



August 14, 2014

The Honorable Margaret Hamburg, MD  
Commissioner  
United States Food and Drug Administration  
White Oak Building One  
10903 New Hampshire Avenue, Room 2217  
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

We are writing to urge FDA to make it a priority to promulgate a new rule requiring that all cigarette packages contain graphic warning labels covering the top 50% of the front and back of every cigarette package.

The evidence has long been clear that the current warnings on American cigarette packages are among the least effective in the world. They haven't been changed in 30 years, are rarely seen and are inconsistent with the best available scientific knowledge about what constitutes an effective health-warning label. As FDA has recognized, graphic warning labels are far more effective at communicating information regarding the risks of smoking to consumers than text-only labels. To be effective, labels also have to be seen. For that to occur, the scientific evidence demonstrates that they need to appear in a prominent place on the package so that consumers will see them when they purchase and when they use cigarettes.

For these reasons, Congress required FDA to promulgate graphic warning labels and specified the text of the verbal message, its size and its placement on cigarette packs and cigarette advertisements. The United States Court of Appeals for the Sixth Circuit held that the provision of the Tobacco Control Act requiring graphic warning labels covering the top 50% of the two main sides of the cigarette package was constitutional and the Supreme Court denied the manufacturers' petition for certiorari. *Discount Tobacco City & Lottery, Inc. v. US*, 674 F.3d 509 (6<sup>th</sup> Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013).

Pursuant to this requirement FDA promulgated graphic warning labels in June, 2011. 76 Fed. Reg. 36,628. Cigarette manufacturers challenged the constitutionality of the particular warning labels promulgated by the FDA. In *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), the United States Court of Appeals, in a two-to-one decision, found that the particular graphic warning labels promulgated by FDA were unconstitutional because they concluded that the proposed warnings did not meet the requirements set forth in *Central Hudson Gas & Electric Corp. v. Public Service*

*Commission*, 447 U.S. 557, 566 (1980). The Supreme Court was not asked to review the D.C. Circuit decision in the *R.J. Reynolds* case.

It has been two years since FDA's first effort to implement a warning label system consistent with the FDA's Tobacco Control Act mandate. While FDA has publicly stated that it is conducting research to support graphic warnings, the FDA has not yet issued a proposed rule with new warnings.

We urge the FDA to make the adoption of new warnings that will withstand judicial challenge a priority. Two important recent developments have both demonstrated the need for new warnings and overturned a critical component of the legal reasoning underpinning the decision of the two judges of the D.C. Circuit in the *Reynolds* case. There is now a clearer legal standard to enable the FDA to adopt strong, effective and factually accurate graphic warnings consistent with the statute and the Constitution.

### **En Banc D.C. Circuit Ruling in *American Meat Institute v. USDA***

On July 29, 2014, the United States Court of Appeals for the District of Columbia Circuit issued an en banc decision in *American Meat Institute v. United States Department of Agriculture* (No. 13-5281) (attached), that has important implications regarding the promulgation of warning labels on cigarette packs and advertising. That case involved a First Amendment challenge to a regulation promulgated by the Department of Agriculture requiring meat importers to make certain disclosures regarding the origin of imported meat. In its en banc decision, the Court of Appeals, by a vote of 8 to 3, found that *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) supplies the appropriate standard for reviewing the required country-of-origin disclosure, despite the fact that the disclosure being required by the government was not necessary to correct a misleading statement. In so doing, the Court explicitly overruled *R.J. Reynolds* "to the extent that [it] may be read as . . . limiting *Zauderer* to cases in which the government points to an interest in correcting deception." Slip op. at 8.

The Court's ruling makes clear that contrary to the holding in the *R.J. Reynolds* case, governmental interests other than the correction of deception may be sufficient to support commercial disclosure requirements and that where the required statements are "factual and noncontroversial" *Zauderer* provides the standard for review of such requirements. As the Court recognized, citing *Zauderer*, 471 U.S. at 650. "The First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed." Slip op. at 7.

The en banc opinion of the D.C. Circuit in the *Meat Institute* case undercuts one basis for the *Reynolds* holding striking down the FDA's proposed graphic warning labels on cigarette packs and advertising. As indicated above, properly applying the *Zauderer* standard, the Sixth Circuit had found the requirement for graphic warning labels to be constitutional on its face and the only D.C. Circuit judge who applied that standard found eight of the nine graphic warning labels previously promulgated by FDA to be constitutional. 696 F.3d 1222-23 (Rogers, J., dissenting).

## **New Scholarship Challenging the Graphic Warnings RIA**

The recent en banc opinion of the D.C. Circuit is not the only important recent development relevant to the issuance of warning labels. Recently published economic and scientific scholarship has demonstrated that the Regulatory Impact Statement (RIA) accompanying the graphic warning label rule did not accurately measure the benefits of graphic warning labels. The majority in *R.J. Reynolds* found that the government had failed to establish that the warning labels would directly advance a valid governmental interest. The majority based this finding in part on the fact that “FDA’s Regulatory Impact Analysis (“RIA”) essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates.” 696 F.3d at 1219-21.

However, as explained in detail in a recent study submitted by nine distinguished economists (“Economists’ Evaluation”) (attached) in the deeming rule docket (FDA-2014-N-0189), the FDA’s conclusion in the RIA accompanying the graphic warning rule was based on an erroneous understanding of the effect of graphic warning labels on cigarette consumption in Canada. The economists concluded that had FDA correctly interpreted the Canadian data, it would have found that the effect of graphic warning labels in cigarette consumption in Canada was 30 to 50 times greater than that found in the RIA.<sup>1</sup>

Moreover, the economists’ evaluation specifies numerous other omissions in the analysis of health benefits associated with the promulgation of graphic warning labels that resulted in an understatement of the benefits of such a rule in the RIA. Economists’ Evaluation at 6-10. These include omission of benefits that accrue to non-smokers as a result of reductions in smoking associated with graphic warning labels, omission of benefits that result from reductions in maternal smoking during pregnancy, omission of reductions in the cost of health services used to treat diseases caused by smoking, methodological errors in distributing the health benefits of smoking reduction over time, and numerous other errors identified in the Evaluation. In sum, a properly done Regulatory Impact Assessment would make it clear that graphic warning labels would in fact directly advance a valid governmental interest.

The Tobacco Control Act creates a clear statutory requirement for graphic warning labels on cigarette packs and cigarette advertising. The evidence adduced in FDA’s prior rulemaking on graphic warning labels makes it clear that existing warnings are not accomplishing their purpose and that adequate warning labels are essential to ensure that accurate information about the consequences of smoking is conveyed to consumers. The recent en banc decision of the D.C. Circuit in the *Meat Institute* case combined with the decision of the Sixth Circuit in *Discount Tobacco* provides a pathway

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<sup>1</sup> Chaloupka FJ, et al., An Evaluation of FDA’s Analysis of the Costs and Benefits of the Graphic Warning Label Regulation at 5-6; Azagba S, Sharaf MF (2013), The effect of graphic cigarette warning labels on smoking behavior: evidence from the Canadian Experience. *Nicotine & Tobacco Research* 15(2): 708-717 ); 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(Supplement1):i7-i12.

for FDA to adopt strong, effective graphic warnings that can withstand judicial review. Moreover, recent analyses by respected economists and health scientists demonstrates that there is substantial, credible scientific evidence that strong graphic health warnings are sufficiently effective both in better educating consumers and in impacting consumer behavior to establish that they directly advance legitimate governmental interests.

It has been thirty years since the warning labels on cigarettes have been changed. It is time for the FDA to act and to make it a priority to promptly issue a rule requiring strong, effective, factually accurate graphic warning labels.

Sincerely,

American Cancer Society Cancer Action Network  
American Heart Association  
American Lung Association  
Campaign for Tobacco-Free Kids  
Legacy

cc: Mitchell Zeller, JD, Director, Center for Tobacco Products