

Accessed on 21Mar2013 from url: <http://www.medpagetoday.com/PrimaryCare/Smoking/37974>

FDA Abandons Cigarette Warning Fight

By David Pittman, Washington Correspondent, MedPage Today

Published: March 20, 2013

WASHINGTON -- The FDA will not ask for a review of the most recent court decision against its rule requiring graphic warning labels on cigarette packages, several Obama administration officials said Tuesday.

Instead, the agency will go back to the drawing board to develop new warning labels it hopes will pass legal review, they said.

The U.S. Court of Appeals for the District of Columbia ruled in a 2-1 decision in August that cigarette companies' First Amendment rights would be violated by the graphic warning labels the FDA had proposed. The court further ruled that the FDA failed to show that the warning labels would reduce smoking. It was the latest in a series of rulings against the FDA rule.



Further appeal of the decision would have gone to the Supreme Court.

The regulation required that cigarettes sold in the U.S. carry graphic images warning of the dangers of smoking, including pictures of rotting teeth, diseased lungs, a baby enveloped in smoke, and a body on an autopsy table.

The images were to be accompanied by such phrases as "cigarettes are addictive," "cigarettes cause cancer," and "smoking can kill you." They were to have occupied at least half of the front and back of cigarette packs, and 20% of the top of the pack.

A group of the largest tobacco companies, including R.J. Reynolds, sued the FDA soon after the regulation was released. A federal judge nixed the warning labels in March, after earlier placing an injunction on the warnings.

"In these circumstances, the solicitor general has determined, after consultation with [the Department of Health and Human Services] HHS and FDA, not to seek Supreme Court review of the First Amendment issues at this present time," Attorney General Eric Holder wrote in a letter to House Speaker John Boehner (R-Ohio) last week. "If a court of appeals were to set aside new regulations by FDA at a later date, there will be an opportunity to seek full Supreme Court review at that time."

Howard Koh, MD, MPH, assistant secretary of health for HHS, [acknowledged the recent failed court cases in a blog post on *the Huffington Post* Tuesday](#) but maintained that the FDA will "undertake research to support a new rulemaking consistent with the Tobacco Control Act."

That law, enacted in 2009, gives the FDA authority to regulate tobacco products.

"The FDA is committed to reducing the death and disease from tobacco use by bringing science-based regulation to the manufacturing, marketing, and distribution of tobacco products," Koh wrote.

He told *MedPage Today* earlier this year that [tackling tobacco use was a key public health initiative](#) for President Obama's second term in the White House.

The American Cancer Society Cancer Action Network urged the FDA to continue to develop new graphic warnings, which it believes the agency is required to pursue under current law.

"The current warning labels have not been changed in 25 years and are widely considered to be ineffective at communicating the dangers of these addictive and deadly products," [President Chris Hansen said in a statement late Tuesday](#). "Large, graphic cigarette warning labels have been shown to encourage adults to quit smoking and deter children from starting in the first place."

A spokesperson for R.J. Reynolds did not return a request for comment.