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

Marissa G. Hall, PhD
Seth M. Noar, PhD
Noel T. Brewer, PhD

University of North Carolina
October 14, 2019

1. Graphic health warnings on cigarette packs will promote greater understanding of the risks of smoking.

We have spent the last six years studying whether graphic cigarette pack warnings promote understanding of the risks of smoking. The short answer is that they do. We have found that graphic warnings change several outcomes that promote greater understanding of smoking's risks, as follows:

- Graphic warnings increase attention, a necessary precursor to information processing. Our meta-analysis of over 30 experiments that included responses from more than 33,000 people found that graphic warnings were better than text warnings at attracting attention.[1] Our four-week trial with more than 2,000 US smokers also found that graphic warnings attracted more attention than text-only warnings.[2] Importantly, our second trial with over 700 smokers found that text-only disclosures on cigarette packs did *not* increase attention compared to control labels,[3] suggesting that graphic warnings are the least restrictive means necessary to attract attention. Finally, our systematic review of studies involving more than 800,000 people in 20 countries found that national implementation of policies that strengthened warnings (typically from text to graphic) was associated with large increases in attention to warnings.[4]
- Graphic warnings increase objective knowledge about the risks of smoking. The same systematic review of studies in 20 countries found that national implementation of policies that strengthened warnings (typically from text to graphic) was associated with an increase in smokers' knowledge about health risks.[4]
- Consumers say that they have learned something new from graphic warnings. In two studies with over 600 young adult smokers and nonsmokers (ages 18-25), participants randomized to view graphic warnings reported learning something new from the warnings, more so than those who saw text-only warnings.[5]
- Graphic warnings make people think about the risks of smoking. Our meta-analysis of 57 experiments conducted in 13 countries with a cumulative sample size of 42,854 found that graphic warnings made people think about the risks of smoking more than text-only warnings.[6] Our systematic review of warning implementation also found large increases in thinking about the risks of smoking following implementation of strengthened warning policies.[7]
- Graphic warnings elicit social interactions, and these interactions promote greater thinking about the risks of smoking. Our trial of over 2,000 smokers found that graphic warnings increased conversations compared to text-only warnings, which were in turn associated with greater thinking about the risks of smoking.[8] These social interactions,

therefore, are an important mechanism of how graphic warnings are likely to increase public understanding about the risks of smoking.

Our recent meta-analysis found that graphic warnings do not change perceived likelihood of risk or perceived severity of the harms of smoking.[6] Instead, graphic warnings change more immediate risk appraisals, including thinking about smoking's risks, as well as the other outcomes related to public understanding described above.

2. Graphic health warnings on cigarette packs help smokers quit.

Nearly 7 out of every 10 smokers in the US want to quit smoking completely.[9] Our research indicates that graphic warnings also help smokers to quit.

We conducted a randomized controlled trial with more than 2,000 US smokers.[2] We put warnings on their cigarette packs for four weeks, with half randomly assigned to receive the current Surgeon General's text-only warnings and half graphic warnings. More smokers who received graphic warnings made quit attempts and quit smoking than those who received text-only warnings.[2] Our systematic review similarly found that strengthening warning policies was associated with more attempts to quit smoking and a decrease in smoking behaviors.[4] Moreover, a simulation modeling study estimated that implementing graphic cigarette pack warnings in the US would reduce smoking prevalence by 5% over the next 50 years.[10] Thus, in addition to changing precursors to quitting smoking such as quit intentions,[1, 2, 11] graphic warnings also increase smoking cessation behaviors.

We also note that our research[2] and other studies[12, 13] have found that graphic cigarette pack warnings are equally effective for diverse populations, including lower-education, lower-income, racial-minority, and sexual-minority smokers, suggesting that graphic warnings are unlikely to exacerbate smoking disparities.

We note that a common criticism[14] of graphic warnings is that smokers might be annoyed by or feel resistant to the warnings (i.e., reactance), which could cause the warnings to backfire. Our research consistently shows that, although a small subset of smokers are indeed resistant to the warnings, this is not nearly enough to undermine the warnings' beneficial effects.[15-17]

3. The characteristics of the FDA's proposed warnings suggest that they will be effective.

FDA's proposed warnings have followed design principles and best practices in warning development that enhance their effectiveness, as follows:

- Nearly all of the images used in the warnings include human faces or diseased body parts, both of which are known to be more effective than other types of images.[18-23]
- The warnings have a high degree of congruency, meaning the images and the text elements in the warnings reflect a common theme. Studies have shown that congruent graphic warnings increase both recall and attention more than incongruent warnings.[24, 25]
- The warnings use strong causal language. Our recent study of over 1,300 US adults found that warning statements with stronger causal language (e.g., "causes") were perceived as more effective than warnings with weaker causal language (e.g., "may

contribute to").[26] Thus, we strongly support the causal language used in FDA's proposed warnings given the evidence showing a causal link between smoking and the health effects described in the warnings. We urge FDA not to weaken the causal language now used in the proposed warnings.

- The warnings are concise (mean number of words: 10, range: 7 to 16). The short word length of the warning text makes the warnings easier to read and understand.
- The warnings describe health effects that discourage people from smoking. Our study of 388 US adult smokers found that stroke, heart disease, lung damage, and lung disease all performed well in terms of discouragement from smoking (mean of 3.17 to 3.27 on a discouragement scale from 1 (not at all) to 4 (a lot).[27] We note that erectile dysfunction was less discouraging than these other health effects (mean of 2.35), and diabetes may not resonate with smokers as much as other health conditions,[28] but both may still be useful for specific populations.

4. We recommend considering minor modifications to enhance the effectiveness of the warnings.

We suggest that the FDA consider the three issues noted below as the agency finalizes the warnings. Of course, we recognize that FDA will balance the issues we raise with other benefits of their current proposed approach as well as the regulatory framework that they operate within.

- **FDA may wish to consider using a different image to pair with the statement "Smoking causes bladder cancer, which can lead to bloody urine."** The image (of a jar with orange fluid) is the only one that does not depict a body part or a human face, so it may not be as effective as the other images in FDA's proposed warnings.
- **FDA may wish to consider addressing the duplication of images in two warnings.** Two of the warnings include the same image (diseased lungs). Studies show that rotating warnings and using a variety of topics and images can improve the effectiveness of warnings.[29, 30] Thus, FDA may wish to consider using only one of these two or to identify an additional image.
- **FDA may wish to consider using an alternative image for the warning about stunting fetal growth.** The image requires several inferences to understand that the baby depicted has stunted fetal growth. The "4.00 lbs." text is hard to read and nothing in the image gives context for the baby's size. To better communicate the text in the warning statement, FDA may wish to consider an image that more clearly shows a baby with growth problems. Examples might include a baby that is hooked up to monitor, smaller, or is next to a recognizable object (e.g., adult hand) for scale. Please see the example images below.

- **FDA may wish to consider using an alternative image for the diabetes warning, or revising the text to accompany different images.** We recently conducted a study with 443 US adults to test images for a sugar-sweetened beverage warning about type 2 diabetes (Table 1). We showed each participant 5 images displayed in a random order and asked them which one most discouraged consumption of SSBs. When asked which image best represented type 2 diabetes (i.e., congruency), we found that Image 5 (finger prick) was the most common choice (34% of participants). This image (#5) is very similar to the image in FDA's warning about type 2 diabetes. However, only 10% of participants also selected this image as the one that most discouraged them from wanting to drink sugar-sweetened beverages. Thus, these data indicate that a finger-prick image represents type 2 diabetes well, but may not be as effective at discouraging smoking compared to other image possibilities. Instead, FDA may wish to consider revising the text of the type 2 diabetes warning to match images of a diseased foot or amputation that most discourages consumption, such as:
    - **WARNING:** Smoking causes type 2 diabetes, which reduces blood flow to the limbs. [paired with Image 1 below]
    - **WARNING:** Smoking causes type 2 diabetes, which can lead to amputation. [paired with Image 2 below]

Conclusion

In conclusion, we strongly support FDA's draft ruling to require new graphic warnings on cigarette packs and advertisements. Pictorial cigarette pack warnings are urgently needed in the US. These new warnings will promote public understanding about the risks of smoking, will improve public health, and are long overdue in the US.

Table 1. Type 2 diabetes images tested in our study (*n*=443)

Image #	Image	% who selected image as most discouraging from consuming SSBs	% who selected image as best representing type 2 diabetes
1		39%	16%
2		26%	19%
3		13%	7%
4		12%	24%
5		11%	34%

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