



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*®

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Margaret A. Hamburg, MD
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket ID No. FDA-2010-N-0568
RIN 0910-AG41

Dear Commissioner Hamburg,

The American College of Physicians (ACP), representing over 130,000 internal medicine and medical student members, is pleased to provide comments on the Food and Drug Administration's proposed rule, "Required Warnings for Cigarette Packages and Advertisements." The American College of Physicians believes that the efficacy of the current mandated cigarette label warnings have diminished greatly and strongly supports the Food and Drug Administration's efforts to create and require display of fresh, noticeable, and effective cigarette graphic health warnings. While the College does not have a specific recommendation on the choices of proposed warning labels contained in the proposed rule and its accompanying material, the College respectfully recommends that the FDA:

- Require that smoking cessation resource and referral information be included on all new graphic health warning labels,
- Increase the overall size of the warning labels,
- Strengthen the textual warning statement language to be more conclusive and consider adding supporting explanatory language, and
- Adopt more emotionally provocative graphic images and/or graphic health warnings featuring testimony of real-life people expressing how smoking has negatively affected their life.

The College believes that strong cigarette warning labels are a vital part of comprehensive tobacco use prevention and control campaign. ACP feels that the above revisions will ensure that the new labels will help influence smokers to quit and deter potential smokers, particularly young people.

ACP policy

The College has long been a strong proponent of efforts to prevent and treat tobacco addiction. ACP strongly supported the Family Smoking Prevention and Tobacco Control Act, which authorizes the FDA to regulate tobacco products. In addition, ACP has advocated for increasing

the tobacco excise tax to fund the Children's Health Insurance Program and is an active member of the Smokefree Collaborative, a coalition of medical societies working together towards the goal of eliminating smoking and tobacco use.

Most recently the College released the position paper *Tobacco Control and Prevention* which calls for a comprehensive tobacco control strategy built around goals such as increased excise taxes for all tobacco products, improved access to tobacco cessation treatment, expanded youth anti-smoking education campaigns, elimination of menthol from all tobacco products, regulation of electronic cigarettes, and stronger smoke-free laws for workplaces.

The cigarette package as tobacco company marketing tool

A cigarette package is more than just a container for the product. Tobacco companies use cigarette packaging and labeling as a marketing tool, a means of establishing and strengthening the brand's image among consumers.¹ Cigarette packaging has become even more important to tobacco companies facing increasing scrutiny and marketing restrictions, leading one tobacco company executive to state, "Our final communication vehicle with our smokers is the pack itself. In the absence of other marketing messages, our packaging...is the sole communicator of our brand essence."²

The cigarette package as public health information outlet

Since the mid-1960s, cigarette labels have been required to display a message from the United States Surgeon General warning of the punitive effects of cigarettes on health and mortality. Over the years, the cigarette package warnings have varied only slightly, leading to complaints that the messages are overexposed, irrelevant, and ineffective. Further, warning labels remain devoid of illustration and are relegated to the side of the cigarette pack, making them difficult to notice. Meanwhile, other countries have moved to require that cigarette packs display larger text-based messages and/or photographs or illustrations stressing the harm related to tobacco use and exposure. As a public health marketing tool, U.S. cigarette package warnings have been less effective than their international counterparts. For instance, 84% of Canadian smokers cited cigarette package warnings as a source of health information compared with 47% of U.S. smokers.³ Strong, informative warnings increase consumer education on the negative effects of smoking and may motivate smokers to quit.⁴ ACP strongly supports requiring the use of larger, graphic and text-based cigarette warning labels as a way to counter the marketing efforts of tobacco companies and provide trusted, evidenced-based information on the dangers of smoking to consumers.

Graphic and text versus text-only warnings

Myriad research supports that graphic and text-based cigarette label warnings can be an effective part of a comprehensive tobacco prevention and cessation initiative. Among the literature, Hammond et al. surveyed Canadian adult smokers following the introduction of prominent graphic and text label warnings and determined that the warnings "engaged" smokers and concluded that such labels may serve as an effective cessation intervention tool.⁵ Research comparing Canadian and U.S. warning labels conclude that the larger text and graphic-based

Canadian warnings are more noticeable and informative than their U.S. counterparts.⁶ A study of smoker reactions to Canadian labels and text-only labels on cigarette packs sold in Mexico found that the Canadian labels were also more effective in communicating the risks of smoking and promoting cessation.⁷ Another study found that Canadian and Australian graphic warnings were more effective in eliciting cessation behavior than the text-only warnings of cigarettes sold in the United Kingdom.⁸ Further, a study that asked smokers to "bid" on either a text-only cigarette pack or a graphic/text warning message pack concluded that the graphic/text warning pack was 17% less desirable than the text-only pack, potentially leading to reduced use of the product.⁹ Graphic warnings that clearly communicate the dangers of smoking may also be better understood by those with limited English proficiency or literacy skills.¹⁰ The current cigarette warning labels are especially problematic in this area as they require college-level reading proficiency.¹¹

Message variation and the need for regular warning label updates

ACP agrees that rotating the graphic images and text messages displayed on the cigarette pack will strengthen the salience of the message (Sec. 1141.10 of the proposed rule). Messages are likely to have greater impact as they are introduced.¹² Meaningful impact of warning messages may decline with repeated exposure; therefore, revising and/or rotating a variety of cigarette warning labels may counteract the threat of overexposure, keeping the messages fresh and noticeable.¹³ Further, different warning labels can feature messages targeted to specific audiences. Strahan et al. recommend that warning messages should address the different attitudes and beliefs of different demographic groups. Adolescents considering initiating smoking may have different beliefs about smoking than a long-time adult smoker who has made multiple quit attempts.¹⁴ A Canadian warning label directed at young males, for instance, stresses that tobacco can make the smoker impotent.¹⁵ Warning labels should also be updated to reflect new evidence-based findings and consumer research related to the effects of smoking and improving cessation.

Recommendations

Cigarette warning labels should include information on smoking cessation information, including a message encouraging consumers to contact their physician or other health care professional

ACP strongly believes that cigarette warning labels should inform smokers and potential smokers of the dangers of tobacco use but also provide assurance that quitting is possible and that assistance is available. It is important to emphasize not only the dangers of smoking but also the benefits of quitting and the availability of helpful resources.¹⁶ ACP is not in the position to endorse or sponsor a particular quitline or smoking cessation website (Sec. 1141.16 of proposed rule); however, the College believes that the FDA should consider requiring that all cigarette warning labels include a message that smokers can quit as well as information on how to seek help.

Physicians and other health care professionals are crucial partners in assisting smokers in their cessation efforts. Not only do physicians help patients break free of tobacco addiction, they also provide education to patients about the harms of smoking and why it is important not to start.

Studies support that physician advice is effective in encouraging smoking cessation.¹⁷ According to one estimate, 42,000 lives could be saved each year if 90% of U.S. smokers received advice and offer of medication or other assistance to quit smoking from their health professional.¹⁸

Both the Australian and European Union graphic warning labels recognize the vital role that physicians play in assisting their patient's cessation efforts.¹⁹ All Australian cigarette label warnings feature the message, "You CAN quit smoking. Call the Quitline 131 848, talk to your doctor or pharmacist, or visit www.quitnow.info.au."²⁰ In addition to physician intervention, quitlines provide important support to smokers who want to quit. Maine's HelpLine program has been effective in helping smokers quit: 21% of smokers who had received assistance from the Helpline remained tobacco-free for 6 months.²¹ In 2006, the year the new quitline graphic warning labels were introduced in Australia, calls to the quitline doubled compared with either of the preceding 2 years.²²

Make warning labels larger

The FDA's decision to increase the size and location of cigarette warning labels to 50% of the front and rear panels of the package is a step in the right direction (Sec. 1141.10(a)(4)). The proposed size and location requirements reflect the recommendations of the World Health Organization's (WHO) Framework Tobacco Convention on Tobacco Control, which states that cigarette warning labels should comprise of at least 50% of principal display areas of the cigarette package.²³ While this significant enhancement will undoubtedly make the graphic health warnings more noticeable and more memorable than the current labels, evidence suggests that larger labels may be more effective.²⁴ Studies have also found that smokers correlate the size of the warning label to the importance of the message, e.g. the larger the message, the greater magnitude of the risk.^{25,26} A number of countries have taken action to require warning labels beyond the size recommended by the WHO. Warning labels for cigarettes sold in Australia must cover 30% of the front of the pack and 90% of the rear of the pack and Uruguay recently required that warnings cover 80% of the front and rear of cigarette packaging.^{27,28} Such prominent labels may be more effective; a majority of Canadian smokers, for instance, found that a warning label that covered 80% of the pack was most effective.²⁹ Placement of the warning label is also important. Larger warnings displayed on the front of the package are more effective than warnings located on the side or rear of the package.

Use simple, direct text; avoid technical jargon and incorporate explanatory information

ACP largely supports the proposed textual warning statements outlined in the proposed rule. To achieve maximum efficacy, textual warning statements that accompany graphic warnings must be simple, direct, and free of jargon that may confuse the reader. Additionally, they should focus on a range of themes such as the social consequences of smoking, the negative health effects of smoking, and the benefits of quitting.³⁰ A study of text-based warnings on cigarette packs sold in a number of European nations found that direct, powerful messages such as "smoking kills," "smoking causes cancer," and "smoking when pregnant can harm your baby" were deemed most effective.³¹ Less direct terms such as the current Surgeon General warning that "smoking by pregnant women *may result* in fetal injury" [italics added] could undermine the effectiveness by inferring that the claim is speculative.³² A focus group of Australian young adults found that a

tobacco warning's claim that as a result of smoking "Central vision is lost, blindness may follow," seemed less credible because the word "may" hinted that the connection between smoking and blindness was inconclusive.³³ Given the irrefutable evidence that smoking during pregnancy harms fetal health and development, the FDA should consider altering the proposed warning headline "Warning: Smoking During Pregnancy Can Harm Your Baby" to an unambiguous phrase such as "Smoking When Pregnant Harms Your Baby" (European Union warning label) or "Tobacco Smoke Harms Babies" (Canada warning label).³⁴ Future warning labels should also use language that removes doubt about the credibility of the message.

The FDA should also consider adding explanatory text to the warning label to support the claim made in the warning tagline. Australia and Canada have required display of text explaining the primary claim of the warning label, such as a brief sentence explaining that smoking causes one's arteries to clog, potentially causing a stroke. Such supporting text that is simple, brief, direct, free of jargon, understandable, and unequivocal may strengthen the message and make it more believable.^{35,36}

Graphic warnings should be visually compelling and use factual testimonials expressing the negative consequences of smoking

ACP appreciates the FDA's proposed warning graphics and believes that those which are most graphically arresting or emotionally provocative will have the strongest impact. The type of graphic warning displayed on a cigarette package may also affect whether the warning will discourage smoking. A survey initiated by the Canadian Cancer Society found that Canadian adults believed that graphic/text-based images depicting a diseased mouth and a lung tumor were most effective at discouraging smoking.³⁷ Another survey of Canadian adult smokers found that over 30% were able to recall warning label images of diseased lungs or rotted teeth while only 5% were able to recall an image of a dirty ashtray.³⁸ Research conducted for the government of New Zealand also found that the more "confrontational" styled messages that are considered shocking, unpleasant or unsettling have the greatest impact.³⁹ Graphically compelling images – such as those depicting diseased lungs, rotted teeth, and yellowed fingers – may be the most effective way of provoking an emotional response to the warnings. A Canadian study concluded that respondents who reported greater levels of "fear and disgust" after viewing warning labels were more likely to have quit, attempted to quit, or reduced smoking at follow-up questioning.⁴⁰ Brazil issued new warning labels in 2004 and researchers found that the more visually engaging labels enhanced intentions to stop smoking.⁴¹

However, not all graphic images need to induce intense reaction.⁴² Warnings that feature real people and testimonials can have great impact, as do emotionally poignant warnings that show how children and family members are harmed by a loved one's smoking.⁴³ Chile's graphic health warnings depict Chilean Don Miguel, a victim of larynx cancer with a tracheotomy.⁴⁴

Conclusion

ACP strongly supports the use of graphic health warnings on cigarette packaging and advertisements. The College believes that the proposed warnings will likely have the intended effect of deterring potential smokers from smoking and influencing current smokers to consider

quitting. ACP agrees with the FDA that the new graphic health warnings should be rotated and continuously updated to strengthen their effectiveness and make them more noticeable. The College also supports textual warnings that state the connection between smoking and specific diseases such as lung cancer and stroke.

The College respectfully recommends that the FDA require:

- All graphic warning labels to include smoking cessation information and language supporting smokers in their efforts to quit,
- Larger graphic warning labels,
- More straightforward and unequivocal textual warnings and explanatory information, and
- Graphic images that are emotionally provocative and feature testimonies from actual smokers and their loved ones.

Such improvements will strengthen the new graphic health warnings and ensure that they are an effective part of the nation's comprehensive tobacco control and prevention strategy. For more information contact Ryan Crowley, Health Policy Senior Analyst, at rcrowley@acponline.org.

Sincerely,



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