoking 2018: Global Survey Findings and Insights. Retrieved from https://www.smokefreeworld.org/sites/default/files/uploads/derek-yach-press-conference-presentation.pdf, Popova, L., Owusu, D., Weaver, S. R., Kemp, C. B., Mertz, C. K., Pechacek, T. F., & Slovic, P. (2018). Affect, risk perception, and the use of cigarettes and e-cigarettes: a population study of U.S. adults. BMC Public Health, 18(1), 395. doi:10.1186/s12889-018-5306-z, Song, A. V., Morrell, H. E., Cornell, J. L., Ramos, M. E., Biehl, M., Kropp, R. Y., & Halpern-Felsher, B. L. (2009). Perceptions of smoking-related risks and benefits as predictors of adolescent smoking initiation. Am J Public Health, 99(3), 487-492. doi:10.2105/AJPH.2008.137679

[12] ALCS internal analysis.

[13] 83 Fed. Reg. 48,627.

[14] *Id.*

[15] *Id.*