

Proposed Cigarette Product Warning Labels

Submission for public comment on the proposed rule *Required Warnings for Cigarette Packages and Advertisements*.

Docket No. FDA-2010-N-0568

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FOREWORD

This submission comments on the proposed rule *Required Warnings for Cigarette Packages and Advertisements*. The submission was prepared by Dr. David Hammond from the University of Waterloo, Canada. Dr. Hammond has published extensively in the areas of health warning labels, including forthcoming chapters in a World Health Organization monograph and a U.S. Surgeon General's report. Dr. Hammond previously served as an Expert Advisor for the World Health Organization for Article 11 of the WHO Framework Convention on Tobacco Control, which establishes packaging and labeling guidelines for the 172 countries that have ratified the treaty. As part of this role, Hammond helped to author the Elaborated Guidelines under Article 11, which includes recommendations for health warnings on tobacco packages. Dr. Hammond has also worked closely with regulators in a number of countries to assist with the development of labelling regulations, including Canada, the United Kingdom, Australia, Mexico and the European Union.

Dr. Hammond is the Principal Investigator of the International Packaging Study, an NIH-funded study that is testing health warnings for tobacco packaging in seven countries, including the United States, as well as China, India, Mexico, Bangladesh, South Korea, and Germany. Dr. Hammond also conducted a study in December 2010 to test the proposed FDA warnings, the results of which are discussed in this report. Finally, Dr. Hammond is one of the core investigators of the International Tobacco Control (ITC) Policy Evaluation Project, which has collected evidence on tobacco labeling policies in 17 countries to date.

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1.0 DISCLOSURE

Dr. Hammond served as a consultant to Siegle+Gale, the advertising agency that was awarded the contract to design the proposed FDA warnings. In this role, Dr. Hammond provided background information to assist with the contract application; however, he was not involved in any way with the development of specific designs and has not received any financial compensation for this work. Dr. Hammond has also been retained as a Senior Consultant to the Centres for Disease Control and Prevention to provide periodic advice on tobacco labelling issues.

I would like to acknowledge the assistance of Jessica Reid (MSc) and Samantha Daniel (BA) in preparing this submission.

2.0 EXECUTIVE SUMMARY

To date, more than 30 countries have implemented pictorial health warnings on cigarette packages. There is substantial evidence that large pictorial health warnings increase perceived risk, reduce the appeal of tobacco products among young people, and promote cessation among current smokers. However, the effectiveness of health warnings depends upon their design and content.

The current submission is based upon an extensive review of the evidence base, as well as research undertaken in December 2010 to test the FDA Proposed warnings for each of the nine “statements” or health effects.

Specific recommendations

1. Warnings should include graphic depictions of health effects that elicit an emotional reaction.
2. Incorporate themes of human suffering and “testimonial” elements within graphic health warnings.
3. Portray “real” examples of health effects and actual victims of disease whenever possible.
4. Use symbolic and “cartoon-style” images with caution.
5. Use additional text to support the images, and ensure all text is clear, direct, and easy to understand.
6. Integrate toll-free quitline numbers on all warnings.
7. Consider a short, direct “call to action” phrase to motivate cessation behaviour.
8. Consider including website information from a prominent online cessation resource on warnings.
9. Mandate the implementation date for renewing the nine warnings.
10. Consider requiring “inserts” with additional health and cessation information.
11. Develop public education campaign linked with the implementation of the health warnings.

Proposed warnings: Recommendations

The table below summarize recommendations for the adoption of specific warnings for each of the nine statements. Note that not all recommended warnings were included in the set proposed by the FDA. A description of the research study upon which these recommendations are based is presented in Section 5 of this report, with additional detail provided in Appendix A.

Addiction		<ul style="list-style-type: none"> • Strong image, engaging image illustrating addiction and the highest ranked warning tested.
Cancer		<ul style="list-style-type: none"> • All three warnings depict engaging images. • “Face” warning (far right) more effective than FDA-proposed warnings. • Alternative warning of lung cancer patient with personal information added at bottom of warning better than original FDA-proposed warning. • “Teeth” is best among FDA proposed warnings.
Death		<ul style="list-style-type: none"> • Strong image, rated and ranked higher than other warnings. • Possible improvements to warning image. • Consider replacing image with more graphic image from “<i>Tobacco Smoke & Lung Disease</i>” set below
Fatal Lung Disease		<ul style="list-style-type: none"> • FDA-proposed warning with “comparison” lungs was highest rated and ranked. • Also consider alternate “tumour” warning.
Pregnancy		<ul style="list-style-type: none"> • FDA-proposed pregnancy warnings rated very poorly. • Warning depicting “real” baby substantially more effective than any FDA warnings.
Quitting Smoking		<ul style="list-style-type: none"> • FDA-proposed quitting warnings rated very poorly. • Alternative with quitline information added to bottom of warning was highest rated and ranked.
Stroke/Heart Disease		<ul style="list-style-type: none"> • FDA proposed warnings rated very poorly. • Alternate “surgery” and “brain” warnings more effective than any FDA-proposed warnings.
Tobacco Smoke & Children		<ul style="list-style-type: none"> • These two warnings rated highest; select one • Image of child with mask and alternate warning of child with smoking parents comparable options.
Tobacco Smoke & Lung Disease		<ul style="list-style-type: none"> • Alternate “body” warning substantially better than FDA-proposed warnings. • Gravestones were highest rated among FDA-proposed set.

3.0 BACKGROUND

Tobacco use is responsible for one in ten global deaths and is the second major cause of mortality in the world.¹ In the US, more than 400,000 people die every year from tobacco use.² Despite this, more than 45 million Americans continue to smoke.³

Health warnings on cigarette packages provide governments with a direct and cost-effective means of communicating with smokers. Tobacco packages provide high reach and frequency of exposure— pack-a-day smokers are potentially exposed to the warnings over 7000 times per year— as well as an opportunity to communicate with smokers during the act of smoking.⁴

The proposed FDA warnings will soon become one of the country's most high profile public health campaigns. However, the impact of the new health warnings depends upon their design and content. The warnings must not only fulfill the governments mandate to warn the public about the risks of smoking, they should also engage the public, help to prevent youth smoking initiation, and support smokers' efforts to quit. The warnings should also serve as a platform for linking with other media campaigns and tobacco control initiatives.

4.0 GENERAL RECOMMENDATIONS

The following section provides a brief summary of the evidence on the general impact of health warnings labels, following by general recommendations for health warning design.

Pictorial health warnings on tobacco packages increase perceptions of risk, reduce the appeal of tobacco use and promote smoking cessation.

A wide variety of research has demonstrated the effectiveness of using pictures and imagery in health communications.^{5,6,7,8,9, 10,11,12,13} These studies suggest that health warnings with pictures are significantly more likely to draw attention, result in greater information processing, and improve memory for the health message than text-only warnings. Picture warnings also encourage individuals to imagine health consequences and are also more likely to be recalled when an individual is making relevant judgments and decisions.

Experimental research on cigarette warnings has also found that picture-based warnings are more likely to be rated as effective than text-only warnings both as a deterrent for potential new smokers and as a means to increase cessation among current smokers.^{14,15,16,17,18}

Extensive focus group testing and market-research commissioned by government health agencies also support the effectiveness of pictorial health warnings on packages.^{16,19,20,21,22,23,24,25,26,27,28,29} This research consistently demonstrates that health warnings with pictures are rated by smokers and non-smokers as more effective than text-only warnings.

Since 2001, when Canada became the first country to implement pictorial health warnings on cigarette packs, a series of population-based surveys have compared the effectiveness of text versus pictorial warnings. These findings are consistent with both experimental studies and government-commissioned research: pictorial warnings are more likely to be noticed and read by smokers, and are associated with stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking.^{14,15,19,20,21,22,23,29,30,31,32,33,34,35}

The extent to which health warnings lead to changes in smoking behaviour is difficult to ascertain within the context of population-based data.³⁶ However, significant proportions of adult and youth

smokers report that large comprehensive health warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit, and increased the likelihood of remaining abstinent following a quit attempt.^{37,38,39,40,41,42,43,44,45,46} Surveys among former smokers also suggest that health warnings promote long term abstinence from smoking.^{40,47,48}

Few studies have attempted to directly assess the impact of health warnings on smoking initiation among youth using prevalence rates. Although youth smoking rates have declined dramatically in countries such as Canada after the implementation of large pictorial health warnings, there is no reliable way to attribute these changes specifically to the warnings rather than other tobacco control measures. However, population-based surveys indicate that significant proportions of youth non-smokers, including the youth populations in Canada, the UK, and Australia report that warnings have discouraged them from smoking.^{40,41,47,49,50,51}

Overall, while it is not possible to quantify the impact of health warnings on smoking prevalence, all of the evidence conducted to date suggests that comprehensive health warnings can promote cessation behaviour and discourage initiation, and that larger pictorial warnings are most effective in doing so.

Health warnings that show graphic health effects and elicit negative emotional arousal are most effective.

The primary objective of health warnings is to depict the negative consequences of tobacco use. As a result, negative emotional reactions, such as fear, are an important indicator of health warning impact.^{52,53} Negative emotional reactions to cigarette health warnings have been associated with increases in key outcomes such as intentions to quit, thinking about health risks, or engaging in cessation behaviour.^{55,54,55,56 57} Other negative emotions, such as disgust, may also play a role in message acceptance for graphic pictorial health warnings, particularly with respect to warnings that depict aesthetically unpleasant, externally visible health effects that highlight negative social consequences.^{58,59,60}

Graphic depictions of diseaseⁱ appear to be the most reliable way to elicit negative emotional reactions to health warnings.^{55,61,62,63,64,65,66,67,68,69,70} In a recent study conducted in Mexico, health warnings that featured graphic depiction of health risks were perceived as significantly more effective than non-graphic warnings among youth and adults.ⁱⁱ A parallel study conducted in the United States, in which sets of five or six health warnings were tested for each of 15 health effects, found that graphic health warnings were more likely to be rated as effective.ⁱⁱⁱ These findings are supported by qualitative research with key target groups. For example, research conducted in Canada with 40 focus groups to test new health warning concepts concluded that:

Participants in all groups consistently expected or wanted to be shocked by HWMs, or emotionally affected in some way. Even if the feelings generated were unpleasant ones to tolerate, such as disgust, fear, sadness or worry, the emotional impact of a warning appeared to predict its ability to inform and/or motivate thoughts of quitting. HWMs which worked on emotions rather than on knowledge or beliefs were often acknowledged as effective and noticeable, and actually motivated thinking. When a strong emotion generated by a HWM was supported by factual information, that was the best combination possible.(p.3)⁷⁰

Studies of the pictorial warnings developed in the European Union also support the effectiveness of fear-arousing health warnings. Studies in France⁶⁸, Belgium⁷¹, Romania⁷², Spain⁷³, Bulgaria⁷⁴, and the UK⁶⁹ consistently demonstrated that warnings with hard-hitting images (such as rotten teeth or throat cancer tumours) were rated as most effective. Shocking images are also most likely to be recalled by smokers in population-based studies of warnings on Canadian^{75,76}, Australian⁷⁷, and European⁷¹ cigarette packs. For example, the top four warnings recalled by Australian smokers and nominated as most effective, all depicted graphic health effects, including a picture of a lung cancer tumour, a sick baby in a hospital, a picture of mouth cancer and a gangrenous foot.⁷⁷ Likewise, a series of national surveys indicates that Canadian smokers and non-smokers are most likely to recall images of diseased lungs and diseased mouths—both graphic depictions of disease—as well as a picture of a limp cigarette depicting impotence.^{75,76}

ⁱ The term “graphic” is used throughout this report to refer to stark images of the physical health effects of tobacco use, some of which may be considered grotesque or “hard hitting”.

ⁱⁱ See *Mexico Health Warnings Study* shown in Appendix C.

ⁱⁱⁱ See *US Health Warning Study* in Appendix B.

Graphic warnings that also highlight the negative aesthetic effects of smoking may be particularly effective among young people.^{62,65,67,69,78} These messages include those that specifically target physical health consequences of smoking, such as wrinkled skin, premature ageing, and skin discolouration, as well as warnings that feature an externally visible health consequences, particularly on highly visible areas such as the face, such as rotting teeth and cancerous gums.

Warnings that also depict elements of human suffering—depictions of personal experience including the social and emotional impact of tobacco use, or consequences for quality of life—have also been found to be effective. In a study recently conducted in Mexico, warnings that depicted elements of human suffering—both to oneself and others—were rated as significantly more effective than warnings without elements of human suffering.^{iv} In contrast, warnings that relied on symbolic representations, including imagery or symbols, were significantly less likely to be effective.

The effectiveness of warnings can also be enhanced with supporting text. The appropriate amount of text depends upon the overall size of the warning: the size of the picture should not be substantially reduced in order to make room for text. given that excessive amount of text has the potential to diminish the size of the picture. However, effective text statements can provide important information that helps to explain and enhance a depiction of disease shown in the accompanying picture. The repeated-exposure of health warnings in “real life” gives smokers ample opportunity to become familiar with the supporting text. Text can be used to communicate “narratives” or personal testimonials that depict the images and experiences of “real” people represent another approach that has been found to increase credibility and emotional impact of warnings.⁷⁸ In Mexico, adding names and ages of the individuals portrayed in health warnings increased the perceived effectiveness of warnings (see Appendix C). Research also suggests that factual or “scientific” information can enhance emotionally vivid warnings to maximize message acceptance, particularly when it is written in a clear, direct manner.^{65,70,79,80}

Regardless of the style or message theme, the credibility or believability of images is an important consideration. Warnings that appear to be “staged” or “fake” undermine a message and lead to

^{iv} See *Mexico Health Warnings Study* shown in Appendix C.

message rejection.⁹¹ As far as possible, images of actual or “real” health effects should be used and the use of “models” should be minimized as far as possible.

Recommendations

1. Use graphic depictions of health effects that elicit an emotional reaction.
2. Incorporate themes of human suffering and “testimonial” elements within graphic health warnings to enhance effectiveness.
3. Use “real” examples of health effects and models whenever possible.
4. Use symbolic images and “cartoon-style” themes with caution.
5. Ensure that all text is clear, direct, and easy to understand.

Quitline numbers, website and other cessation resources should be included in health warnings.

Toll-free telephone “quitlines” are an effective smoking cessation intervention and an important component of comprehensive tobacco control programs.^{81,82,83,84,85} Integrating quitline numbers within health warnings represents a highly cost-effective means increasing the reach and use of these cessation services (see example from Australia, at right). Research conducted in the UK, the Netherlands, Australia and Brazil has examined changes in the use of national telephone quitlines after the contact information was displayed within package health warnings. Each of these studies reported a significant increase in call volume following the introduction of new warnings.^{86,87,88,89,90}

For example, calls to the smoking cessation helpline in the Netherlands increased more than 3.5 times in the 12 months after the helpline number was printed on the back of one of 14 package warnings.⁸⁸ In the UK, call volume increased by as much as 4,000 calls per month after the introduction of larger text warnings.⁸⁷ Less research has been conducted on the impact of including a website address for online cessation programs, as is currently the practice in Canada and other jurisdictions, although some evidence suggests that this information is desirable to smokers.⁹¹ Including cessation resources, such as quitline numbers on tobacco



packaging is consistent with scientific evidence on the effectiveness of fear appeals, in which warnings that increase both perceived threat and perceived efficacy have been shown to have the greatest impact. Research has also shown that smokers express a strong desire for information on quitlines and other forms of cessation support on health warnings.^{70,91,77}

Recommendations

6. Integrate toll-free quitline numbers on all warnings.
7. Consider a short, direct “call to action” phrase to motivate cessation behaviour.
8. Consider including website information linking to a national, high profile smoking cessation resource.

New warnings must be implemented every 2 to 4 years to maintain effectiveness.

Health warnings that are new or periodically updated are likely to have greater impact than “older” warnings, even in the absence of changes in size and location. Canadian research monitored the effectiveness of pictorial warnings implemented in 2001 among nationally representative samples using 12 waves of data collection and indicated that health warnings have their greatest impact shortly after implementation, and then decline in effectiveness over time. This is consistent with national survey data from other countries, including the UK, and Australia.^{92,93,94,95} In particular, youth commonly report on the stale or ineffective nature of “old” warnings that remain unchanged for more than several years.^{96,97,98} This is consistent with the basic principles of advertising and health communications, which suggest that the salience of a communication is greatest upon initial exposure and erodes thereafter.^{99,100}

Recommendation

9. Identify two images for each warning set and mandate the implementation date for renewing the nine warnings. If selecting an additional set of images is not feasible given timelines, ensure that the date for renewing the nine warnings is established, and allow for the additional set of warnings to be identified in the interim.

The effectiveness of health warnings is enhanced by including inserts and “onserts”.

The external display surfaces of the package represent the most important location for health warnings or any other information. However, there are also possibilities for using the “inside” of packages. Canada currently requires one of 16 messages to appear on the inside of packages—see image at right. Although this information is less noticeable than the health warnings on the exterior of the package, interior messages nevertheless represent an added opportunity to communicate with the smoker and many Canadian smokers report reading this information.¹⁰¹ Indeed, a recent study of Canadian smokers supported the inclusion of additional information on health effects and cessation on the “inside” of packs.⁹¹ Similar opportunities exist with respect to “onserts”, messages attached to the outside of packages. It should be noted that tobacco manufacturers routinely include “inserts” or “onserts” with tobacco packaging.



Recommendation

10. Consider providing “inserts” with additional health and cessation information.

Warnings should be integrated with media initiatives and public education campaign.

The introduction of new health warnings and messages represents an excellent opportunity to link and leverage other policy initiatives. Where resources allow, mass media initiatives timed to coincide with the new messages appearing on the market. A coordinated media campaign will reinforce warnings and messages, improve access to target groups, provide additional information on health warnings and messages and also communicate other information that increases tobacco users motivation and confidence in their ability to quit, such as the benefits of quitting, attitudes to quitting, quit advice and contact details of quit organizations. See example from Australia at right.^v



11. Develop public education campaign to leverage the impact of the warnings and to enhance their effectiveness.

^v Examples of this media campaign are available at: http://www.cancerinstitute.org.au/cancer_inst/campaigns/healthwarnings2006.html

5.0 PROPOSED FDA WARNINGS: RESEARCH & RECOMMENDATIONS

Overview

An online study was conducted in December 2010 with 783 adult smokers (19 years and older) and 510 youth aged 16-18 (including both smokers and non-smokers). The primary objective of the study was to evaluate the potential effectiveness of the set of warnings proposed by the FDA.^{vi} Specific aims included testing the impact of colour (vs. black and white images), the use of cartoon/graphic novel styles (vs. “real” people), inclusion of a 1-800 “quitline” number, including of personal information, and using graphic fear-arousing images. Appendix A includes a summary of the study, including methodology and data tables.

Nine “sets” of health warnings were tested, one for each of the nine statements required under the Tobacco Control Act. Each set included a total of six or seven warnings: each of the warnings proposed by the FDA for public comment and at least one additional warning featuring alternative themes or components comparative purposes. Each respondent was randomly assigned to view two of the nine sets of health warnings. Warnings within each set were presented in random order. Respondents rated each warning on a scale of 1 to 10 for a series of outcomes (e.g., concerns about health risks, motivation to quit, youth prevention and overall effectiveness), as well as potential mediators of label impact (e.g, ability to attract attention, personal relevance, fear, disgust, unpleasantness). After all warnings within a set were rated one at time, respondents ranked the warnings within the set on overall effectiveness. In the summary below, the numbers below each image refer to the rating out of 10 for “overall effectiveness.” In the discussion of the findings, “rankings” refer to the percentage of respondents who ranked that warning most effective relative to the other warnings in the set. A full summary of the findings, including statistical differences between warnings is provided in Appendix A.

^{vi} See: <http://www.fda.gov/TobaccoProducts/Labeling/CigaretteProductWarningLabels/ucm2024177.htm>.

Addiction

	Proposed FDA Warnings				Alternate Warnings	
Youth	 3.7	 3.9	 5.4	 7.8	 5.2	 5.8
Adults	4.4	4.9	5.4	8.1	5.4	6.0

The graphic warning depicting a man smoking through a stoma was the highest rated FDA Proposed warning, rated more than 2 points higher than any other warning, and ranked most effective by 80% or more of respondents. Other proposed depictions of addiction were rated lower, and the symbolic “puppet” warning was rated lowest among warnings in this set. When comparing the proposed comic-book style image of a smoker “shooting up” with a cigarette to an alternate version featuring a real person, the ‘real’ version was rated higher. The alternative warning depicting a patient smoking outside a hospital was rated higher than all FDA-proposed warnings except the smoking stoma. The pattern of ratings was similar among adults and youth, although youth rated warnings somewhat higher than adults, particularly for the highest-rated warning.

Recommended warning



This warning was rated significantly more effective than other warnings. The warning combines the addiction message with a compelling, concrete image of the consequences of cigarette addiction. Research in other countries, including Canada and Mexico, has also found this to be effective among adults and youth. Note that the cartoon warning was rated as significantly less effective than the parallel warning featuring a “real” person and there is no evidence that this style was more effective among either youth or adults.

Cancer

	Proposed FDA Warnings				Alternate Warnings	
Youth	 4.9	 4.9	 6.8	 7.6	 7.5	 7.6
Adults	4.9	5.5	7.7	8.4	8.2	8.6

In the set about cancer, the graphic warnings were rated significantly higher than the warnings that featured a burning cigarette and larger text. The warning featuring a diseased mouth was rated highest among the proposed FDA warnings, followed by the warning featuring a dying cancer patient. However, the warning showing a man’s face with mouth cancer (not included in the proposed FDA

set) was rated highest of all. Indeed, in the ranking task, the majority of respondents chose one of the alternate warnings rather than one of the warnings proposed by the FDA. When comparing the proposed image of the dying cancer patient to an alternate version that also included personal information, the version with personal information was rated higher. The pattern of ratings among adults and youth was similar, although youth scores were generally higher, particularly for the warnings featuring graphic content.

Recommended warnings



All three of these warnings are likely to be effective. Priority should be given to the mouth cancer warning showing the full face. This warning received the highest rating of effectiveness among youth compared to all warnings tested in this study. If the image of the cancer victim is selected, it should include personal, identifying information to enhance credibility and emotional engagement. It should also be noted that warnings should not feature images of burning cigarettes on their own, as is the case with two the FDA proposed warnings in this set. Previous research has shown that these types of images are significantly less effective and may serve as smoking cues in the absence of other compelling images integrated in the same warning.⁶¹

Death

	Proposed FDA Warnings			Alternate Warnings		
						
Adults	4.9	5.3	6.2	7.0	5.2	6.2
Youth	4.9	5.2	6.4	7.6	6.3	6.3

The graphic warning depicting a dead man with a chest incision received the highest overall rating and ranked most effective by nearly half of respondents. Of the remaining proposed warnings, the image of the man in a coffin received the next highest rating. This warning was rated comparably to the alternate warning of a widow grieving over a hospital bed. In the ranking task, approximately one in five respondents chose the alternate warning with the gun. The warnings featuring people were rated higher than the more symbolic representations. The alternate warnings were generally rated between the graphic proposed warnings and the symbolic proposed warnings. Ratings among adults and youth were generally similar, although youth scores were higher for the warnings with the gun and the dead man with the chest incision.

Recommended warning



This warning clearly stands out as the highest rated warning among youth and adults from the proposed set. Other proposed warnings were rated poorly. It would be preferable to use a body with a lighter build to avoid the possibility of smokers attributing disease to obesity. The ethnicity/race of the body should also be more ambiguous. A similar warning was tested as part of the “Tobacco Smoke and Lung Disease” warning set and received higher ratings.

Fatal Lung Disease

Proposed FDA Warnings



Alternate Warnings



Adults	4.8	5.2	6.3	7.9	6.3	7.6
Youth	4.7	5.1	6.0	7.5	5.6	7.4

Graphic internal images of fatal lung disease were rated as most effective. The highest rated warning (both overall and among the FDA proposed warnings) featured the two pairs of lungs, whereas the alternate warning showing a lung tumour was rated just slightly lower. While half of adults (and a third of youth) selected the lungs as the most effective warning, nearly half of youth (and a third of adults) selected the lung tumour. The proposed warning featuring feet on an autopsy table and the alternate warning featuring a person with an oxygen tank were rated similarly, and fared better than the more symbolic representations of cigarette-filled lung shapes and a lung x-ray image. Ratings of adults and youth followed the same pattern, although youth scores were slightly lower.

Recommended warning



This warning was the highest rated among the set of proposed and alternate warnings. This warning has also tested very well in other countries, including Canada, Mexico, and the European Union. Respondents tend to like the “before” and “after” comparison of the healthy and diseased lungs. The image appears to illustrate a common concern among smokers about “tar build-up” in the lungs: even though the image does not show “tar”, it nevertheless reinforces this health concern.

Pregnancy

Proposed FDA Warnings



Alternate Warnings



Adults	5.6	5.7	5.3	5.7	6.1	7.2
Youth	5.5	5.6	5.3	5.9	6.1	8.1

Only two warnings were proposed for pregnancy, both of which received similar ratings. The alternate warning depicting a baby in the hospital was the highest rated warning overall, rated a full point higher among adults and nearly 2 points higher among youth; this warning was also ranked most effective by more than three-quarters of respondents. The second-highest rated warning was also an alternate image, of a foetus in utero. The rest of the warnings in this set were rated fairly similarly. When comparing the proposed colour image of a pacifier and ashtray to an alternate black and white version of the same image, the colour image was rated higher. When comparing the proposed comic-book style image of a baby to an alternate version featuring a real baby, the ‘real’ version was rated much higher. Ratings among adults and youth were similar, although youth scores on the highest-rated warning were higher than among adults.

Recommended warning



Only two warnings were proposed for this topic. Neither of the FDA proposed warnings featured an actual person or health effect. Instead, they used a very abstract symbolic image and a cartoon depiction of a sick baby. Both of these warnings were rated very poorly. The recommended warning was rated significantly higher than all other warnings tested. Note that this warning has been implemented in other countries and is very similar in composition to the cartoon-style baby included in the FDA proposed list. The cartoon-style warning was rated significantly lower than the “real” baby among youth and adults. Although there may be a rationale for selecting cartoon-style warnings for abstract themes or messages (such as addiction) that are difficult to depict, cartoons are less effective at communicating actual health effects, for which a real person (a baby in this case) is likely to be far more engaging and credible.

Quitting Smoking

Proposed FDA Warnings



Alternate Warnings



Adults	4.0	4.9	5.0	4.1	4.9	5.3
Youth	3.7	4.7	4.8	3.8	4.9	5.2

The highest rated FDA Proposed warning varied by age group: adult smokers rated the “quitter” most effective, whereas youth rated the cigarettes in a toilet as most effective, although the scores for these warnings were very close in both age groups. However, the alternate warning featuring a “quitter” with a quitline number was rated as the most effective warning overall among both youth and adults, and ranked most effective by around half of respondents. The proposed warning with a woman blowing a bubble was ranked lowest by nearly a full point. When comparing the proposed color image of this warning to an alternate black and white version of the same image, the black and white image was rated slightly (0.1) higher, but this similarity may be due to a floor effect: in other words, the two warnings were rated so poorly that there was little difference as to whether a color or black and white image was used. Indeed, these were the lowest rated warnings in the entire study.

Recommended warning



As a set, the cessation warnings all received relatively low warnings. This is typical for cessation oriented warnings which usually feature symbolic representations of quitting and for which the images are typically less engaging than graphic health effects. Among the FDA Proposed warnings, there was little to distinguish the warnings, with the exception that the image of the woman blowing a bubble was rated significantly lower (in fact, it was the lowest rated warning in the entire study). The only warning that was rated significantly higher than the others, was the “alternate” warning that included the telephone quitline number at the bottom. This speaks to the importance of integrating a quitline number and other concrete cessation information in the warnings. This is absolutely critical for cessation-themed warnings, but should also be the case for all warnings.

Tobacco Smoke and Children

	Proposed FDA Warnings						Alternate Warning
Adults	4.4	5.0	5.6	5.9	6.3	6.3	6.1
Youth	4.4	5.4	5.8	6.2	6.4	6.5	6.3

The warnings depicting a mother blowing smoke onto her baby were rated the highest and ranked most effective by half of respondents. Although scores were very close, the comic-book style version of the image rated slightly higher among adults, whereas the ‘real’ version rated slightly higher among youth. The alternate warning depicting a child with parents smoking in the background was rated higher than all but those two leading FDA Proposed warnings. The proposed text-only warning written

in a child-like font was ranked lowest by a considerable margin. Adult and youth ratings were similar, although youth scores were generally somewhat higher than those of adults.

Recommended warnings



The two warnings above were the highest rated warnings. Although the cartoon image was slightly higher on the rating scale among adults and slightly lower among youth, this difference was not statistically significant. Overall, the ratings for these warnings indicate they are reasonable, although alternatives could be explored. For example, versions of the girl wearing an oxygen mask have tested well in other countries; however, the version tested in the current study features a model that look like an older child or youth. This warning may be improved by using a younger model.

Tobacco Smoke and Lung Disease

	Proposed FDA Warnings					Alternate Warning
						
Adults	4.6	4.6	4.8	5.0	5.4	7.1
Youth	5.9	6.0	6.1	6.2	6.7	8.3

The highest-rated FDA Proposed warning featured an image of gravestones; however, this warning was ranked most effective by less than one in ten respondents. The alternate graphic warning featuring a body with lung removal incisions was rated the highest overall by a large margin, and ranked most effective by more than three-quarters of respondents. Mean ratings for the other warnings were very similar. Youth rated all of the warnings in this set at least a point higher than adults, and only the top two warnings were ordered the same between the age groups.

Recommended warnings



The warning featuring the body with lung removal incisions was clearly superior to the other warnings in this set. Overall, the FDA Proposed warnings were rated poorly: although the gravestone image was the highest rated FDA Proposed warning, the rating score was modest. Note that the warning of the body is very similar to the warning recommended for the “Death” statement and both should not appear in the same series. The body picture tested in the current set was rated significantly higher than the FDA Proposed version in the “Death” set and is likely to be the more effective of the two. If one of the FDA Proposed warnings is selected for the SHS Lung Disease set, I would recommend the gravestone warning; however, I would urge the FDA to consider alternatives, particularly given the

importance of “lung disease” as a health effect for tobacco use and the range of engaging images that are available to depict this health effect.

Stroke and Heart Disease

	Proposed FDA Warnings				Alternate Warnings	
Adults	 4.9	 5.1	 5.7	 6.4	 6.7	 7.1
Youth	4.9	5.2	5.6	6.6	7.6	8.1

In the set about stroke and heart disease, the highest-rated proposed warning featured a man with a mask and breathing apparatus; however, this warning was ranked most effective by only 9-17% of respondents. The alternate graphic warnings featuring an image of open-heart surgery, and a bloody brain were rated higher than any of the FDA-proposed warnings, and ranked most effective by the majority of respondents; the heart surgery image was particularly highly rated and ranked. The warnings depicting human consequences were rated higher than the two more symbolic images. Ratings were similar among adults and youth for the FDA Proposed warnings, but approximately one point higher among youth for the alternate graphic warnings.

Recommended warnings



This warning was among the best rated warnings in the study and clearly outperformed the FDA Proposed warnings, which performed relatively poorly. Indeed, both of the alternate warnings tested for this set were rated as significantly more effective than the FDA Proposed images. It should be noted that the two FDA proposed warnings that show images of people’s faces (warnings 3 and 4 in the above list) both depict white males wearing a dress shirt and tie. The clothing of these models should be somewhat more ambiguous to connect with a broader socio-economic target group. In addition, smokers prone to defensive reactions may attribute the heart attack to stress or work load rather than tobacco use.

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