

FDA's Proposed Collection of Information on the Experimental Study on Warning Statements for Cigarette Graphic Health Warnings Should be Addressing the Graphic Images, not Merely the Textual Statements

Docket Number: FDA-2017-N-0932

UCSF TCORS

Lauren Lempert, Minji Kim, Lucy Popova,¹ Stanton Glantz

May 26, 2017

More than four years after FDA's March 2013 announcement¹ that it would develop new graphic warnings in accordance with the D.C. Circuit Court of Appeals' dictates,² FDA's proposed study does not even look at the graphic components of the warnings, and instead focuses only on the textual warning statements for cigarette graphic health warnings. An April 2013 New York Times editorial called on FDA to "move quickly to find court-acceptable graphic images,"³ and a July 2013 essay in the New England Journal of Medicine complained that, "at best, it will be 2 to 3 years before new graphic warning labels will appear on U.S. cigarette packages," which "may well be measured in morbidity and mortality."⁴ Researchers have estimated that based on Canada's experience, if the U.S. had implemented graphic warnings in 2012 as required by law, there would have been 5.3 and 8.6 million fewer adult smokers in 2013.^{5,6} FDA's failure to move quickly – or at all – to implement graphic health warnings to inform consumers about the deadly harms of cigarette smoking is unconscionable.

1. FDA has not developed new graphic images for health warning labels, despite the legal authority and Congressional mandate to do so.

In June 2011, nearly six years ago, FDA adopted a rule^{7,8} requiring that new graphic warnings accompanying nine textual statements cover fifty percent of the front and back of cigarette packs and twenty percent of advertisements, and issued a set of nine pictorial warnings.⁹ In March 2012, more than five years ago, the Sixth Circuit Court of Appeals upheld¹⁰ the graphic warning label requirement mandated by the 2009 Family Smoking Prevention and Tobacco Control Act.¹¹ In August 2012, the D.C. Circuit Court of Appeals found that the *particular graphic warning labels* chosen by FDA were unconstitutional.² However, in that case the tobacco companies did not challenge the factual accuracy of the text statements proposed for the new warning labels; rather, they objected to the specific graphic images selected by FDA to accompany those text statements.² In rejecting the tobacco industry's challenge to the Sixth Circuit Court's ruling that graphic health warnings per se are constitutional, the U.S. Supreme Court in April 2013¹² cleared the way for FDA to study, develop, and proposed a new set of specific graphic images for the health warnings to accompany the unchallenged textual statements. Although more than four years have passed since FDA got the green light, FDA stalled and has not developed a new set of graphic images.

¹ Georgia State TCORS

2. By examining only the textual components of warning labels instead of the graphic images, FDA’s proposed study fails to address the issues raised by the D.C. Circuit and therefore fails to take the steps necessary to protect the public health by implementing graphic health warnings.

FDA’s proposed experimental study¹³ would analyze consumer reactions to two different versions of textual warning statements that focus on the negative health consequences of cigarette use. The study would examine whether revised versions of the textual warning statements improve public understanding of the risks associated with smoking as compared to the warning statements mandated in the Tobacco Control Act. **The proposed experimental study on warning statements for cigarette graphic health warnings fails to collect information about how to design graphic images that would effectively inform consumers about the harms of smoking.** It is unclear why FDA is expending resources to conduct an experimental study on the textual warning statements that were upheld by the courts, rather than study ways to redesign the graphic images in the warnings so that they would not only be effective, but also would address the issues raised by the D.C. Circuit.

The graphic warnings FDA issued in June 2011 were based on substantial scientific evidence demonstrating that the text-only warnings that were last revised in 1984 are stale and unnoticed by consumers, and have failed to convey relevant information about the harms of smoking. Graphic warnings are more effective than text-only warnings in drawing consumers’ attention and communicating the health consequences of smoking, especially among youth.^{5, 14, 15} Extensive evidence from other countries that have implemented graphic warnings demonstrates their effectiveness to reduce smoking.^{5, 6, 16-18}

Since the D.C. Circuit court’s finding in 2012 that the government had failed to provide sufficient evidence that pictorial warnings would accomplish the government goal of reducing smoking, significant scientific evidence has amassed showing that pictorial warnings are more effective than text-only warnings.^{16, 19-26} A recent study published in May 2017 found that message congruency (defined as the degree to which pictorial and textual features reflect a common theme) between pictorial and textual information is beneficial to recall of label content. Moreover, images captured and held smokers’ attention better than the text.²⁷

The D.C. Circuit also found that the graphic warnings (as compared with textual statements alone) were unconstitutional because they were emotional, rather than purely factual and uncontroversial. Researchers have pointed out that any allegation that the emotive quality of images conflicts with the purpose of communicating facts is hypocritical coming from the tobacco industry that regularly uses emotive, image-based advertising to keep existing and recruit and addict new smokers.²⁸ In any case, a recent scientific study published in April 2017²⁹ contradicted the D.C. Circuit’s conclusions and found that pictorial labels as well as textual statements are perceived to be informative and factual, and both evoke emotion.

FDA should fulfill its mandate and immediately reissue graphic warning labels that will pass constitutional muster.

3. If FDA chooses to change the textual statements, any changes should be evidence-based in both form and content and should be analyzed along with accompanying graphic images.

a) *Textual statements should be examined along with graphical images, as the law requires, not alone.*

Section 201(a) of the Tobacco Control Act requires that color graphics depicting the negative health consequences of smoking “*accompany* the [nine textual] label statements” specified in the law (emphasis added). While Section 202(d) of the Tobacco Control Act authorizes FDA to adjust, through an appropriate rulemaking, the format, type size, color graphics, and text of any of the label requirements, it does *not* authorize FDA to eliminate color graphics component of the required graphic label statements. As outlined above, a substantial body of scientific evidence demonstrates that textual warnings alone are not as effective as textual warnings combined with graphical images.

Even when the textual component shows some effectiveness, it does not guarantee the effectiveness of the graphic health warning label including the textual component as the addition of graphical images can affect its effectiveness. As shown by previous research, texts accompanied with incongruent graphical images yield lower recall by the audiences²⁷. Unless FDA plans to conduct another experiment testing possible combinations of textual and graphical components following the test of textual components, the currently proposed experimental study design would not help FDA determine the effectiveness of graphic label statements since it only examines the textual component of those labels.

b) *Textual statements should appear in black text on a yellow background to seize and hold consumers’ attention and signal the danger of cigarettes*

The cigarette labeling law provides that the text of warning labels shall be black on a white background or white on a black background. However, this color scheme is not as effective as black text on a yellow or other brightly contrasting light background. The tobacco companies’ internal research on pack color choices found that yellow most quickly and effectively seizes and holds consumers’ attention. Yellow signals warning or danger, whereas white connotes health and safety.³⁰⁻³⁷

The tobacco industry’s research on improving the prominence of pack elements should be used by FDA when designing graphic warning labels.³⁰ FDA should require textual statements in graphic warning labels to use black lettering on a contrasting yellow background.

FDA's proposed experimental study design¹³ states at page 3: "In all conditions, participants will view a set of 9 textual warning statements presented in a sequential order as ***black text on a white background...***" (emphasis added). This study design does not test the efficacy of white text on a black background, which is permitted under the current law. If this is deliberate because FDA is planning to change the font color as Section 202 permits it to do, FDA should instead change the text format to require black text on a yellow background, and should change its study design accordingly.

- c) ***Given the evidence that adults and adolescents do not understand addiction, it is vitally important to provide comprehensive, detailed messages on nicotine addiction.***

FDA's textual warning statements, including the 15 revised warning statements to be tested in the proposed study, fail to address nuanced concerns regarding individuals' understanding of addiction. Specifically, FDA's proposed warning statements fail to recognize youth and young adults' lack of understanding and skepticism of addiction. Instead, messages need to provide more detailed examples and definitions of addiction in order to be effective.³⁸

Extensive research shows that youth and young adults do not just underestimate the risk of addiction. Adolescent smokers and those who eventually become smokers perceive significantly less risk of many health consequences, including long-term consequences such as heart attack and lung cancer, as well as short-term consequences such as having trouble breathing.³⁹ Such perceptions predict subsequent smoking.⁴⁰

Warnings should speak to the lack of control associations with addiction. For example, the following warning statements regarding addiction would be more effective³⁸:

- 85% of smokers wish they had never started smoking. Nicotine is highly addictive.
- 70% of smokers want to stop smoking. Nicotine is highly addictive.
- The process of nicotine addiction starts well before you are smoking every day. Nicotine is highly addictive.
- Tobacco can be harder to quit than heroin or cocaine. Nicotine is highly addictive.
- Most smokers smoke for years longer than they want. Nicotine is highly addictive.
- Most smokers take 6-11 attempts to successfully quit. Nicotine is highly addictive.
- 75% of teens who smoke are still smoking five years later. Nicotine is highly addictive.
- Addiction is the disease. Smoking is the symptom. Nicotine is highly addictive.

- d) ***The word "WARNING" should be removed from the textual statements in the graphical warning labels.***

While the word “WARNING” can function as a signal word, it can also function as a “stop” word; that is, consumers read the word “warning,” but read nothing after it.⁴¹ Also, consumers are bombarded with so many labels marked “WARNING” or “DANGER!” that they learn to ignore the warnings, just as the farmer ignored the shepherd boy who cried “WOLF!”⁴² Textual warning statements are more effective when the word “WARNING” is removed and allowing consumers to focus on the more important message in the remaining text.

References

1. Holder E Jr. Letter to the Honorable John Boehner, Re: R.J. Reynolds v. Food & Drug Administration, No. 11-5332 (D.C. Cir.). March 15, 2013. Available at <http://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Ltr%20to%20Speaker%20re%20Reynolds%20v%20FDA.PDF>.
2. *R.J. Reynolds Tobacco Co. v. United States Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).
3. NY Times Editorial Board, "Wins and Losses in the Fight Against Tobacco." April 28, 2013. Available at <http://www.nytimes.com/2013/04/29/opinion/wins-and-losses-in-the-fight-against-tobacco.html>.
4. Bayer R, Johns D, Colgrove J. The FDA and graphic cigarette-pack warnings--thwarted by the courts. *N Engl J Med.* 2013; 369(3):206-208
doi:10.1056/NEJMp1306205
5. Bach L, The Campaign for Tobacco-Free Kids, "Tobacco Health Warnings: Evidence of Effectiveness," Nov. 3, 2016. Available at <https://www.tobaccofreekids.org/research/factsheets/pdf/0325.pdf>.
6. Huang J, Chaloupka FJ, Fong GT. Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis. *Tob Control.* 2014; 23 Suppl 1:i7-12
doi:10.1136/tobaccocontrol-2013-051170
7. Food and Drug Administration, Final Rule: Required Warnings for Cigarette Packages and Advertisements. 21 CFR Part 1141, 76 FR 120, June 22, 2011. Available at <https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM339834.pdf>.
8. 15 U.S.C. § 1333.
9. Image of FDA's nine graphic warning labels. Available at <https://consumermediallc.files.wordpress.com/2012/06/finalsmokingwarningsthumb.jpg>.
10. *Discount Tobacco City & Lottery, Inc. v. United States Food & Drug Admin.*, 674 F.3d 509 (6th Cir. 2012).
11. Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §§ 387–387u; Pub. L. No. 111-31, 123 Stat. 1776 (2009).
12. Reinberg S, U.S. News & World Report, "U.S. Supreme Court Rejects Challenge to New Cigarette Labeling," April 22, 2013. Available at <http://health.usnews.com/health-news/news/articles/2013/04/22/us-supreme-court-rejects-challenge-to-new-cigarette-labeling>.

13. Food & Drug Administration, GHW - Quant Study 1 - Supporting Statement - A and B - Final Draft - 3.8.17 re: Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings. Available at <https://www.regulations.gov/document?D=FDA-2017-N-0932-0002>.
14. Hammond D. Health warning messages on tobacco products: a review. *Tob Control*. 2011; 20(5):327-337 doi:10.1136/tc.2010.037630
15. O'Hegarty M, Pederson LL, Nelson DE, Mowery P, Gable JM, Wortley P. Reactions of young adult smokers to warning labels on cigarette packages. *Am J Prev Med*. 2006; 30(6):467-473 doi:10.1016/j.amepre.2006.01.018
16. Azagba S, Sharaf MF. The effect of graphic cigarette warning labels on smoking behavior: evidence from the Canadian experience. *Nicotine Tob Res*. 2013; 15(3):708-717 doi:10.1093/ntr/nts194
17. Thrasher JF, Hammond D, Fong GT, Arillo-Santillan E. Smokers' reactions to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada. *Salud Publica Mex*. 2007; 49 Suppl 2:S233-240
18. Hammond D, Fong GT, Borland R, Cummings KM, McNeill A, Driezen P. Text and graphic warnings on cigarette packages: findings from the international tobacco control four country study. *Am J Prev Med*. 2007; 32(3):202-209 doi:10.1016/j.amepre.2006.11.011
19. Brewer NT, Hall MG, Noar SM, et al. Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial. *JAMA Intern Med*. 2016; 176(7):905-912 doi:10.1001/jamainternmed.2016.2621
20. Guydish J, Tajima B, Le T, et al. Do cigarette graphic warnings encourage smokers to attend a smoking cessation programme: a quasi-experimental study. *Tob Control*. 2016; doi:10.1136/tobaccocontrol-2016-053207
21. 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):341-354 doi:10.1136/tobaccocontrol-2014-051978
22. Noar SM, Francis DB, Bridges C, Sontag JM, Ribisl KM, Brewer NT. The impact of strengthening cigarette pack warnings: Systematic review of longitudinal observational studies. *Soc Sci Med*. 2016; 164:118-129 doi:10.1016/j.socscimed.2016.06.011
23. Noar SM, Hall MG, Brewer NT. Pictorial cigarette pack warnings have important effects. *Am J Public Health*. 2015; 105(3):e1 doi:10.2105/AJPH.2014.302510
24. Yong HH, Borland R, Thrasher JF, et al. Mediation pathways of the impact of cigarette warning labels on quit attempts. *Health Psychol*. 2014; 33(11):1410-1420 doi:10.1037/hea0000056
25. Yong HH, Fong GT, Driezen P, et al. 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):1339-1347 doi:10.1093/ntr/nts241
26. Chang FC, Sung HY, Zhu SH, Chiou ST. Impact of the 2009 Taiwan tobacco hazards prevention act on smoking cessation. *Addiction*. 2014; 109(1):140-146 doi:10.1111/add.12344

27. Lochbuehler K, Mercincavage M, Tang KZ, et al Effect of message congruency on attention and recall in pictorial health warning labels. *Tobacco Control* Published Online First: 16 May 2017. doi: 10.1136/tobaccocontrol-2016-053615.
28. Thrasher JF, Osman A, Anshari D. Images in cigarette warning labels: how should they warn? *Virtual Mentor*. 2013; 15(8):704-712
doi:10.1001/virtualmentor.2013.15.8.imhl1-1308
29. Popova L, Owusu D, Jenson D, Neilands TB. Factual text and emotional pictures: overcoming a false dichotomy of cigarette warning labels. *Tob Control*. 2017; doi:10.1136/tobaccocontrol-2016-053563
30. Lempert LK, Glantz SA. Implications of Tobacco Industry Research on Packaging Colors for Designing Health Warning Labels. *Nicotine Tob Res*. 2016; 18(9):1910-1914 doi:10.1093/ntr/ntw127
31. Product Communication. British American Tobacco.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=yhvc0196>.
32. Bockweg T, Chapple N, Cornell C, Swaim WF. Color Documentation for Doral Packaging Colors. 2001. RJ Reynolds.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=pgbd0190>.
33. Color Scheming. 1990. Philip Morris.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=qnmj0074>.
34. Wagner C. Color Cues. 1990. Philip Morris.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=rnmj0074>.
35. The Total Package. 1995. Philip Morris.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=fqlg0089>.
36. Project XG Packaging Briefing Document. 1984. RJ Reynolds.
<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=mnvp0100>.
37. Cheskin L. How to Predict What People Will Buy. New York, NY: Liveright Publishing Corporation; 1957.
38. Roditis ML et al. The FDA's Proposed Warnings on Addiction are Inadequate and Do Not Reflect Current Understanding of Appropriate Messaging on Addiction. Docket No. FDA-2014-N-0189, June 10, 2014. Available at <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-warning%20label%20comments%20for%20proposed%20deeming%20rule%20part%201%20June%2012-1jy-8cmm-zjhq.pdf>.
39. Halpern-Felsher BL, Biehl M, Kropp RY, Rubinstein ML. Perceived risks and benefits of smoking: Differences among adolescents with different smoking experiences and intentions. *Preventive Medicine*. 2004;39(3):559-567.;
40. Song AV, Morrell HE, Cornell JL, Ramos ME, Biehl M, Kropp RY, et al. Perceptions of smoking-related risks and benefits as predictors of adolescent smoking initiation. *American Journal of Public Health*. 2009;99(3):487.
41. Roditis ML et al. FDA's Proposed Warning Statements Are Weak and Ineffective in Form and Content and Should Be Replaced with Effective Messages. Docket No. FDA-2014-N-0189, June 10, 2014. Available at <https://tobacco.ucsf.edu/fda%E2%80%99s-proposed-warning-statements-are-weak-and-ineffective-form-and-content-and-should-be-replaced-e>.

42. Robinson L. et al., "Consumer Warning Labels Aren't Working," Harvard Business Review, Nov. 30, 2016. Available at <https://hbr.org/2016/11/consumer-warning-labels-arent-working>.