

Federal Court Orders FDA to Finish Overdue Graphic Warning Labels For Cigarettes



On September 5, 2018, Judge Talwani of the U.S. District Court for the District of Massachusetts [ordered](#) the U.S. Food and Drug Administration to comply with a 2009 Congressional mandate requiring full color graphic warning labels on cigarette packs and advertising. Studies have shown that graphic warnings on cigarette packs and advertising are effective at informing consumers about health risks of smoking, preventing children and nonsmokers from starting to smoke, and motivating smokers to quit. More than 120 countries require large, graphic warnings on packs of cigarettes, but the United States has yet to do so. FDA promulgated a rule concerning text and images in 2011, but the portion of the rule regarding images was struck down by the D.C. Circuit. Since remand to the agency, the Court found that FDA has completed “little to no work” on the graphic images, despite a Congressional deadline to act.

In its ruling, the Court agreed with the Plaintiffs, which include the Campaign for Tobacco Free Kids, American Academy of Pediatrics, American Cancer Society, American Lung Association, and other public health organizations and Massachusetts pediatricians, that the FDA has “unlawfully withheld” and “unreasonably delayed” promulgating a final rule on graphic warning labels. In light of this delay on an issue of “substantial” public health importance, the Court wrote that it “must compel agency action.” FDA must provide an expedited rulemaking schedule to the Court by September 26, 2018 for the Court’s review.

Scott Lewis and Jessica Wall represent the plaintiff public health organizations and Massachusetts pediatricians in this action.