

**Comments for Submission to the FDA Regarding
Required Warnings for Cigarette Packages and Advertisements
Docket No. FDA-2010-N-0568
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by

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The American Association for Cancer Research (AACR), the oldest and largest scientific organization in the world dedicated to the prevention and cure of cancer through research, education, communication, and collaboration, sincerely thanks the U.S. Food and Drug Administration (FDA) for the opportunity to provide comments in response to the Proposed Rule on Required Warnings for Cigarette Packages and Advertisements.

The enormity of the burden that tobacco use places on Americans is staggering, killing more than 440,000 people, causing 18 different cancers and 30% of cancer deaths, and resulting in \$193 billion in economic loss every year. We deeply appreciate the FDA's dedicated and swift action in implementing the Family Smoking Prevention and Tobacco Control Act with the goal of reducing the morbidity and mortality caused by tobacco use.

The AACR believes any proposed new graphic warning labels for cigarette packaging and advertisements should be based on the best available scientific evidence and consistent with international standards. The AACR recommends that the FDA:

- Invest in research to evaluate the effectiveness of warning labels over time in longitudinal studies and specifically evaluate the effects of warning labels on different population groups, especially minorities and people of lower socioeconomic status who face disproportionate burden as a result of tobacco use. FDA should examine the adequacy of existing warning labels regularly to ensure the warning labels remain as effective as possible.
- Include 1-800-QUIT-NOW as the cessation resource on the warning labels.
- Amend the impact analysis of the Proposed Rule, which is currently too conservative, to more accurately reflect the benefits of the proposed warning labels.
- Establish a scientific advisory body focused on communications.

A Strong Evidence Base Supports the Proposed Warning Labels

The Proposed Rule clearly delineates the scientific evidence that led Congress to find that current U.S. warning labels are ineffective and to mandate the specific, science-based changes put forth in the Tobacco Control Act.

Authoritative scientific sources, including the Institute of Medicine and the Surgeon General, have issued reports¹ stating that the U.S. is in dire need of updated cigarette warnings, which have not been altered in 25 years. The AACR concurs that the comprehensive body of evidence indicates current U.S. cigarette warning labels fail to effectively convey information about the dangers of smoking. The complexity of the text, the small size, the lack of graphic images and the lack of change contribute to the ineffectiveness of the current U.S. warning labels.

A vast body of international evidence has established critical elements that increase a warning label's effectiveness and are included in the World Health Organizations guidelines for the Framework Convention on Tobacco Control,² stipulating parameters for the most effective location, size, use of graphics and full-color, rotation, and text. The warning labels mandated by the statute and proposed by the FDA are consistent with these science-based international standards. The proposed warning labels would be placed at the top of the front and back of the cigarette packs; comprise 50% of the front and back panels of a cigarette pack; include full-color graphic images to indicate the ill-effects of tobacco use; include nine warnings (as opposed to the current four) that will be rotated; and include simpler text that is shorter and more direct than existing warning text.

FDA Should Invest in Additional Research on Long-term Efficacy of Warning Labels

The AACR commends the FDA for requiring scientific evaluation of the relative effectiveness of the proposed warning labels. The first study that the FDA commissioned collected responses for a number of short-term emotional and cognitive effects of viewing the 35 warning labels to assess the relative efficacy of the labels.³ The researchers concluded that certain warnings were likely to be more effective than others in eliciting strong emotional and cognitive reactions, recall, and a better understanding of health risks. The AACR believes that the FDA should choose images based on the available data. Importantly, the FDA should not use those labels that were not found effective, but should invest in development, deployment and evaluation of additional labels.

While this is a good start, the AACR believes that the FDA should continue to gather evidence based on representative samples with adequate representations of minorities and people of lower socioeconomic status. It is particularly critical to look at how these labels affect different groups, particularly given the differential and mixed effects seen in this preliminary study.

In addition, longer-term behavioral changes such as cessation could not be assessed in this study. Likewise, the wear-out effect, a critical component of overall effectiveness of the warning label, could not be assessed in the short-term study. Thus, longitudinal studies need to be completed to fully understand the efficacy of the proposed warning labels. The AACR urges the FDA to prioritize this research area and invest in rigorous longitudinal studies. Further, the FDA should be responsive to new data and integrate new scientific evidence to ensure that the most effective warning labels are being used.

The tobacco industry has traditionally invested heavily in advertising and promotion and has successfully targeted numerous population groups. NCI Monograph 19, “The Role of the Media in Promoting and Reducing Tobacco Use,” states that cigarettes are one of the most heavily marketed products in the U.S. In 2005 alone, U.S. cigarette manufacturers spent \$13.5 billion (in 2006 dollars) on cigarette advertising and promotion, an average of \$37 million per day.⁴ The Monograph also provides evidence that the tobacco industry has been strategic in targeting various population groups—including men, women, youth and young adults, specific racial and ethnic populations, religious groups, the working class, and gay and lesbian populations.

Historically, one of the main themes of tobacco advertising has been to assuage anxieties about the dangers of smoking.⁵ Given the tobacco industry’s long history of using highly effective marketing practices coupled with its financial means to continue market research, it is likely the industry will develop ways to undermine the health warning labels with its own advertisements. Thus, it is absolutely imperative for the FDA to invest in research that will help to elucidate how and why new warning labels and related health communications are effective across the various smoking populations targeted by tobacco industry. The FDA should refine future iterations of warning labels based on the best empirical data.

Inclusion of a Reference to a Cessation Resource on the Warning Label

The AACR fully supports the proposal in the Proposed Rule for the warning label to include a telephone number or website reference that would provide smokers interested in quitting with evidence-based assistance in doing so.

Although a majority of smokers want to quit, only about 40% of smokers try to quit in a calendar year, and most of these quit attempts are both unaided and unsuccessful.⁶ More than 95% of those who try to quit on their own relapse; most do so within a week because tobacco is extremely addictive.⁷ Smokers who use evidence-based services of telephone quitlines have a two-to-three times higher rate of success in quitting than those who make unassisted quit attempts.⁸ International experience has demonstrated that inclusion of a quitline number in the warning label increased the number of smokers who contacted the quitline and who make a quit attempt.⁹

The AACR believes that 1-800-QUIT-NOW, which provides access to the network of publicly-sponsored state quitlines, is the most appropriate resource to include on the warning label, based on the evidence at this time.¹⁰ The criteria for a cessation resource put forth in the Proposed Rule, while largely unobjectionable, create a set of requirements, independent of the requirements of the Centers for Disease Control and Prevention (CDC), which administers the program and maintains standards for quitline operation. Therefore, the Proposed Rule may unintentionally inhibit effective operation of the CDC-administered quitlines. The AACR recommends that the Final Rule mandate inclusion of 1-800-QUIT-NOW in the label and specify that quitlines authorized by CDC for connection to the network are qualified, rather than subjecting quitlines to two sets of requirements.

Among the criteria listed in the Proposed Rule for a cessation resource to be included in the warning label is the requirement that the quitline or website not “include derogatory statements regarding cigarette manufacturers, importers, distributors, or retailers or advocate public policy changes.” The

website also cannot contain a link to any website or reference to any quitline that says anything derogatory about tobacco companies or advocate policy changes. The definition of derogatory is unclear, and this vague requirement could precipitate litigation by the industry, unnecessarily impeding the implementation of the warning labels. The AACR is deeply concerned that such a vague requirement could eliminate most if not all the most potentially useful sources of information and would create a wholly unnecessary and inappropriate limitation on the effectiveness of such sources. The AACR recommends deleting this limitation.

As American culture adopts different forms of communication, it will be important to assess the effectiveness of using new technologies and approaches to determine which are the most effective in helping people, including subpopulations, quit using tobacco. The AACR believes the FDA should prioritize the funding of research to learn which approaches will encourage the most people to quit.

The Proposed Rule's Impact Analysis is Conservative, Fails to Fully Reflect Benefits of Rule

The AACR is concerned that the Proposed Rule's impact analyses, in Section VII and VIII of supplementary information, is too conservative and does not fully capture the positive impact of the proposed warning labels.

The estimates of costs attributable to smoking do not include the costs borne by cancer patients and their communities due to morbidity, including pain, distress, and lost occupational and social functioning. The FDA states: "The estimated totals may understate the full public health benefits of the proposed rule because they fail to quantify reductions in smokers' non-fatal illnesses other than emphysema, the reduction in external effects attributable to passive smoking, and the reduction in infant and child fatalities caused by mothers' smoking during pregnancy." The rate of smoking during pregnancy remains distressingly high, at 13.2% nationwide in 2006. Furthermore, rates are much higher in socially disadvantaged groups and in some geographic regions, approaching 50% in some sub-groups.¹¹

In section VII, the FDA has determined that there is no environmental impact, when in fact a reduction in the number of cigarettes consumed will result in a reduction of cigarette-related waste.¹² Philip-Morris USA "recognize[s] that cigarette butt litter is a significant contributor to litter in our environment."¹³ The Ocean Conservancy noted that cigarette butts were among the three most common items collected in the United States during its International Coastal Cleanup.¹⁴ Cigarette butts pose a greater health hazard than most other litter because they contain toxins which can be leached into water systems.

Thus, key advantages are missing from the FDA's analysis and should be included to understand the large positive impact the warning labels will have on the public's health.

Integration of Warning Labels with Broader Tobacco Control Efforts

The AACR feels it is critically important to accompany the introduction of the new graphic warning labels with a public relations and public education campaign designed to complement and build on the hoped-for impact of the new warnings and the messages they are intended to convey. Public

mass media counter-marketing campaigns, especially when combined with other approaches, have been successful in both tobacco prevention as well as cessation.¹⁵ Such a campaign should encompass messages delivered through a wide range of media, including social media. Recognizing that the proposed new graphic warning labels are indeed a critical component of tobacco control, the AACR urges the FDA to coordinate and lead efforts to integrate this effort with broader tobacco control efforts. Warning labels alone will not have the desired outcome of eliminating tobacco use and attendant disease.

FDA Should Establish Advisory Body Focused on Communications

The rapidly changing environment of mass media, including social networking, is providing new opportunities to reach different populations. While this allows innovation in approaches to communicating important public health messages to the public, it also creates opportunities for the tobacco industry to circumvent restrictions and devise new ways to reach their target audience, as they have done in the past.¹⁶ In reflecting on both the historical behavior of the tobacco industry¹⁷ and the fundamental importance of the myriad issues surrounding communications, including health warning labels, the AACR believes the FDA may benefit from establishing an advisory body that would provide frequent recommendations on media, marketing, and communications based on the latest scientific findings. The AACR is keenly aware of the notable work of the Tobacco Products Scientific Advisory Committee and appreciates the communications expertise among its membership; however, the speed with which the field is changing, the new data being generated and the likelihood of having to counter new industry approaches aimed at undermining the new labels suggest strongly that this issue may warrant increased vigilance. Therefore, the AACR urges the FDA to consider establishing an advisory body specifically focused on communications to facilitate the dissemination of the best available scientific evidence to the FDA and to better understand new approaches implemented by the tobacco industry that could potentially undermine FDA efforts.

In summary, the AACR and its Task Force on Tobacco and Cancer,¹⁸ representing researchers across the continuum of the tobacco problem, commend the FDA for its commitment to a science-based approach to tobacco control. The AACR stands with the FDA in its efforts to eliminate tobacco use, and its members are prepared to work with the FDA and other partners to make that happen in our lifetime.

The mission of the American Association for Cancer Research is to prevent and cure cancer. Founded in 1907, the AACR is the world's oldest and largest professional organization dedicated to advancing cancer research. The membership includes 33,000 basic, translational and clinical researchers; health care professionals; and cancer survivors and advocates in the United States and more than 90 other countries. The AACR marshals the full spectrum of expertise from the cancer community to accelerate progress in the prevention, diagnosis and treatment of cancer through high-quality scientific and educational programs. It funds innovative, meritorious research grants, research fellowships and career development awards. The AACR Annual Meeting attracts more than 18,000 participants who share the latest discoveries and developments in the field. Special conferences throughout the year present novel data across a wide variety of topics in cancer research, treatment and patient care. Including Cancer Discovery, the AACR publishes seven major peer-reviewed journals: Cancer Research; Clinical Cancer Research; Molecular Cancer Therapeutics; Molecular Cancer Research; Cancer Epidemiology, Biomarkers & Prevention; and Cancer Prevention Research. AACR journals represented 20 percent of the market share of total citations in 2009. The AACR also publishes CR, a magazine for cancer survivors and their families, patient advocates, physicians and scientists.

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 - ¹⁸ For more information see: www.aacr.org/home/scientists/working-groups--task-forces/task-forces/tobacco-and-cancer.aspx.
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