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Federal Court Orders FDA to Quickly Implement Graphic Cigarette Warnings as Mandated by Law

Statement of the American Academy of Pediatrics, Massachusetts Chapter of the American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative

WASHINGTON, D.C. – In a major victory for the nation’s health and the fight against tobacco, a federal court today ordered the U.S. Food and Drug Administration (FDA) to expeditiously issue a final rule requiring graphic health warnings on cigarette packs and advertising, as mandated by a 2009 federal law.

The [ruling](#) by U.S. District Judge Indira Talwani of the U.S. District Court for the District of Massachusetts was in response to a [lawsuit filed in October 2016](#) by eight public health and medical groups and several individual pediatricians. Judge Talwani agreed with the health groups that the FDA has both “unlawfully withheld” and “unreasonably delayed” agency action to require the graphic warnings.

Judge Talwani set a deadline of September 26, 2018, for the FDA to “provide to this court an expedited schedule for the completion of outstanding studies, the publication of the proposed graphic warnings rule for public comment, review of public comments, and issuance of final graphic warnings rule in accordance with the Tobacco Control Act.”

Today’s ruling is a major victory in the fight against tobacco use, the nation’s No. 1 cause of preventable death. In accordance with the court’s order, we urge the FDA to quickly issue, finalize and implement a rule requiring graphic cigarette warnings. The current U.S. cigarette warnings, which are printed on the side of cigarette packs and haven’t been updated since 1984, are stale, unnoticed and a major impediment to greater progress in reducing cigarette smoking. [Studies around the world](#) have shown that graphic warnings are most effective at informing consumers about the health risks of smoking, preventing children and other nonsmokers from starting to smoke, and motivating smokers to quit. Requiring graphic cigarette warnings in the U.S. will protect kids, save lives and reduce tobacco-related health care costs, which total \$170 billion a year.

The 2016 lawsuit was filed by the American Academy of Pediatrics, the Massachusetts Chapter of the American Academy of Pediatrics, the American Cancer Society, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for

Tobacco-Free Kids, Truth Initiative and several individual pediatricians. The plaintiffs have been represented by the legal staff of the Campaign for Tobacco-Free Kids and the Boston law firm of Anderson & Krieger LLP.

Background

The 2009 Family Smoking Prevention and Tobacco Control Act required graphic warnings covering the top half of the front and back of cigarette packs and 20 percent of cigarette advertising and gave the FDA until June 22, 2011, to issue a final rule requiring such warnings. While the FDA met that deadline, the specific graphic warnings required by the FDA were struck down in August 2012 by a three-judge panel of the U.S. Court of Appeals for the D.C. Circuit, which ruled 2-1 that the proposed warnings violated the First Amendment. That ruling only applied to the specific images proposed by the FDA and did not address the law's underlying requirement.

Ruling in a separate case in March 2012, the U.S. Court of Appeals for the Sixth Circuit upheld the law's requirement for graphic warnings, finding that this provision did not violate the First Amendment. That court found the graphic warnings "are reasonably related to the government's interest in preventing consumer deception and are therefore constitutional." The U.S. Supreme Court declined to hear a tobacco industry appeal of this ruling.

Taken together, these two federal court decisions mean the FDA is still legally obligated to require graphic health warnings, and the agency is free to use different images than those struck down by the D.C. Circuit in 2012. The FDA stated in March 2013 that it planned to issue a new rule requiring graphic warnings, but has yet to act.

The graphic warnings were mandated by a large, bipartisan majority of Congress, which relied on an extensive scientific record demonstrating the need for the warnings and their effectiveness. Because of this evidence, [at least 122 countries](#) now require large, graphic cigarette warnings.

The 2012 D.C. Circuit ruling striking down the FDA's proposed warnings was based, in part, on the court's judgment that the FDA had not provided sufficient evidence that graphic warnings would reduce the number of Americans who smoke. But the evidence of the public health benefits of graphic warnings has grown even stronger since that ruling. [A 2013 study](#) based on Canada's experience with graphic warnings found that if the U.S. had implemented such warnings in 2012 as planned, the number of adult smokers in the U.S. would have decreased by 5.3-8.6 million in 2013.

Tobacco use is the No. 1 preventable cause of death in the United States, killing more than 480,000 Americans and costing about \$170 billion in health care expenses each year.

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