Public Comment on Docket No. FDA–2019–N–3065 for ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.''

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1. **FDA used a rigorous, systematic and scientifically sound process to develop the proposed graphic warnings.**

Developing effective warnings requires systematic research to identify text statements and images that, when paired together, will have the intended impact. This requires qualitative research to inform the *development* of warnings as well as quantitative studies to examine the *impact* of warnings on key outcomes. After reviewing the studies that were conducted to develop the proposed graphic warnings, it is clear to us that FDA followed precisely this rigorous, scientifically-based development process.

FDA conducted four qualitative studies with a total sample size of 378 participants. One major strength of these studies is the use of purposive sampling to arrive at a diverse sample in terms of age, tobacco use status, English language proficiency, geographic location in the US, and other important characteristics. Moreover, these studies used a variety of best-practice methods such as in-depth interviews, focus groups, and ranking tasks.

FDA also conducted a quantitative study with more than 2,500 participants - including both adolescents and adults - to inform its selection of text statements for the warnings. Finally, they conducted a very large quantitative study (*n*=9,760 participants) to examine the impact of the graphic warnings on key outcomes. This study included both youth and adult populations as well as both smokers and never smokers at-risk of starting smoking.

The series of qualitative and quantitative studies conducted by FDA followed a high standard for the development of graphic warnings. The methods used in these studies also meet the high standards of peer-reviewed research and are aligned with the approach that our own research group uses for message development and evaluation. After reviewing the findings of these studies, we believe that the studies have appropriately and successfully informed FDA's development of the 13 proposed warnings.

2. **FDA appropriately used the qualitative data from the newly-released studies to inform their development of warnings**

One of the key principles of qualitative research is that analysis must look for patterns across the responses. In other words, themes and patterns will emerge from the collective body of data, rather than from any one comment or quotation. Each individual quote in these reports represents a single data point, akin to one participant's survey responses in a randomized trial.

A potential pitfall is to place too much emphasis on a single quote or comment that sparks interest. FDA has successfully avoided this pitfall by basing their decisions on the holistic body of findings within and across their studies.

FDA has appropriately used the data from these qualitative studies to develop and select warnings to increase public understanding about the health risks of smoking. These qualitative studies have given FDA the range of possible responses that consumers could have to graphic images and warnings. This has allowed them to develop warnings that will effectively inform smokers about the health risks of smoking and therefore benefit public health.

3. **The qualitative and quantitative studies support the use of photorealistic illustrations.**

In the 2018 study titled "Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images," FDA conducted 54 in-depth, in-person, individual interviews with youth who were susceptible to smoking, young adult smokers, and adult smokers. This number of interviews is quite high for a qualitative study. In general, the study points toward participants perceiving the photorealistic illustrations as clear, understandable, and believable. This study also appropriately provided the basis for the subsequent large quantitative studies.

Moreover, the data from their large (*n*=9,760 participants) quantitative study (OMB Control No. 0910-0866) provides direct evidence that the newly proposed warnings are an effective tool at increasing public understanding of the health risks of smoking. That study found that participants exposed to the new warnings with photorealistic illustrations were more likely, compared to the control, to report that the warnings provided new information, were informative, were understandable, and made them think about the risks of smoking. These are precisely the goals that FDA had in mind when developing these graphic warnings and their study makes a convincing case that these warnings achieve that goal.

Taken together, the findings of these qualitative and quantitative studies suggest that the photorealistic illustrations visually communicate key information and help consumers better understand the risks of smoking described in the text statements.

Conclusion

In summary, we applaud FDA for bringing a rigorous, systematic, science-based approach to the development of this set of 13 proposed graphic warnings for cigarette packs. The use of multiple qualitative and quantitative studies that inform and build upon one another meets a high standard for the development of graphic warnings. FDA's set of studies - which include more than 12,000 participants inclusive of key sub-populations - ensure that these graphic warnings will have their intended impact of increasing public understanding about the health risks of smoking and thereby will benefit public health.