Experimental study on warning statements for cigarette graphic health warnings: Response to FDA request for comments.

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Background

FDA has requested comments on a proposed study related to pictorial cigarette pack warnings. We support FDA's endeavor to select text warnings that increase the public understanding of the risks of smoking. We respond specifically to the request for comment on "ways to enhance the quality, utility, and clarity of the information to be collected." We organize our reply below in five sections: purpose, participants, procedure, measures, and data analysis.

Purpose

The Family Smoking Prevention and Tobacco Control Act (TCA) permits FDA to update the 9 statements required for pictorial cigarette pack warnings if "such a change would promote greater public understanding of the risks associated with the use of tobacco products." An important question is whether the law calls for showing that new messages improve risk understanding compared to 1) no message, or 2) the 9 warning messages required by the TCA. We believe that the answer to this question will dictate the selection of an appropriate control group and study design.

Participants

The proposed participants are the right ones. They include a range of vulnerable and existing cigarette smokers. We agree with the decision not to oversample vulnerable populations because studies, including our own, have demonstrated that cigarette pack warnings work equally well across diverse populations.

We assume that each condition will have 147 participants. This sample size could be sufficient depending on the analytic plan and anticipated effect size. We encourage the investigators to anticipate an effect size (e.g., a 10% increase in correct answers to an awareness or knowledge question) and then conduct a power analysis to ensure that the sample size is adequate for detecting the expected effect size.

Procedure

We find several aspects of the proposed study design compelling and appropriate. We support the idea of having participants evaluate multiple stimuli. The evaluability hypothesis (Hsee, 1996) suggests that evaluating multiple stimuli adds meaning to what people see. We support the idea of having participants in each condition view the same

number of warnings. We assume that the warnings would be presented in a random order, rather than a fixed order, within each condition. We also assume that, within the 16 intervention conditions, participants will view a random selection of 8 of the TCA text warning statements (also called FCLAA warnings) rather than all of them, and we support this decision.

We also have some constructive feedback for the study procedures. We are concerned that the control warnings (i.e., the 9 TCA warnings) may not be appropriate if FDA's goal is to demonstrate that the revised warnings increase beliefs and knowledge more than the control warnings. The TCA warnings have not been implemented yet due to litigation, and may be too novel/strong to serve as a proper control. Perhaps a more appropriate control group for this new set of warning statements would be to compare them to the status quo messages currently on cigarette packs.

In addition, we suggest using caution in choosing warnings solely on the basis of changes in knowledge, as there is limited evidence from the behavioral science literature that knowledge is a key mechanism through which pictorial warnings have impact. However, we realize that the language of the statute may require a focus on knowledge. In a recent study related to constituent disclosures, we found that while some health effects of tobacco use were not widely known (e.g., high cholesterol), such health effects rated low in discouragement of smoking. The health effects that smokers reported most discouraging them from smoking were lung and throat cancer, other lung diseases, and heart damage (Kelley et al., 2017). While educating the public about the many health effects of smoking is important, some health effects are more impactful than others, and we suggest FDA take this into account when choosing warning statements. One way to do this is to choose the health effects featured in warnings based on multiple outcome measures rather than on knowledge alone.

Measures

The law points to understanding risk, and the proposal suggests that FDA will assess "knowledge" and "beliefs". We consider several separate issues below.

The law places a special emphasis on understanding of risks. We previously convened several meetings of legal experts to parse the meaning of the term "understandable" as used elsewhere in the law. The paper that summarizes our thinking will be published in August 2017 in *Food & Drug Law Journal* (Berman et al., In Press). Understandable could mean being able to repeat a fact, a deeper level of comprehension, or even behavior change that reflects an internalization of the nature of the treat.

With respect to a minimal level of understanding, one could assess *awareness* ("Have you heard that smoking can cause bladder cancer?" Yes, No, Don't know) or *knowledge* ("Smoking can cause bladder cancer." True, False, Don't know). We generally prefer awareness questions because we suspect they may elicit less guessing and socially desirable responding. We prefer response scales that include a "don't know" option

because understanding how many people willingly state they do not know an answer can have implications for how easy it may be to change a misunderstanding.

With respect to a deeper level of understanding, many options exist. The Tri-risk model (Ferrer, Klein, Persoskie, Avishai-Yitshak, & Sheeran, 2016) suggests risk perceptions have three components. The first component is deliberative and includes the extent of risk such as the percent chance of getting cancer. Ample evidence shows that pictorial warnings to do not increase deliberative risk perceptions (Brewer et al., 2016; Noar, Hall, et al., 2016). The second component is experiential, which refers to one's "gut" feeling about a risk and whether they can imagine themselves being affected by it. Little or no data are available on pictorial warnings and experiential perceived risk, making this an important research gap and one we find promising. The third component is affective and includes fear and worry. Warnings increase negative affect such as fear (Brewer et al., 2016; Noar, Hall, et al., 2016), an important finding because emotion helps people derive meaning from facts (Peters, Lipkus, & Diefenbach, 2006). Indeed, recent research finds that even text statements elicit emotion, and that this negative affect is strongly correlated with perceived informativeness of warnings (Popova, Owusu, Jenson, & Neilands, 2017).

Other risk measures to consider include cognitive elaboration. Studies of pictorial warnings – both experimental and observational – consistently find that they increase thinking about the warning messages and thinking about the harms of smoking (Brewer et al., 2016; Noar, Francis, et al., 2016; Noar, Hall, et al., 2016). Keeping smokers thinking about warning content is an important goal given that smokers regularly discount the risks of smoking as compared to nonsmokers (Weinstein, Marcus, & Moser, 2005).

With respect to behavior, the proposed online study cannot assess changes in smoking behavior given the brief exposure to the warnings and immediate assessment of outcomes. However, many antecedents to behavior could serve as helpful proxies for smoking behavior and we recommend that you consider assessing these as potential outcome variables. The message impact framework, developed by our team at UNC, suggests a broad array of options (Noar, Hall, et al., 2016). One is behavioral intentions ("How likely are you to quit smoking in the next six months"; Klein, Zajac, and Monin (2009)), a known longitudinal predictor of smoking quit attempts (Vangeli, Stapleton, Smit, Borland, & West, 2011).

Our research group also draws a distinction between *effectiveness* and *perceived effectiveness outcomes* (Francis, Hall, Noar, Ribisl, & Brewer, 2017; Noar, Hall, et al., 2016). Effectiveness measures assess actual differences in an outcome like risk perceptions, behavioral intentions or behavior. Perceived effectiveness examines one's belief about how much a warning does or may affect them ("The warning discourages me from wanting to use e-cigarettes"). Many message testing studies use some form of

perceived effectiveness, and the FDA used their own perceived effectiveness items to evaluate the pictorial warnings initially proposed for cigarette packs (Nonnemaker, Farrelly, Kamyab, Busey, & Mann, 2010). We believe perceived effectiveness is an important outcome to assess when examining the potential effectiveness of new warning statements.

Our team developed the UNC perceived effectiveness scale (Baig et al., In Preparation) to evaluate text and pictorial tobacco product disclosures and warnings. The strengths of the scale include being brief at only 3 items, having strong psychometric properties across many studies, focusing on later stages of the message impact framework that are closer to behavior, using scale items that reference the behavior (i.e., cigarettes, smoking), and inclusion of the respondent as referent (i.e., this warning discourages me). We offer this as a potential set of measures for evaluating potential warning messages.

Table 2. Potential measures

Construct	Item (response scale)	Source
Cognitive elaboration	How much did the warning cause you to think about the harmful effects of smoking? (Not at all, A little bit, Somewhat, Quite a bit, Very much)	Brewer et al., 2016
Fear	How much did the warning make you feel scared? (Not at all, A little, Somewhat, Very, Extremely)	Brewer et al., 2016
Perceived effectiveness	*Say how much you agree or disagree with the next statements about the warning.* The warning makes me concerned about the health effects of smoking. The warning makes smoking seem unpleasant to me. The warning discourages me from wanting to smoke. (Strongly disagree, Somewhat disagree, Neither agree nor disagree, Somewhat agree, Strongly agree)	Baig et al., working paper [UNC Perceived Effectiveness Scale]

Data analysis

Without more information about the study, it is difficult to provide detailed feedback about data analysis. The primary research question is not fully clear to us. Should FDA try to determine whether the revised warnings as a set are better than the existing warnings as a set (compare 9 TCA warnings averaged vs. 15 new warnings averaged)? Or, does FDA want to know which of the *individual* revised warnings are the best, out of the revised warnings (compare 15 new warnings among one another so that you can winnow them to only the best ones)? Another question could be: How do all of the warnings compare to each other (rank order all 24 warnings)? How does each new warning compare to the full set of 9 TCA warnings? What are the key criteria FDA should use to select warnings? Our general consensus is that it would be more useful to have a design that allows FDA to examine the perceived effectiveness of specific

warnings (to facilitate selecting the ones likely to have the greatest impact) rather than testing the average impact of a group of warnings. We anticipate that the diabetes warning statement, based on our past work, would be less effective than most of the others. Having a design that allows FDA to select the best messages would avoid the problem of some of the “weaker” messages lowering the average effect size and perhaps causing FDA to discard potentially strong messages if they are in a set that includes weaker messages.

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