

# ***F.D.A. Issues New Images to Add to Warnings on Cigarette Packages***

**By Sheila Kaplan**

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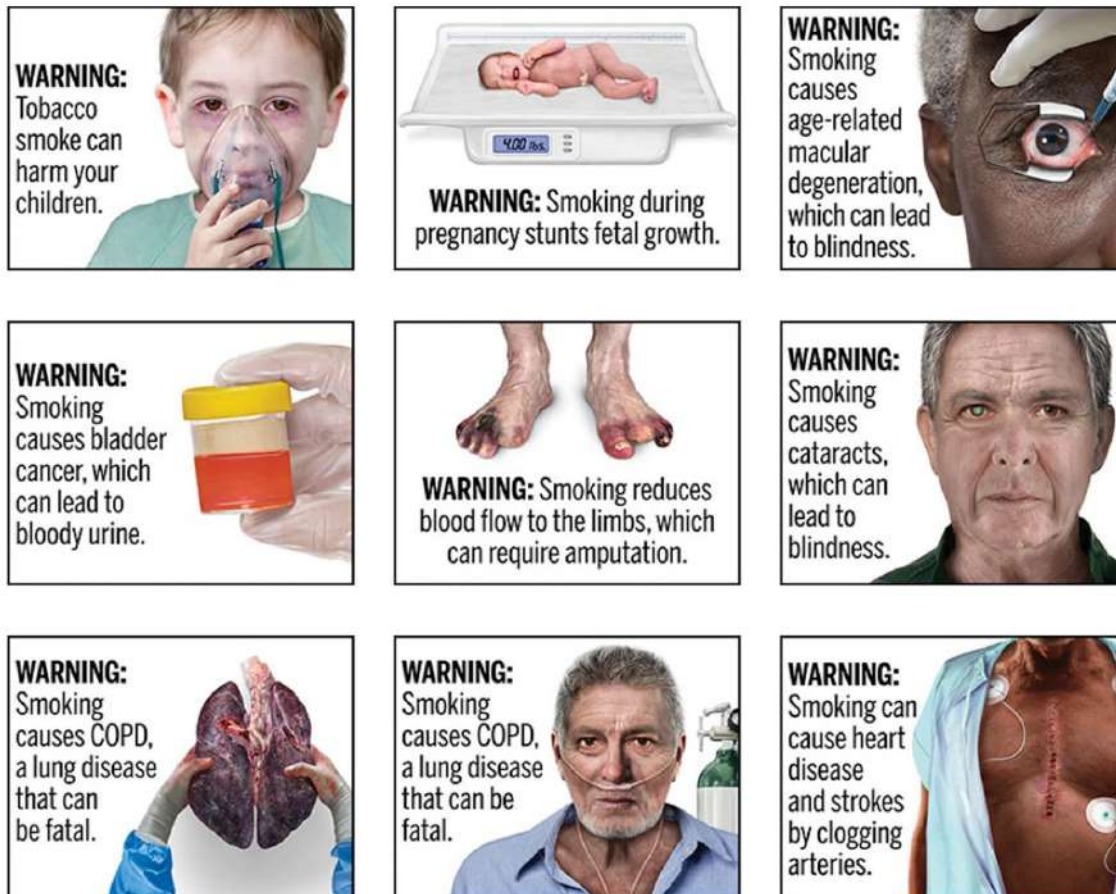
WASHINGTON — The corpse is gone.

So are the grief-stricken woman and the man struggling to smoke despite a hole in his windpipe.

Nine years after the Food and Drug Administration first proposed graphic images as new warnings on cigarette packs but was thwarted by major tobacco companies in a successful court battle, the agency announced on Thursday that it is finally issuing a new set of images.

“The 13 proposed warnings, which feature text statements accompanied by photo-realistic color images depicting some of the lesser-known health risks of cigarette smoking, stand to represent the most significant change to cigarette labels in 35 years,” the F.D.A. said in a release.

The new images include depictions of chest incision scars from surgery, blackened lungs, a bulging tumor on a woman’s neck and an underweight infant.



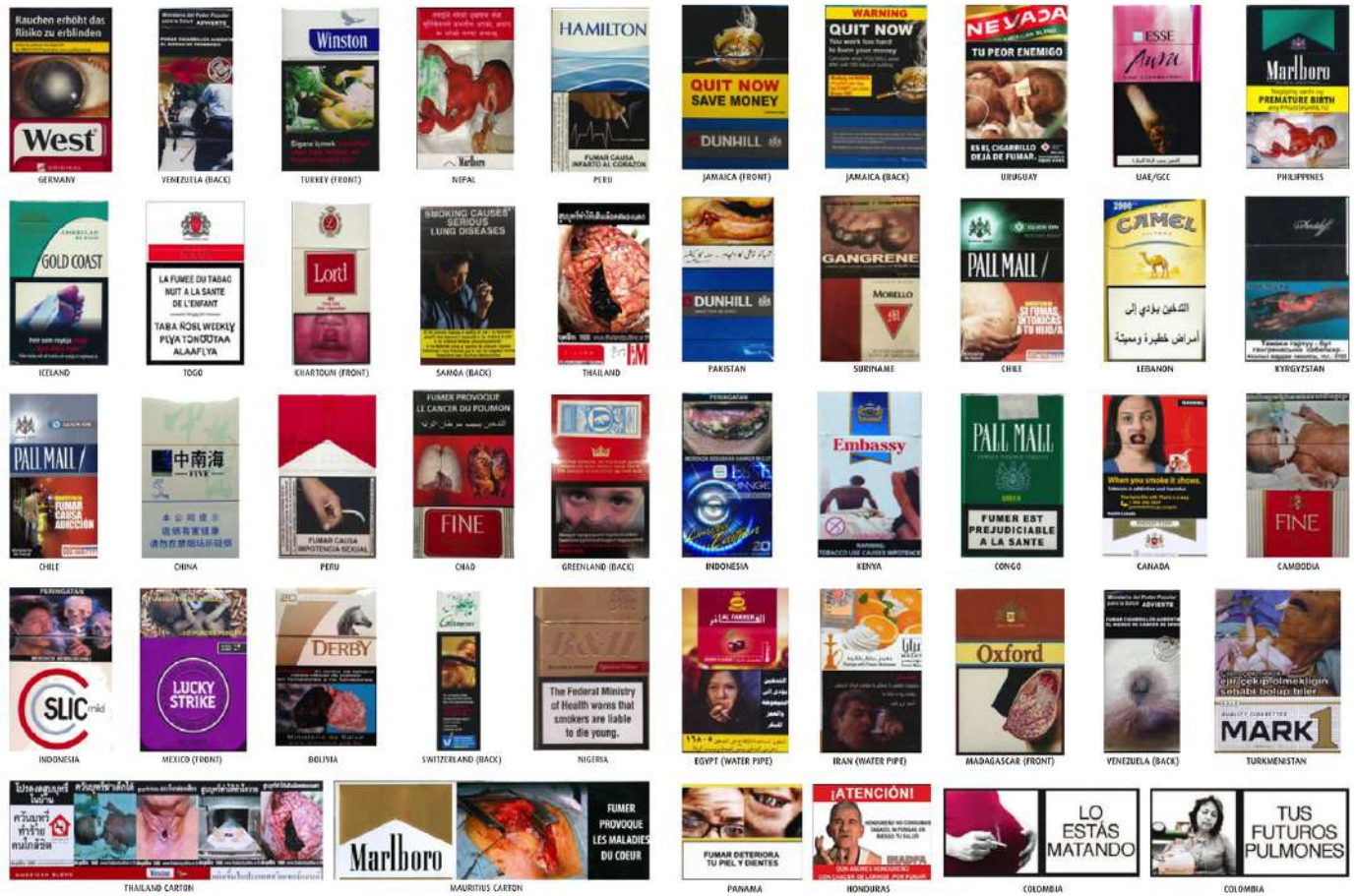
There would be a total of 13 proposed warnings on the packages.  
U.S. Food and Drug Administration

The Tobacco Control Act, which Congress passed in 2009, required the F.D.A. to impose graphic warning labels on cigarettes.

The agency unveiled its first choices in 2010, featuring colorful — and gruesome — pictures to wrap around the top half of cigarette packages and also on 20 percent of the surface area of advertisements.

A year later, the F.D.A. whittled its final selection to nine images. Public health advocates loved them, but tobacco companies fiercely objected. Led by R.J. Reynolds Tobacco, a group of businesses sued the F.D.A., and in 2012 convinced an appeals court that these specific graphic images violated its First Amendment rights of free speech. Altria, the nation's largest tobacco company, was not part of the lawsuit.

The court mandated that the warnings be purely informational, not aimed at scaring smokers, nudging them to quit or imposing an ideology.



Various cigarette packages with graphic warning labels from around the world.  
Canadian Cancer Society

The ruling was a huge setback for the F.D.A., which has spent the ensuing years trying to devise a set of warning labels that would be a strong deterrent. As the agency delayed doing anything, many other nations have imposed graphic images of smoking-related damage.

Eric Lindblom, a former F.D.A. tobacco lawyer, said the agency hadn't tried very hard.

“Once that ruling came through, the reason the F.D.A. didn’t do another one is that the lawyers were scared to death,” said Mr. Lindblom, who is now director for tobacco control and food and drug law at the O’Neill Institute for National and Global Health Law at Georgetown University. “The F.D.A. lawyers, the health and human services lawyers, the Department of Justice lawyers, they are all scared of any F.D.A. issue that raises First Amendment issues because they lost big, and they don’t want to lose again.”

Although the rate of smoking declined from 21 percent in 2005 to 13.8 percent in 2018, there are still nearly 38 million smokers in the country and it remains the nation’s leading preventable cause of death. According to the Centers for Disease Control and Prevention, about 480,000 people die from smoking-related illnesses in the United States each year. Secondhand smoke can also be lethal, and is especially dangerous for children. A C.D.C. report this week said that from 2013 through 2016, more than 35 percent of nonsmoking youths aged 3 to 17 were exposed to secondhand tobacco smoke.

The United States was the first nation to require warnings on cigarettes, but they have not been updated since 1985. The National Academy of Medicine has called the current, text-only warnings “woefully deficient.”



In 2011, the F.D.A. proposed several graphic warning labels to add to cigarette packaging. via U.S. Food and Drug Administration

In the new proposal released on Thursday, the F.D.A. offered a series of new warnings to accompany the photographic images. Those include that tobacco smoke can harm children and that smoking cigarettes can cause chronic and fatal lung disease, strokes and heart disease, and type 2 diabetes; can lead to cataracts and blindness, limb amputation, bladder and other cancers of the neck and head, and erectile dysfunction; and can stunt fetal growth.

In a 2019 report, the World Health Organization said warning labels “are most effective when they are pictorial, graphic, comprehensive, and strongly worded.” More than 91 countries have adopted what the organization considers strong labels, which cover at least half of the package. These include warnings about impotence — featuring sad-

looking couples in bed — and magnified images of rotten teeth and cataract-covered eyeballs. Another 22 countries require graphic warnings that cover 30 percent of the pack, according to the organization.

Several published studies found mixed smoker reactions to the initial nine proposed labels. A February 2016 study published by University of Illinois researchers in the journal *Communication Research* suggests that graphic images could backfire, with smokers viewing the lurid images as “a threat to their freedom, choice or autonomy.”

Researchers at the University of North Carolina, Chapel Hill said in June 2016 that 40 percent of participants in their study said they were more likely to consider quitting after exposure to the graphic images, compared with 34 percent with the text warning. And a study led by Cornell University researchers found that graphic warnings reduced the appeal of cigarette brands among youth relative to social cue advertisements with the Surgeon General’s warnings. Neither graphic nor text warnings influenced people’s beliefs about the health risks of smoking.

But public health organizations have been pushing for them. In 2016, with the F.D.A. lagging on its revised labels, a coalition of public health groups, including the American Academy of Pediatrics, the American Cancer Society, the American Lung Association and others, sued the agency for taking too long.

In March, a federal court ruled in the groups’ favor, noting that the F.D.A. had “unlawfully withheld,” and “unreasonably delayed” action to require the graphic warnings. Judge Indira Talwani set a deadline of Thursday, Aug. 15 for the agency to issue a draft, and March 15, 2020 for the final rule.