TOBACCO HEALTH WARNINGS: EVIDENCE OF EFFECTIVENESS

In March 2020, the U.S. Food and Drug Administration (FDA) finalized a rule requiring 11 new cigarette health warnings. The rule required that these warnings, which include new text and color graphics, cover 50 percent of the front and rear panels of cigarette packs and at least 20 percent of the area at the top of cigarette advertisements in the U.S. The rule would have required these warnings to be implemented by June 18, 2021, but it was subsequently vacated by a federal judge.

Despite the numerous public reports on the risks of smoking, studies show that a large number of smokers have inadequate knowledge of the health effects of smoking.[1] While some smokers generally know that tobacco use is harmful, they underestimate the severity and magnitude of the health risks and tend to perceive other smokers to be at greater risk for disease than themselves.[2] Knowledge of the health risks of smoking is even lower among people with lower income and fewer years of education because of limited access to information about the hazards of smoking.[3]

According to the U.S. Surgeon General, "The evidence is sufficient to infer that large, pictorial health warnings increase smokers' knowledge about the health harms of smoking, interest in quitting, and quit attempts and decrease smoking prevalence."[4] Warnings on tobacco products are an ideal way of communicating with smokers because they pair the warning directly with smoking behavior. According to the U.S. Surgeon General, "health warnings on cigarette packages are a direct, cost-effective means of communicating information on health risks of smoking to consumers."[5] Given the reach and frequency of exposure, warnings have the potential to have a significant impact on smoking behavior. For example, a pack-a-day smoker could be exposed to the warnings more than 7,000 times per year.[6] Consequently, warnings on cigarette packages are one of the most important sources of health information.[7]

According to the Institute of Medicine, "restrictions on package labeling are critical to reducing tobacco use and ensuring that smokers are adequately informed about the risks of smoking. Indeed, prominent health warnings on packages are among the most cost-effective forms of public health education available."[8]

Status of Tobacco Health Warnings in the United States

Health warnings were first required on cigarette packs by the Federal Cigarette Labeling and Advertising Act of 1965. The current health warnings consist of four text-only messages that have not changed since they were required as part of the Comprehensive Smoking Education Act of 1984. In the 35 years since the implementation of these warnings, their effect on smokers has drastically weakened, and the current warnings are now virtually ineffective. These warnings are small and easily overwhelmed by the designs on cigarette packages. Moreover, smokers have become habitualized to the style of labels, to the point that the labels go unnoticed altogether. According to the Institute of Medicine,

> "In the committee's view, the current warnings are inadequate even when measured against an informed choice standard, but they are woefully deficient when evaluated in terms of proper public health criteria."[9]

The 2009 Family Smoking Prevention and Tobacco Control Act requires graphic (pictorial) health warnings to cover the top 50 percent of the front and rear panels of the cigarette package. The same warnings are required in advertising and must comprise at least 20 percent of the advertisement's area. The new law's requirements are based on the best available science and real world experience regarding graphic warnings, including best practices from other countries and the recommendations of the World Health Organization (WHO), Institute of Medicine of the National Academy of Sciences, the U.S. Surgeon General and other leading health experts.

In June 2011, the FDA issued a comprehensive set of graphic warnings. Following the issuance of these warnings, tobacco companies filed two lawsuits challenging them, leading to two federal appellate court rulings. The U.S. Court of Appeals for the D.C. Circuit struck down the specific warnings proposed by the FDA. However, the U.S. Court of Appeals for the Sixth Circuit upheld the law's underlying requirement for graphic warnings, finding that the 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 the Sixth Circuit ruling, preserving the FDA's authority to develop new graphic warnings.

After years of delays in pursuing new graphic warnings, public health and medical organizations and several individual pediatricians filed a lawsuit in October 2016 to force the FDA to comply with provisions of the Tobacco Control Act. In a September 2018 ruling, 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. In accordance with a court-ordered deadline of March 15, 2020, FDA issued a final rule with new graphic warnings. The rule would have required these warnings to be implemented by June 18, 2021, but it was subsequently vacated by a federal judge.

Researchers have estimated that based on Canada's experience, if the US had implemented graphic warnings in 2012 as required by law, there would have been a reduction in the number of adult smokers of between 5.3 to 8.6 million in 2013.[10] Based on evidence of the impact of graphic warnings in other countries, another study estimated that graphic warnings would reduce smoking prevalence by 5% within just a few years and that over a 50-year period would avert 652,800 deaths, 46,600 low-birth-weight cases, 73,600 preterm births and 1,000 cases of sudden infant death syndrome.[11]

The FDA Act's Graphic Warning Requirements are Based on Sound Science and Experience

A comprehensive review of the evidence on the impact of health warnings found that warnings with the following characteristics are noticed more, are an important source of health information, increase knowledge about tobacco use harms and perceptions of risk and promote smoking cessation. In addition, comprehensive health warnings are effective among youth and there is evidence that they prevent smoking initiation.[12]

- Large warnings are the most effective. Warnings must be large enough to be easily noticed and read, and should be as large as possible.[13] While the majority of countries with graphic warnings require the messages to comprise 50 percent of the overall package, evidence from countries such as Uruguay, that have increased the size of their warnings even further, has shown even greater effectiveness on all measures of effectiveness including thinking about the risks of smoking, thinking about quitting and foregoing having a cigarette "many times".[14]

- Warnings with pictures are more effective than text-only warnings. Pictures also increase the message's accessibility by people with low levels of literacy. Color pictures are more effective than black and white pictures.[15]

- Smokers report greater recall for warnings that appear on the front, compared to the side, of packages.[16]

- Warnings that contain a clear, direct and accurate message about the dangers of tobacco use, including messages about specific health effects, are the most effective. Messages that are worded simply and speak directly to the reader have the greatest impact.[17]

- Warnings need to be rotated regularly with new text and images to avoid overexposure.[18]

- Warnings include information for smokers who want to quit about where to find help have been shown to increase the number of smokers who try to quit.[19]

Tobacco Graphic Warnings Encourage Smokers to Quit and Discourage Nonsmokers from Starting to Smoke

A systematic review of studies in 20 countries found that strengthening pack warnings is associated with increased knowledge about the risks of smoking, increased quitline calls, reduced smoking consumption, increased quit attempts, increased short-term smoking cessation, and reduced smoking prevalence.[20]

Graphic Warnings Encourage Smoking Cessation

The evidence that graphic warnings can and do work is solid and extensive. The International Tobacco Control Policy Evaluation Project ("ITC"), an international cohort study that surveys adult smokers in nineteen countries, provides much of the evidence base for health warnings. According to ITC research, adult and youth smokers report that large, comprehensive warnings reduce smoking consumption, increase motivation to quit and increase the likelihood that they will remain abstinent following a quit attempt.[21] ITC research shows graphic warnings are more effective than text-only warnings in leading people to think about quitting and deterring them from having a cigarette.[22] Evidence from countries that have implemented graphic warnings demonstrates their impact on smoking cessation. For example:

- ITC studies of smokers in Australia, Canada, the United Kingdom and the US revealed that graphic warnings are more effective than text-only warnings at making smokers think about quitting and deterring them from having a cigarette and that larger, pictorial warnings are associated with increased quit attempts.[23]

- Evidence from Canada, the first country to implement graphic warnings, shows that after controlling for price, graphic warnings significantly decreased the odds of being a smoker and significantly increased the odds of making a quit attempt.[24] Another study found that graphic warning labels reduced smoking rates by between 2.87 to 4.58 percentages points in Canada.[25]

- After Singapore introduced their graphic warnings in 2004, 28 percent of the smokers surveyed reported smoking fewer cigarettes because of the warnings; 14 percent of the smokers surveyed said that they made it a point to avoid smoking in front of children; 12 percent said that they avoided smoking in front of pregnant women; and 8 percent said that they smoked less at home.[26]

- Since Thailand introduced their second set of pictorial labels in 2006, 44 percent of smokers said the warnings made them "a lot" more likely to quit over the next month.[27]

- In Brazil, after the introduction of new graphic warnings in 2002, 67 percent of smokers said the new warnings made them want to quit. The impact was particularly strong among less educated, lower income people.[28]

Experimental studies testing the impact of graphic warnings have also confirmed the impact of graphic warnings on precursors to cessation behavior. A recently published clinical trial following over 2000 smokers over a 4-week period found that, compared to smokers with text-only warnings on their cigarette packs, smokers exposed to graphic warnings on their cigarette packs were 50% more likely to have quit smoking for at least a week by the end of the trial and also had increased quit attempts, intentions to quit, and foregoing of cigarettes.[29] A meta-analysis of the experimental literature found that graphic warnings are more effective than text-only warnings at increasing intentions to not start smoking and intentions to quit smoking.[30]

Graphic Warnings Increase Awareness of Smoking Harms

Research conducted to inform FDA's March 2020 rule shows that both smokers and nonsmokers perceive the new required graphic warnings as more informative, understandable, and attention-drawing compared with the existing text-only Surgeon General's warnings.[31]

According to ITC research, "Large, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers [and] health warnings may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information." [32] This is important because smokers who perceive greater health risk from smoking are more likely to intend to quit and quit smoking successfully. [33] Evidence from countries that have implemented graphic warnings shows greater awareness and attention to the warnings and a subsequent increase in knowledge of smoking harms. For example:

- ITC research shows that text-only warnings (as seen in the U.S.) were associated with lower levels of awareness about the health risks of smoking than prominent, graphic warnings (as seen in Canada and Australia). [34]

- Smokers in countries where a warning depicts a particular health hazard of smoking were much more likely to know about that hazard and smokers who reported noticing warnings were 1.5 to 3.0 times more likely to believe in each health hazard. [35]

- After new, large pictorial warnings were introduced in 2000, 91 percent of Canadian smokers surveyed reported having read the warning labels and demonstrated a thorough knowledge of their content. Further, smokers who read, thought about, and discussed the warning labels in greater depth at baseline were significantly more likely to either quit, attempt to quit, or reduce their smoking at follow-up. [36] Additionally, 84 percent of Canadian smokers report health warnings as a source of health information, compared to only 47 percent of smokers in the US. [37]

- A study of smokers in Australia, Canada and Mexico found that smokers from countries where graphic warnings contained information about specific tobacco-related diseases had higher knowledge of those diseases than smokers in countries that did not have information about those diseases in their graphic warnings. [38]

- Since Thailand introduced their second set of pictorial labels in 2006, 53 percent said the pictorial warning labels made them think "a lot" about the health risks. [39]

- After Brazil introduced new graphic warnings in 2002, 54 percent of smokers said they had changed their opinion about the health consequences of smoking. [40]

- Data from the Global Adult Tobacco Survey (GATS) found that adults in Brazil, Egypt, India, Malaysia, Panama, Qatar, Romania, Thailand and Uruguay who noticed graphic warnings demonstrated significantly greater knowledge of tobacco harms compared to those adults who did not notice them. [41]

- An investigation of the impact of the text-only Chinese labels compared to other text and pictorial labels from around the world found that larger pictorial labels were perceived to be more effective at informing about the dangers of smoking, convincing youth not to start and motivating smokers to quit. [42]

Graphic Warnings are Also Effective among Youth

Research also shows that graphic warnings demonstrate similar effects among youth:

- More than 90 percent of Canadian youth agree that graphic warnings on Canadian cigarette packages have provided them with information about the health effects of smoking and make smoking seem less attractive. [43]

- Following the introduction of Australia's graphic warnings, adolescent experimental and established smokers were more likely to think about quitting, and intentions to smoke were lower among those students who discussed the new warning labels. [44]

- A Greek study of adolescents indicates that proposed European Union pictorial warning labels were more effective at informing about the health effects of smoking and preventing initiation than the previous text-only labels. Approximately 84 percent of non-smoking adolescents reported that the proposed EU graphic warnings were more effective than the old EU text warnings in preventing smoking initiation.[45]

At least 125 countries and jurisdictions have implemented or finalized requirements for graphic warnings on cigarette packs.[46] A 2008 European Union directive requires its 28 member countries to add pictures to warnings as a way to educate smokers about the risks of continuing to smoke (each country must pass its own law to comply with this directive). These actions reflect the consensus that warning labels are effective at communicating health messages and discouraging tobacco use.

More information on graphic warnings around the world is available at
http://global.tobaccofreekids.org/en/solutions/international_issues/warning_labels/.

The Campaign for Tobacco-Free Kids, December 8, 2022 / Laura Bach

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