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FDA's Graphic Cigarette Warnings Show and Tell the Deadly Truth About Smoking – They Must Be Fully Implemented and Vigorously Defended

Statement 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. – By issuing a [final rule](#) requiring large, graphic health warnings on cigarette packs and advertising, the U.S. Food and Drug Administration today has taken a critical and long-overdue step forward in the nation's battle against tobacco use – the number one cause of preventable death. The new warnings show and tell the truth about the deadly consequences of smoking and will promote greater public understanding of the many ways in which smoking harms the human body.

[View the final warnings.](#)

The graphic warnings are a dramatic improvement over the current text-only warnings, which have become stale and unnoticed since they were last updated in 1984. They are supported by [extensive scientific evidence](#) and will help the United States catch up to the [120-plus countries](#) that have adopted this best-practice strategy to reduce tobacco use and save lives.

By law, the new warnings are required to appear on cigarette packs and ads 15 months after a final rule is issued (June 18, 2021). The FDA must now ensure these warnings are fully implemented and vigorously defended against likely legal challenges by the tobacco industry. Congress first mandated graphic cigarette warnings more than 10 years ago and we cannot afford more delays – not when tobacco use still kills half a million Americans, sickens millions more and costs the nation \$170 billion in health care expenses each year. The FDA's rule makes a comprehensive and compelling case for the graphic warnings that shows they stand on firm scientific and legal ground. The rule is also entirely consistent with what Congress required in the 2009 Family Smoking Prevention and Tobacco Control Act.

The FDA faced a court-ordered deadline of March 15 to submit to the Federal Register a final rule requiring the graphic warnings as a result of a successful [lawsuit filed by our public health and medical organizations and several individual pediatricians](#) in October 2016 (the court's order required that the final rule be submitted to the Federal Register for publication by March 15). Our lawsuit sought to force the FDA to comply with provisions of the Tobacco Control Act, which required graphic warnings covering the top half of the front and back of cigarette packs and 20 percent of each cigarette ad.

In a [September 2018 ruling](#), Judge Indira Talwani of the U.S. District Court for the District of Massachusetts found the FDA “unlawfully withheld” and “unreasonably delayed” agency action to require the graphic warnings. Judge Talwani subsequently ordered the FDA to issue a proposed rule by August 15, 2019, and a final rule by March 15, 2020.

The 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 & Kreiger LLP.

Background on Graphic Warnings

The graphic warnings are a dramatic improvement over the current text-only warnings, which haven’t been updated since 1984 and are now barely noticed by smokers or kids thinking about smoking. They are supported by [extensive scientific evidence](#) showing that graphic warnings are far more effective at communicating the health risks of smoking than text-only warnings. And they will help the United States catch up to the [120+ countries](#) that have adopted graphic cigarette warnings. Prior to 2009, when Congress passed the Tobacco Control Act, only 18 countries required graphic warnings, showing how far behind the rest of the world the U.S. has fallen over the past 10 years.

The 2009 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 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.

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