August 3, 2016

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
White Oak Building One
10903 New Hampshire, Room 2217
Silver Spring, MD 20993

Dear Dr. Califf:

In 2009, Congress concluded that the textual warnings currently on cigarette packages do not adequately communicate to Americans the serious and broad health risks of tobacco use. Seven years later those same inadequate, barely visible words remain the only warnings on cigarette packages sold in the United States. We are writing to express our deep concern regarding the failure of the Food and Drug Administration (FDA) to issue a rule requiring graphic warnings on cigarette packs and advertising, as required by Section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA).

Section 4(d) of FCLAA requires FDA to issue a final rule requiring graphic warnings within twenty-four months of enactment of the TCA. Thus, FDA was statutorily required to issue the rule on or before June 22, 2011. The U.S. has a long history of warning labels on cigarette packages. The first warning appeared on cigarette packs in 1965, but America's health warnings on cigarette packages have not been updated since 1984, over 30 years ago. The TCA mandate of new warnings that are both larger and include graphic images is a clear indication that Congress concluded that the current warnings on cigarette packages are inadequate and no longer effective.

Although FDA issued a final rule requiring new warning labels by June 22, 2011, the tobacco industry challenged the specific images mandated by that rule and the rule was vacated by a federal district court order that was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (2012). The district court's order simply returned matters to where they stood before the Court ruled, meaning that the agency's obligation to issue a final rule by the statutory deadline remains unfulfilled.[1] That FDA's initial graphic warning rule was struck down does not give the agency authority to ignore the statutory deadline, allowing it to issue a subsequent rule at a time of its own choosing. As a federal district court held in similar circumstances in *Oxfam*

[1] *See e.g., Independent U.S. Tanker Owners Comm. V. Dole*, 809 F.2d 847, 854-55 (D.C. Cir. 1987) (vacatur of an agency rule returns conditions to the status quo ante); *Sierra Club v. Johnson*, 374 F.Supp.2d, 33 (D.D.C. 2005) (after an order vacating agency action the agency's "duty to act is still (or again) unfulfilled" because the order merely "operated to restore the status quo ante"); *Environmental Defense v. Leavitt*, 329 F.Supp. 2d 55, 64 (D.D.C. 2004) (vacatur of agency promulgations "restored the status quo," which "presented a situation wherein [the agency] had failed to promulgate regulations in accordance with [an] express deadline . . . despite its nondiscretionary, statutory obligation to do so.")

America, Inc. v. U.S. Securities and Exchange Commission, 2015 WL 5156554 (D. Mass., Sept. 2, 2015), "[w]ere the rule otherwise, an agency could take inadequate action to promulgate a rule and forever relieve itself of the obligations mandated by Congress."

Significantly, while the court that considered the legality of the specific images in *R.J. Reynolds Tobacco Co. v. FDA* found that those specific images violated the tobacco companies' First Amendment rights, the court in *Reynolds* did not rule that the graphic warning requirement in the statute was unconstitutional. In *Discount Tobacco City & Lottery v. FDA*, 674 F.3d 509 (6th Cir. 2012), the U.S. Court of Appeals for the Sixth Circuit upheld the Congressional requirement that mandated graphic warnings covering 50% of the cigarette pack. The result of these two decisions is clear: FDA is legally obligated to promulgate a rule that complies with the FCLAA as amended by the TCA, but uses different images than those struck down in *Reynolds* and carries out the lawful goals of the statute.

FDA's failure to issue a final rule under Section 4 of FCLAA more than five years past the statutory deadline violates Section 706(1) of the Administrative Procedure Act (APA), which authorizes federal courts to "compel agency action unlawfully withheld . . . ." Where Congress – as in Section 4(d) of FCLAA – has required an agency to act by a date certain, FDA has no discretion to violate that deadline. *See Forest Guardians v. Babbitt*, 174 F.3d 1178, 1190 (10th Cir. 1999) ("[W]hen Congress by organic statute sets a specific deadline for agency action, neither the agency nor any court has discretion. The agency must act by the deadline. If it withholds such timely action, a reviewing court must compel the action unlawfully withheld.")

Indeed, even if the Court of Appeals' decision in *Reynolds* reset the two-year statutory clock, FDA would be in violation of the APA for its failure to act. It has been almost four years since FDA's first proposed rule was struck down in *Reynolds*, and over three years since the government announced that it would pursue a new rulemaking to implement the statutory graphic warning label requirement when it informed the Congress (on March 15, 2013) that the Justice Department would not seek further review of the *Reynolds* ruling.[2] Thus, even giving FDA the benefit of all doubts, the agency's action on graphic warnings has been "unlawfully withheld" under the APA.

This is not the first time we have raised this issue. By letter of November 25, 2013 to Mitchell Zeller, Director of the FDA Center for Tobacco Products, and by letter of August 14, 2014 to then-Commissioner Margaret Hamburg, we urged FDA to take action to issue a new rule on graphic warnings. But FDA has still not acted and has not provided any indication of when it will act.

FDA's failure to abide by the law is having serious public health consequences. As FDA itself has acknowledged, the scientific evidence is strong that such warnings are far more effective than textual warnings alone in increasing knowledge of the risks of smoking, preventing smoking initiation, increasing the motivation to quit smoking, increasing the likelihood of successful quit attempts, and reducing smoking prevalence.[3] Over the five

[2] *See* letter from Attorney General Eric Holder to House Speaker John Boehner (March 15, 2013).
[3] *See e.g.* Huang J, Chaloupka FJ, Fong, GT (2014), Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis, Tobacco Control 23 (Supp 1): i7-i12; Azagba S, Sharaf MF (2013), The effect of graphic cigarette warning labels on smoking behavior: evidence

years that has passed since the FDA first announced its warning labels rule, the evidence of the effectiveness of graphic warning labels has continued to grow. For example, the recently-published report of a randomized clinical trial[4] involving a sample of over 2100 adult smokers found that smokers exposed to pictorial cigarette pack warnings were 50% more likely to have quit smoking for at least one week during the 4-week trial than smokers exposed to only textual warnings. Pictorial warnings were also found to have increased quit attempts, intentions to quit and foregoing cigarettes. Another study based on the Canadian experience with graphic warning labels on cigarettes found that if the U.S. had implemented such warnings in 2012, the number of adult smokers in the U.S. would have decreased by 5.3-8.6 million in 2013.[5] FDA's unlawful delay in issuing a graphic warnings rule is depriving our citizens of the well-documented public health benefits of such warnings and reducing the effectiveness of efforts to educate children and other persons about the dangers of smoking.

The World Health Organization has recognized the strength of this evidence and supports the conclusion that graphic warning labels are more effective than text-only labels at providing needed information to consumers, helping consumers better understand the risk of tobacco use to their health, and raising awareness of the health risks of tobacco use.[6] At least 89 countries throughout the world require pictorial warnings on cigarette packages.[7] While the laws of these countries may vary in terms of the level of protection they provide to commercial speech, the scientific evidence that has been developed, and has become the world standard, is more than sufficient to support the adoption of graphic warnings in the United States.

We await your prompt reply setting out a timeline for a graphic warnings rulemaking, with a firm commitment to issue a proposed rule by the end of the current Administration. In the absence of such a commitment, we will explore all available legal remedies to compel FDA to comply with this important statutory mandate.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

Cc: Elizabeth H. Dickinson, FDA Chief Counsel
Mitchell Zeller, Director, FDA Center for Tobacco Products

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from the Canadian Experience, Nicotine & Tobacco Research 15(2): 708-717); Hammond D., (2011), Health Warning Messages on Tobacco Products: A Review, Tobacco Control 20:327.

[4] Brewer, N.T. et al., (2016), Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial, JAMA Internal Medicine 176(7): 905-912.

[5] Huang, et. al., *supra.*

[6] World Health Organization, WHO Report on the Global Tobacco Epidemic (2015): 66-69.

[7] Canadian Cancer Society, *Cigarette Package Health Warnings, An International Status Report* (4th ed., Sept. 2014). See also http://www.tobaccocontrollaws.org/.