

Delayed Implementation of Graphic Warning Labels on Cigarettes Harms Public Health

The Family Smoking Prevention and Tobacco Control Act (TCA) of 2009 required graphic warnings cover the top half of the front and back of cigarette packs and 20 percent of cigarette advertising. Studies have found the current text-only warnings on cigarettes do not attract attention and do not provide sufficient information about the harmful health effects of smoking. Despite the significant research findings showing how smoking increases the risk for many cancers,ⁱ many individuals who smoke are not aware of the full health harms smoking causes. This is not surprising given the tobacco industry has spent decades lying to the public, saying their products are not addictive, harmful or deadly. Studies around the world have shown that graphic warnings are effective at informing consumers about the health risks of smoking, preventing children and others from starting to smoke, and motivating people who smoke to quit.^{ii,iii,iv}

Prior to passage of the TCA in 2009, only 18 countries required graphic warnings. Now, more than 120+ countries require large, graphic cigarette warnings. In 2021, the World Health Organization (WHO) estimated that 4.7 billion people (60% of the world's population) benefit from large graphic warnings on cigarette pack labels featuring all WHO-recommended characteristics.^v The U.S. is far behind the rest of the world on implementing graphic warnings.

Implementation of graphic warnings in the U.S. has been thwarted by tobacco industry legal challenges. The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN), along with our partners, have fought back in the judicial system, using litigation to both compel the U.S. Food and Drug Administration (FDA) to issue graphic warning regulations and help the U.S. Department of Justice (DOJ) defend the regulations finalized by FDA.

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 successfully sued the FDA for its delay in issuing a rule requiring graphic warnings. The agency issued a final rule in March of 2020 that has been tied up in courts ever since.

The FDA's Responsibility to Create Graphic Warning Labels to be Displayed on Cigarette Packages

While tobacco products display text warnings, the language for these warnings goes unnoticed and has become stale, as they have not been updated since 1984.^{vi} Alternatively, graphic warnings that use a combination of both pictures and text are an effective and well-known fact-based strategy to quickly highlight the various health harms of smoking directly on the cigarette package.^{i,ii,iii}

The TCA gave the FDA until June 22, 2011, to issue a final rule requiring the graphic warning labels on cigarettes. In the meantime, a lawsuit was filed to invalid a number of statutory provisions of the TCA such

as its prohibition of free samples of products and the one requiring graphic warnings. That case was *District Tobacco City & Lottery v U.S.* After FDA met the deadline for issuing a final rule on graphic warnings, a different lawsuit was filed to invalid that rule, *RJ Reynolds et al v. FDA*. In March 2012, the U.S. Court of Appeals for the Sixth Circuit upheld most of the law’s requirements in the *District Tobacco* lawsuit, including the statute’s requirement for graphic warnings, finding that the TCA’s provision did not violate the First Amendment. That court found the graphic warnings generally “are reasonably related to the government’s interest in preventing consumer deception and are therefore constitutional.” However, the actual graphics warnings rule that had been finalized by FDA was not at issue in that case. In August 2012, the final graphic warnings rule issued by FDA was struck down in the U.S. Court of Appeals for the D.C. Circuit for violating the First Amendment. Under First Amendment doctrine, public health warnings are considered “compelled speech” and must be “purely factual and noncontroversial” to withstand constitutional challenge. The D.C. Circuit panel split 2-1 with the majority finding the warnings were not purely factual, but rather inflammatory and intended to elicit an emotional response. The tobacco industry appealed the original case in the Sixth Circuit to the U.S. Supreme Court, which declined to hear it. The government did not appeal the graphic warnings rule case in the D.C. Circuit to the U.S. Supreme Court.

Taken together, these two conflicting federal court decisions meant the FDA was still legally obligated to require graphic health warnings, and the agency was free to use different images than the ones struck down by the D.C. Circuit in 2012. The FDA stated in March 2013 that it planned to develop new, improved graphic warnings by issuing a new rule requiring graphic warnings. After excessive delay by the FDA, Americans were still waiting. In October 2016, ACS CAN, along with seven other public health and medical groups and individual pediatricians, filed a lawsuit to force the FDA to comply with the graphic warning provisions of the TCA. In a 2018 ruling, Judge Indira Talwani of the U.S. District Court for the District of Massachusetts ruled in favor of the public health groups, finding that the FDA “unlawfully withheld” and “unreasonably delayed” agency action to require the graphic warnings. In a final order issued in March of 2019, Judge Talwani ordered the FDA to issue a final rule by March 15, 2020.



The FDA Mandated New Graphic Warnings with its Final Rule

The FDA met its court-mandated deadline and finalized the rule on March 17, 2020. In the final rule, the FDA included extensive scientific information about why graphic images communicate more effectively than text-only, as well as the disparate burden of smoking on people with lower income and education levels.

In the final rule, FDA provided extensive legal justifications for the images and text. It also provided that any warnings that are found unconstitutional should be severed from the rest of the rule, meaning if some are struck down, the remaining warnings could stand. The graphic warnings the FDA developed are a dramatic improvement over the current text-only warnings which are largely ignored as they do not adequately attract attention or address the health effects of smoking.

The FDA’s final rule requires 11 graphic warning labels be displayed using specific texts and images that focus on “lesser known” health risks of smoking. Including this “new” information on cigarette packages is intended to promote greater public understanding of a variety of risks associated with cigarette smoking. In

other words, there are fewer warnings geared towards health risks the public is already aware of. In addition, the cigarette manufacturers are required to establish marketing plans to meet the requirements for random display and distribution of the required warnings for both packages and advertisements. FDA must approve those plans. The complete compilation of images of the FDA’s graphic warning labels from the final rule can be [found here](#) and examples of the current text warning statements and the FDA’s proposed Graphic Warning images released in 2021 are in the text box below.

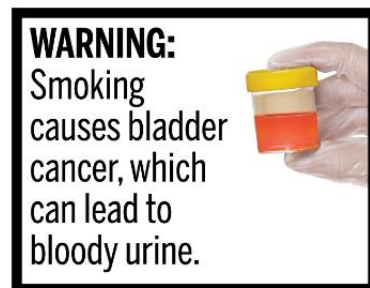
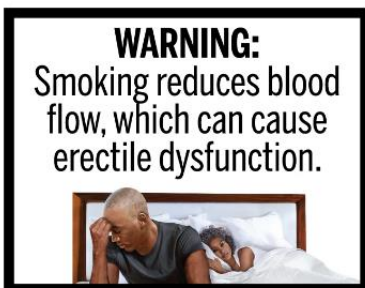
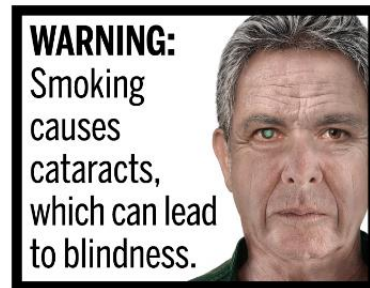
Current Cigarette Text Warning Statements

Tobacco Products	Warning Statements
Cigarettes ⁶	<ul style="list-style-type: none"> • SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy. • SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health. • SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight. • SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Source: [FDA Website: Retailers: Chart of Required Warning Statements on Tobacco Product Packaging and Advertising, updated 2018.](#)

Latest FDA Proposed Cigarette Graphic Warnings

Required Warnings for Cigarette Packages and Advertisements



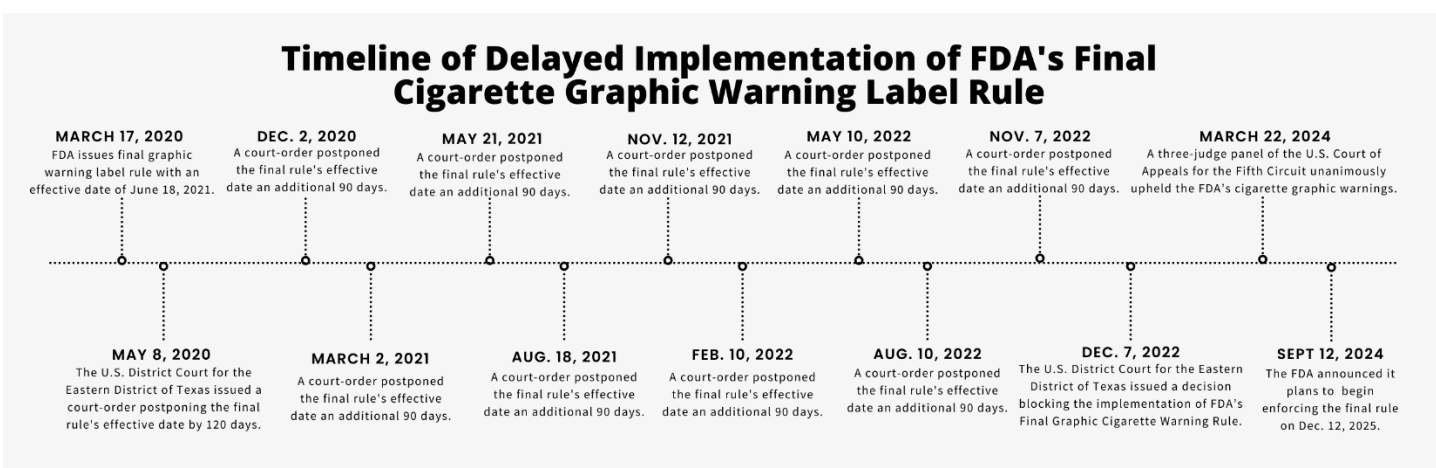
Source: [FDA Website: Cigarette Labeling and Health Warning Requirements, updated 2021.](#)

The Status of Graphic Warning Labels & ACS CAN's Position

The original effective date of the final rule was June 18, 2021, and would have required the new graphic warnings for packages and advertising to be used 15 months after the date the final rule was published, which would have been consistent with the TCA requirement. The TCA provides a 30-day “grace period” from the effective date in which products that were already in inventory that do not bear the new warnings can stay on the market, but a manufacturer may not introduce any new cigarette product without the required warnings.

Less than a month after the FDA’s final rule was released, on April 3, 2020, R.J. Reynolds, Liggett, ITG Brands, Santa Fe Tobacco and several convenience stores in Texas sued the FDA in federal court in the Eastern District of Texas.^{vii} The case seeks to invalidate not only the new rule, but the TCA’s statutory mandate to the FDA on graphic warnings altogether. Plaintiffs claim the statute and the rule violate the First Amendment and the Administrative Procedure Act. Among other arguments, plaintiffs claim the government interest in the warnings is not substantial because the vast majority of the public already knows that smoking is dangerous, and the government can and does run its own anti-smoking campaigns without having to compel the industry to do so with images on its own products.

ACS CAN has filed *amicus curiae*, or “friend of the court,” briefs in both lawsuits to help defend the rule. The links to the ACS CAN briefs are here: [amicus curiae filed in the US District Court in DC](#) and [the amicus curiae filed in Texas](#). In 2020, a court order issued by U.S. District Court for the Eastern District of Texas postponed the effective date of the final rule by 120 days. The tobacco industry continued to seek, and the court continued to grant 90-day postponements to the implementation of the FDA’s final graphic warning rule. Between April 2020 to November 2022 the court issued a total of 10 postponements to delay the implementation of the final rule.^{viii,ix,x,xi,xii,xiii,xiv,xv,xvi,xvii,xviii} The graphic below provides a timeline of the delayed implementation of FDA's final cigarette graphic warning label rule.



In December of 2022, U.S. District Judge J. Campbell Barker in Texas finally issued a decision on the merits of the case blocking the implementation of the rule.^{xix} His ruling struck down the graphic warnings for violating the tobacco industry's First Amendment rights. Judge Barker reasoned the graphic warning labels required by the FDA’s final rule were not “purely factual and non-controversial,” and therefore do not meet

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the constitutional test for compelled speech. In his opinion, he indicated the warnings were subject to varying interpretations, and are “provocative.” Judge Baker did not go so far as to strike down the TCA statutory provision and hold that all graphic warnings are unconstitutional, but rather made a point that a rule requiring different graphic warnings could be valid and emphasized that the government can fund its own anti-smoking public information campaigns. Lastly, Judge Barker conducted an analysis on severability, analyzing whether the graphics could be struck down with the larger text staying in place and found they could not be severed.

ACS CAN and our partners believe Judge Barker’s decision to block implementation of graphic warnings on cigarette packages and ads was wrong on the law and harmed public health. After the court issued its decision, ACS CAN and our partners urged the DOJ to appeal. In early February 2023, the DOJ appealed Judge Barker’s ruling to the U.S. Court of Appeals for the Fifth Circuit. ACS CAN, along with our partners, filed an amicus brief supporting FDA.

In March 2024, ACS CAN and other tobacco control partners celebrated a huge victory for public health when a three-judge panel of the U.S. Court of Appeals for the Fifth Circuit unanimously upheld graphic warnings on cigarette packs and advertising required under the 2020 FDA rule. The decision reversed U.S. District Judge Barker’s decision in December 2022 that blocked the warnings. Rejecting tobacco industry arguments, the appellate court found that the FDA’s warnings are “factual and uncontroversial” and do not violate the First Amendment. The appellate court decision affirmed that the FDA’s graphic cigarette warnings are both scientifically and legally sound. This decision is an important step toward finally implementing graphic cigarette warnings in the United States, which were first mandated by Congress in 2009. In another victory for public health, the full Fifth Circuit “en banc” refused to hear the industry’s appeal of the panel decision. As expected, the industry has petitioned the U.S. Supreme Court to hear the case.

On September 12, 2024, the FDA released a new tobacco industry guidance on how the agency plans to begin enforcing the final rule on December 12, 2025. The “[Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements](#)” states that the FDA will exercise enforcement discretion and not enforce the rule requirements for 15 months after the publication of the guidance, which is December 12, 2025.

ACS CAN and our partners will continue to support the FDA and monitor the industry’s pending petition before the U.S. Supreme Court.

ⁱ American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2021-2022*. Atlanta: American Cancer Society; 2021.

ⁱⁱ Hammond, D., G.T. Fong, R. Borland, et al. “Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study.” *American Journal of Preventive Medicine*, 32(3):202–209, 2007. Available at <https://doi.org/10.1016/j.amepre.2006.11.011>.

ⁱⁱⁱ WHO Report on the Global Tobacco Epidemic, Geneva: World Health Organization; 2019.

^{iv} Fathelrahman, A.I., L. Li, R. Borland, et al. “Stronger Pack Warnings Predict Quitting More than Weaker Ones: Finding from the ITC Malaysia and Thailand Surveys.” *Tobacco Induced Diseases*, 11(1):20, 2013. Available at <https://doi.org/10.1186/1617-9625-11-20>.

^v WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization, 2021. Retrieved from <https://www.who.int/publications/i/item/9789240032095>.

^{vi} Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15638 (March 18, 2020). Accessed March 10, 2023, retrieved from <https://www.federalregister.gov/documents/2020/03/18/2020-05223/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements>.

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- ^{vii} R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al., No. 6:20-cv-00176 (E.D. Tex. filed April 3, 2020).
- ^{viii} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.
- ^{ix} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.
- ^x R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 89.
- ^{xi} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 91.
- ^{xii} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. August 18, 2021) (order postponing effective date), Doc. No. 92.
- ^{xiii} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. November 12, 2021) (order postponing effective date), Doc. No. 93.
- ^{xiv} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. February 10, 2022) (order postponing effective date), Doc. No. 94.
- ^{xv} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. May 10, 2022) (order postponing effective date), Doc. No. 96.
- ^{xvi} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. August 10, 2022) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 100.
- ^{xvii} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. November 7, 2022) (order postponing effective date), Doc. No. 104.
- ^{xviii} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. December 7, 2022) (opinion and order granting in part plaintiffs' motion for summary judgment), Doc. No. 10431.
- ^{xix} R.J. Reynolds Tobacco Co., No. 6:20-cv-00176 (E.D. Tex. December 7, 2022) (opinion and order granting in part plaintiffs' motion for summary judgment), Doc. No. 10431.