



May 30, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-0932

Ladies and Gentlemen:

The undersigned organizations and individuals submit these comments in the above-designated docket.¹ The organizations are all non-profit public health and medical organizations that are actively engaged in efforts to reduce the use of tobacco products; the individuals are all practicing pediatricians who counsel their patients and their families about the hazards of tobacco use. The undersigned parties are all plaintiffs in litigation alleging that FDA has unlawfully withheld or unreasonably delayed the promulgation of a final rule requiring color graphic warnings on cigarette packs and in cigarette advertisements.²

In 2009, nearly eight years ago, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).³ Recognizing that the textual warnings on cigarette packs and in cigarette advertising had not changed since 1985 and were no longer effective, Congress specified nine new textual warnings and directed FDA to promulgate a rule requiring the use of these new textual warnings with color graphic images underscoring the textual messages. The Act required FDA to promulgate such a rule by June 22, 2011, two years after the date of enactment.⁴

Several tobacco manufacturers filed suit in the United States District Court for the Western District of Kentucky arguing that the requirement for graphic warning labels was

¹ See Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings, 82 Fed. Reg. 15359 (March 28, 2017).

² *American Academy of Pediatrics, et al. v. FDA*, Civil Action No. 16-cv-11985-IT (D.Mass.).

³ Pub L. No. 111-31 §2 (1)(6), (8), (12)-(13), 123 Stat. 1776, 177 (2009), *codified at* 21 U.S.C. §387 note.

⁴ 15 U.S.C. §1333(d).

unconstitutional on its face. The Court rejected this argument⁵ and the United States Court of Appeals for the Sixth Circuit affirmed the district court's decision.⁶

FDA, in compliance with the statute, promulgated a final rule on June 22, 2011, requiring specific graphic warning labels to accompany each of the nine new textual warnings.⁷ Subsequently, a group of cigarette manufacturers, some of whom had been plaintiffs in the Kentucky action, filed suit in the United States District Court for the District of Columbia alleging that the specific graphic warnings required by FDA were unconstitutional because they infringed the First Amendment rights of cigarette manufacturers. Although the manufacturers challenged the graphic images, they did not challenge the new textual warnings mandated by Congress and, in fact, they admitted in oral argument that the textual warnings were accurate. The District Court held that the specific graphic images selected by FDA violated the First Amendment⁸ and in August 2012, by a vote of 2-to-1, a panel of the United States Court of Appeals for the District of Columbia affirmed this order and invalidated FDA's rule.⁹

In March 2013, the Attorney General reported to Congress that the Justice Department had decided not to seek review of the Court of Appeals' decision and, instead, that FDA intended to undertake research to support new rulemaking proceedings on graphic warnings. It is now more than four years since the Attorney General's letter and none of the changes in warning labels mandated by the Tobacco Control Act have been made. The warning labels on cigarette packs and cigarette advertisements remain precisely the same as they have been for more than thirty years, despite overwhelming evidence in the administrative record supporting FDA's 2011 final rule and elsewhere that the current warnings are outdated and have little or no effect. Moreover, the nine textual warnings specified in the Tobacco Control Act have not been put on the packs or advertisements, despite the fact that the cigarette companies challenging the graphics in the *Reynolds* case explicitly agreed that these textual warnings are accurate and did not challenge any of them.

During the more than four years since the Attorney General's announcement, various of the undersigned organizations have written to FDA on several occasions urging the agency to comply with its statutory obligations. FDA's responses conveyed nothing more than a generalized intention to promulgate a rule requiring graphic warning labels, but shed no light on the specifics the agency was considering. Given the importance of the issue to the public health, the multi-year delay, and the lack of specificity as to when such a rule would be promulgated, on October 4, 2016 the undersigned organizations brought suit to require FDA to comply with its statutory obligation. The research proposed in this docket represents the first publicly announced

⁵ *Commonwealth Brands, Inc. v. United States*, 678 F.Supp. 2d 512 (W.D. Ky. 2010).

⁶ *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012).

⁷ 76 Fed. Reg. 36,628 (June 22, 2011).

⁸ *R.J. Reynolds Tobacco Co. v. FDA*, 845 F.Supp. 2d 266 (D.D.C. 2012).

⁹ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *reh'g & reh'g en banc denied*, Nos. 11-5332 & 12-5063 (D.C. Cir, Dec. 5, 2012), *overruled in part by Am. Meat Inst. V. U.S. Dept. of Agriculture*, 760 F.3d 18, 26 (D.C. Cir. 2014).

measure undertaken by FDA to implement the statutory requirements since the 2012 *Reynolds* decision.

When Congress provided for nine specific textual warnings in the Tobacco Control Act, it undoubtedly expected FDA to require that these warnings appear on cigarette packs and in cigarette advertising. Congress did make provision for FDA to make changes in the text of the warnings in subsequent rulemaking proceedings, a step that was important because the effectiveness of specific warnings declines over time as consumers become accustomed to seeing the same text. However, when Congress specified the text of nine warning labels, it did not expect FDA to change them before they ever went into effect. Moreover, Congress could not possibly have expected FDA to undertake research on modified textual warnings when doing so would have the effect of delaying the implementation of new textual and graphic warning labels long after the statutory deadline expired.

In light of the fact that none of the nine warning labels specified in the statute has ever been implemented and that the accuracy of those statutory warnings has never been challenged, it is surprising that FDA's first announced step toward developing new warning labels—more than four years after it announced that it would develop new graphic warning labels—addresses the text of the labels rather than graphics. The undersigned parties are concerned that pursuing this research, rather than developing new graphic images to accompany the textual warnings in the statute, will further prolong FDA's noncompliance with its statutory obligation.

As noted above, the undersigned organizations and individuals recognize the appropriateness of FDA's considering alternative textual warnings for use after the effectiveness of the text specified in the statute has declined. We are concerned, however, that the consideration of alternative textual warnings at this time, before the warnings required by the statute are implemented, will further delay FDA's compliance with its statutory obligation to promulgate graphic warning labels.

We urge FDA and OMB to act to implement graphic warning labels at the earliest possible date. OMB should take action on this request that is consistent with this objective.

Respectfully submitted,

American Academy of Pediatrics
Massachusetts Chapter of the American Academy of Pediatrics, Inc.
American Cancer Society, Inc.
American Cancer Society Cancer Action Network, Inc.
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative
Dr. Ted Kremer
Dr. Jonathan Winickoff
Dr. Lynda Young.

