

October 15, 2019

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

Submitted to <https://www.regulations.gov>

Re: Docket No. FDA-2019-N-3065, Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

To Whom It May Concern:

The American Association for Cancer Research (AACR), with over 42,000 members, is the first and largest professional scientific organization in the world dedicated to advancing cancer research and to accelerating progress in the prevention and cure of all cancers. We appreciate the opportunity to provide comments in response to the U.S. Food and Drug Administration's (FDA) proposed rule: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.

The AACR is strongly supportive of actions by the U.S. government to develop new graphic health warnings for cigarette packages and advertisements, as required by the 2009 Family Smoking Prevention and Tobacco Control Act. Tobacco use continues to be the leading cause of preventable disease and death in the United States. About 34.3 million adults in the U.S., or 14 percent of the population, smoked cigarettes in 2017.¹ Cigarette smoking causes more than 480,000 deaths annually in the U.S., equal to 30 percent of all cancer deaths.² Smoking is linked to adverse health effects in cancer patients who continue to smoke, including second primary cancers, poor treatment response, and increased complications after surgery.³ Despite these

¹ Wang TW, Asman K, Gentzke AS, et al. Tobacco Product Use Among Adults—United States, 2017. Morbidity and Mortality Weekly Report 2018;67(44):1225-32. <https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm>

² U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: 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. https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm

³ National Comprehensive Cancer Network (NCCN) Guidelines in Oncology: Smoking Cessation. Version 2.2019—May 6, 2019. https://www.nccn.org/professionals/physician_gls/pdf/smoking.pdf

adverse effects, studies have shown that two-thirds of smokers continue smoking after a cancer diagnosis.⁴

New mechanisms are needed to convey the negative public health impact of smoking to Americans. As the FDA notes in the proposed rule, the current Surgeon General’s warnings have been unchanged for almost 35 years since 1985, and they are therefore essentially invisible to consumers. Data from the Population Assessment of Tobacco and Health Study showed that 73.5 percent of youth and adults in the study “never” or “rarely” noticed health warnings on cigarette packages.⁵

There is a strong body of evidence that graphic warnings are more effective than text-only warnings in communicating the negative effects of smoking. A few of the relevant research outcomes are outlined in the next section. Furthermore, the AACR applauds the FDA for building on the existing body of research and utilizing additional consumer research studies to develop and select the 13 graphic health warnings in the proposed rule. The agency’s iterative, evidence-based approach has enabled it to develop cigarette graphic health warnings that are relevant to the U.S. population and that will be a significant improvement on the current text-only Surgeon General’s warnings. The AACR urges the FDA to work diligently and expeditiously to advance the proposed rule to a final rule by the court-ordered deadline of March 15, 2020.

Graphic Health Warnings are More Effective than Text-Only Warnings in Conveying Public Health Information about the Effects of Tobacco Use

Graphic warnings are more likely to be noticed by both smokers and non-smokers alike. Research from the International Tobacco Control (ITC) Project showed that a change from “U.S. style” (small, text only, on the side of the package) warnings to pictorial warnings in Malaysia resulted in a significant increase in smokers’ self-reported noticing of the warnings.⁶ The eye-catching effect of graphic warnings is sustainable, with noticeability shown to persist for years after implementation.⁷ Studies also reveal that graphic warnings are more effective than text

⁴ Tseng, TS, Lin HY, Moody-Thomas S, et al. Who tended to continue smoking after cancer diagnosis: the national health and nutrition examination survey 1999-2008. *BMC Public Health* 2012; 12:784.

⁵ FDA, Center for Tobacco Products. “Memorandum of Summary of Data from Wave 4 of the Population Assessment of Tobacco and Health (PATH) Study.” 2019 (data available at <https://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231>)

⁶ Elton-Marshall T, Xu SS, Meng G, Quah AC, Sansone GC, Feng G, Jiang Y, Driezen P, Omar M, Awang R, Fong GT. The lower effectiveness of text-only health warnings in China compared to pictorial health warnings in Malaysia. *Tob Control*, 2015. **24** Suppl 4: p. iv6-iv13.

⁷ Yong HH, Fong GT, Drizen P, Borland R, Quah AC, Sirirassamee B, Hamann S, Omar M. Adult smokers’ reactions to pictorial health warning labels on cigarette packs in Thailand and moderating effects of type of cigarette smoked: findings from the international tobacco control southeast Asia survey. *Nicotine Tob Res*, 2013. **15**(8): p. 1339-1347.

warnings in preventing people from taking up cigarette smoking.⁸

For smokers, graphic images showcasing the negative outcomes of smoking evoke emotional responses that support intentions to quit. While text warnings are not predictive of quitting, studies confirm that pictorial warnings effectively promote quitting behavioral responses, such as forgoing a cigarette or avoiding cigarette packs.⁹ Graphic warnings can also prevent relapse of former smokers.¹⁰

Research shows that graphic warnings may help bypass health literacy issues hindering public awareness of the negative health consequences of smoking. Text warnings are least effective with less-educated individuals. Conversely, the cognitive impacts of graphic warnings and effects on intentions to quit are strongest among the less educated.^{11,12} Since those with lower levels of education have higher rates of cigarette smoking than the general U.S. population, graphic warnings will provide an effective tool to reach more current smokers and those at risk of becoming smokers.¹³

The FDA Expanded Upon a Strong Foundation of Existing Research with Additional Research Studies on Proposed Graphic Health Warnings

The AACR applauds the FDA for its extensive set of qualitative and quantitative studies with adult smokers, non-smokers, and adolescents to test different combinations of photorealistic graphic images and text warnings. The agency set out to identify which graphic warnings increased understanding of the negative health consequences of cigarette smoking. Through this research, the FDA selected 13 graphic warnings that impacted respondents significantly in two areas assessed to correlate with increased understanding of health consequences: 1) conveyed

⁸ Noar SM, Hall MG, Francis DB, Ribisl KM, Pepper JK, Brewer NT. Pictorial cigarette pack warnings: a meta-analysis of experimental studies. *Tob Control*, 2016. **25**(3): p. 341-354.

⁹ Li L, Fathelrahman AI, Borland R, Omar M, Fong GT, Quah AC, Sirirassamee B, Yong HH. Impact of graphic pack warnings on adult smokers' quitting activities: Findings from the ITC Southeast Asia Survey (2005-2014). *J Smok Cessat*, 2016. **11**(2): p. 124-134.

¹⁰ Parlos TR, Borland R, Yong HH, Thrasher J, Hammond D. Cigarette packet warning labels can prevent relapse: findings from the International Tobacco Control 4-Country policy evaluation cohort study. *Tob Control*, 2013. **22**(1): p. 43-50.

¹¹ Thrasher JF, Villalobos V, Szklo A, Fong GT, Pérez C, Sebríe E, Sansone N, Figueiredo V, Boado M, Arillo-Santillán E, Bianco E. Assessing the impact of cigarette package health warning labels: a cross-country comparison in Brazil, Uruguay and Mexico. *Salud Publica Mex*, 2010. **52**(Suppl 2): p. 206-215.

¹² Nagelhout GE, Willemsen MC, de Vries H, Mons U, Hitchman SC, Kunst AE, Guignard R, Siahpush M, Yong HH, van den Putte B, Fong GT, Thrasher JF. Educational differences in the impact of pictorial cigarette warning labels on smokers: findings from the International Tobacco Control (ITC) Europe surveys. *Tob Control*, 2016. **25**(3): p. 325-332.

¹³ CDC. "Cigarette Smoking and Tobacco Use Among People of Low Socioeconomic Status."
<https://www.cdc.gov/tobacco/disparities/low-ses/index.htm>

“new information” and 2) resulted in “self-reported learning”.¹⁴ The panel of graphic warnings selected through FDA’s consumer research is consistent with existing research investigating which graphic warnings are most effective. Analysis of an ITC survey concluded that graphic images of diseased organs and human suffering have greater impact on individuals than abstract images.¹⁵

The FDA states in the proposed rule that all or some of the 13 graphic warnings may be selected for the final rule. If the agency must select a subset of the 13 proposed warnings, we recommend the following rank ordering based on the effect sizes (as measured by Odds Ratios) for “new information”:

1. Bladder cancer
2. Cataracts
3. Macular Degeneration
4. Diabetes
5. Head and Neck Cancer
6. Erectile Dysfunction
7. Amputation
8. Clogged Arteries
9. Stunt Fetal Growth
10. Fatal Lung Disease in Nonsmokers
11. COPD 1
12. COPD 2
13. Harm Children

The FDA Should Consider the Addition of a Gain-Framed Message to the Graphic Warnings

While there is a body of evidence demonstrating that consumers are impacted by imagery that illustrates the negative impacts of continued smoking, there is also evidence that physicians can encourage current adult smokers to quit by emphasizing the benefits of quitting smoking, what is known as “gain-framed” messaging.¹⁶ This type of messaging is based on Prospect Theory, which predicts that gain-framed warning labels are more effective than loss-framed warnings. In its consumer studies, the FDA tested one gain-framed message which was also included in the original set of nine warnings outlined in the Tobacco Control Act: “Quitting smoking now

¹⁴ FDA. Experimental Study of Cigarette Warnings: Study 2 Report. May 2019.

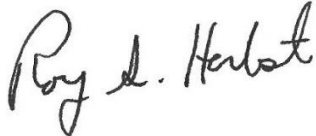
¹⁵ Thrasher JF, Villalobos V, Szklo A, Fong GT, Pérez C, Sebríe E, Sansone N, Figueiredo V, Boado M, Arillo-Santillán E, Bianco E. Assessing the impact of cigarette package health warning labels: a cross-country comparison in Brazil, Uruguay and Mexico. *Salud Publica Mex*, 2010. **52**(Suppl 2): p. 206-215.

¹⁶ Toll BA, Rojewski AM, Duncan LR, Latimer-Cheung AE, Fucito LM, Boyer JL, O’Malley SS, Salovey P, Herbst RS. “Quitting smoking will benefit your health”: The evolution of clinician messaging to encourage tobacco cessation. *Clin Cancer Res*, 2014. **20**(2): p. 301-309.

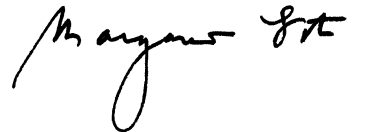
greatly reduces serious risks to your health (quit now).” However, because this message is very similar to the current Surgeon General’s warning, it did not show a statistically significant effect compared to the control text-only Surgeon General’s warnings. We recommend that the FDA consider testing other gain-framed messages to identify and include a gain-framed message that shows an effect on its selected outcomes.

In conclusion, the AACR commends the FDA for its rigorous and evidence-based efforts to develop new graphic health warnings for cigarette packages and advertisements, and urges the agency to issue the final rule by March 15, 2020. Thank you for very much for considering our input on this important issue. These comments are based on careful discussion of the AACR’s Subcommittee on Tobacco Products and Cancer (see Appendix 1). If the AACR can provide any additional information or assistance to the FDA, please do not hesitate to contact Audrey Jackson, PhD, Director of Science and Health Policy, at 215-309-4350 or audrey.jackson@aacr.org

Sincerely,



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APPENDIX 1
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