

# United States Senate

WASHINGTON, DC 20510

July 25, 2011

Margaret A. Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

Recently, the U.S. Food and Drug Administration (FDA) published, “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” 76 Fed. Reg. 91912 (April 6, 2011), pursuant to section 4205 of the Patient Protection and Affordable Care Act of 2010. We believe FDA’s proposed rule is unnecessarily broad and will penalize establishments like grocery stores, which Congress did not intend to be a covered establishment. To avoid such a result, we urge FDA to adopt its alternative definition of “restaurant or similar retail food establishment” contained in part III.A.1. of the proposed rule.

Section 4205 of the Patient Protection and Affordable Care Act of 2010, required disclosure of nutrient content for: “food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations . . . and offering for sale substantially the same menu items . . . .” As evidenced by the plain language of the statute, grocery stores were not the target of this section of the Act. Grocery stores generally do not offer standard prepared food menu items and more importantly do not fit the definition of a restaurant or similar retail food establishments.

Although a grocery store may have over 20 locations, prepared foods served at the various locations are typically not standardized. Requiring nutrient analysis to enable accurate labeling of these prepared foods would place a disproportionate cost on grocery store chains compared to restaurant chains because grocery store chains lack the menu standardization of restaurant chains. The disproportionate costs that will be borne by grocery stores under FDA’s proposed rule are proven by its own cost analysis. In “Table 1b : Summary of Estimated Annualized Compliance Cost for Each Option” FDA identified that adopting the alternate definition of “restaurant or similar retail food establishment” would result in a 12.5 percent reduction in total compliance cost, but only a 5.0 percent reduction in total dollars of sales covered by the rule. This means grocery stores and similar non-restaurant establishments would incur 2.7 times the amount of compliance costs per dollar of food sold when compared to

restaurants whose primary business is selling food that has been prepared and processed on the premises for immediate consumption.

In addition to not meeting the standardized menu requirement, grocery stores are not in the primary business of selling food for immediate consumption or food that is prepared and processed on the premises. Prepared food sections in grocery stores are typically provided for customer convenience and often stores lack dining areas. Furthermore, while a majority of total grocery store sales are food sales, only a small portion of the food sales are from prepared foods. According to the Food Marketing Institute, 95 percent of the food products sold in grocery stores already have nutrition labels. This fact highlights why the alternative rule, which defines covered food as “the sale of restaurant or restaurant-type food—as opposed to food in general” should be the definition used to determine the primary business activity of an establishment.

We would also bring to your attention the current budget constraints faced by FDA. Despite the difficult fiscal environment faced by the federal government, the FDA has submitted a budget that asks for a significant increase in funding. While FDA cites new responsibilities under the recently passed Food Safety Modernization Act as justification for its request for additional funds in the 2012 fiscal year, FDA submitted few if any cost containment measures in its budget. Limiting the scope of this rule, as proposed in the alternative definition of a restaurant or similar retail food establishment, is one such common sense cost saving measure.

Finally, we would bring to your attention Executive Order 13563 signed by President Obama on January 18, 2011. Adopting the alternative definition described in the proposed rule complies with Executive Order 13563. The Executive Order directs agencies to use the least burdensome tools to achieve regulatory ends. Based on FDA’s own cost analysis, excluding grocery stores from the final rule by using the term “the sale of restaurant or restaurant-type food” to define the primary business activity of an establishment would be the least burdensome tool to achieve FDA’s regulatory ends.

Thank you for considering our request that FDA adopt the alternative definition of “restaurant or similar retail food establishment” contained in the proposed rule. We believe the alternative definition more closely resembles Congressional intent and will lead to lower costs for both retail grocers and ultimately consumers.

Sincerely,

Jerry Moran

Gene McCasill

Lamar Alexander

Sayby Claiborn

Mike Enzi

Richard G. Lugar

Pat Roberts

Key Bent

John Barrasso

John Boozman

Thad Cochran

Mike Johanns

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