



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

December 22, 2010

Dr. Margaret A. Hamburg
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket No. FDA-2010-N-0568
RIN 0910-AG41

RE: *Required Warnings for Cigarette Packages and Advertisements*

Dear Commissioner Hamburg:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 94,700 family physicians and medical students nationwide, I am writing to offer our comments on the *Required Warnings for Cigarette Packages and Advertisements* proposed rule as published in the November 12, 2010 Federal Register. This regulation implements Section 201(b) from the Family Smoking Prevention and Tobacco Control Act which calls for the Food and Drug Administration (FDA) to implement regulations requiring tobacco companies to include color graphics and nine new textual warning statements depicting the negative health consequences of smoking on cigarette packaging and advertisements.

It is longstanding AAFP policy to strongly oppose both the use of tobacco (cigarettes, cigars, snuff, chewing tobacco and other emerging tobacco products) and all forms of advertisement of tobacco products. Smoking is a known cause of cancer, heart disease, stroke and chronic obstructive pulmonary disease. It is well documented and unfortunate that cigarette smoking is the leading preventable cause of death and illness in the United States. According to the Centers for Disease Control and Prevention's data, tobacco use causes at least 443,000 premature deaths and approximately \$96 billion in direct health care expenditures each year. AAFP therefore adamantly supports the required use of color graphic warnings and new textual warning statements on cigarette packages and advertisements as an important, albeit overdue, step toward reducing the existing and future use of tobacco products.

Given that nicotine is an addictive drug, AAFP advocated for FDA's jurisdiction to be expanded so that the FDA may fully regulate the manufacture, sale, labeling, distribution and marketing of tobacco products and nicotine delivery devices. AAFP therefore lauded enactment of the *Family Smoking Prevention and Tobacco Control Act* in June 2009 and we now urge the FDA to promptly implement this important law.

As the proposed rule indicates, considerable evidence exists suggesting that the current textual warnings are given little attention by viewers, especially since Congress has not changed these warnings in over twenty-five years. While AAFP recognizes that the color graphics and revised textual warnings alone may

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have limited effectiveness in the prevention of tobacco use, we believe the proposed new graphics offer significant improvement in the effectiveness of tobacco warnings. The use of these graphics and revised statements will help minimize tobacco use through the warnings' increased ability to communicate the many health risks attributable to cigarette smoking.

Section 201(b) specifies that these requirements are effective fifteen months after publication of a related final rule. To that end, AAFP urges the FDA to publish the final rule as expeditiously as possible. Though AAFP recognizes that "fifteen months" is specified in the statutory language, we must also draw attention to the approximately \$12.5 billion spent in 2006 by tobacco companies on advertising and promotion. As the proposed rule states, tobacco companies frequently employ large marketing and advertising experts. The tobacco industry is accustomed to continuously updating cigarette packaging and advertisements. Considering that Congress enacted the *Family Smoking Prevention and Tobacco Control Act* seventeen months before publication of this proposed rule, the sizable budgets of tobacco companies, and their ample experience in incorporating current market trends into cigarette packaging and advertisements, AAFP feels an additional fifteen months after publication of a final rule is an excessive amount of time for the tobacco industry to comply with these new requirements.

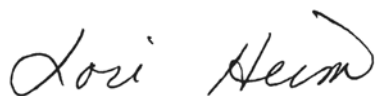
To further accentuate the magnitude of a fifteen month compliance period, we cite data from the Substance Abuse and Mental Health Services Administration suggesting that each day, an estimated 6,600 Americans (nearly 4,000 of them under the age of 18) become new smokers. Therefore approximately 3 million smokers (1.8 million under the age of 18) could become new smokers during the fifteen month compliance timeframe.

AAFP also supports the proposals to include specific information about appropriate tobacco cessation resources on the required new warnings, such as the quitline number 1-800-QUIT-NOW. AAFP also recommends that the warning messages continue to be tested and refreshed with stronger graphic images. Another comment from family physicians is that they do not like the cartoons because it makes the subject look cute and reduces the message and impact. AAFP prefers the pictures over the cartoons, as pictures are more powerful.

The Academy has developed tobacco prevention and cessation programs and resources, such as our Tar Wars (www.tarwars.org) and "Ask and Act" (www.askandact.org) programs. Tar Wars is the AAFP's tobacco-prevention program to help stop kids from starting. Ask and Act is the AAFP's tobacco-cessation program that encourages family physicians and their practice teams to ASK all patients about tobacco use and then ACT to help them quit.

AAFP shares the FDA's interest in reducing the number of Americans who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use. Thank you for this opportunity to comment on this matter. If we may be of further assistance on this, please contact Pamela Rodriguez the AAFP Tobacco Programs Manager (Tar Wars/Ask and Act/Office Champions) at prodriguez@aafp.org.

Sincerely,



Lori J. Heim, MD, FAAFP
Board Chair