

FDA sued over delay on graphic cigarette warning labels

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(HealthDay)—The U.S. Food and Drug Administration is being sued



over its delay in issuing a final rule about graphic health warnings on cigarette packs and ads.

The legal action was launched by eight public health and medical groups—including the American Cancer Society—and several individual pediatricians. They filed suit Oct. 4 in federal court in Boston.

Besides the cancer society, the organizations involved in the lawsuit are: the American Academy of Pediatrics, the Massachusetts Chapter of the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, and Truth Initiative.

Under a 2009 federal law, the FDA was given until June 22, 2011 to issue a final rule on graphic cigarette warnings covering the top half of the front and back of cigarette packs, and 20 percent of cigarette advertising.

The FDA met the deadline but the specific warnings required by the agency were struck down in August 2012 by an <u>appeals court</u>. However, the ruling applied only to certain images proposed by the FDA and did not affect the underlying requirement of the 2009 law.

In March 2012, another appeals court upheld the law's requirement for graphic warnings and the U.S. Supreme Court turned down a tobacco industry appeal of that ruling.

The court decisions mean the FDA is still legally obligated to require graphic health warnings on <u>cigarette packs</u> and ads, according to the lawsuit plaintiffs.

The FDA said in March 2013 that it planned to issue a new rule on those warnings but has yet to do so, even though several of the groups involved



in the lawsuit have repeatedly urged the FDA to take action, according to a news release from the Campaign for Tobacco-Free Kids.

The lawsuit alleges that the FDA's failure to issue a new rule is "agency action unlawfully withheld" and seeks a court order requiring the FDA to issue a new rule.

"The FDA has been in violation [of the 2009 law] for more than four years. During that time, over 3 million Americans, the vast majority of them minors, have begun to smoke on a regular basis. Half of them will die prematurely as a result of tobacco-related disease," according to the lawsuit.

A 2013 study of graphic cigarette warnings in Canada suggests that if the United States had implemented such warnings in 2012, as planned, the number of adult smokers in the United States would have fallen potentially by as much as 8.6 million in 2013.

Tobacco use is the leading preventable cause of death in the United States. Tobacco kills more than 480,000 Americans and costs about \$170 billion in health-care expenses each year, according to the U.S. Centers for Disease Control and Prevention.

More information: The American Cancer Society offers a guide to quitting smoking.

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