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MENU LABELING: DID FDA OVERREACH?

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I. INTRODUCTION

In the fall of 2009, as the nation was gripped with the debate over the most sweeping changes to our health care system in generations, a little-noticed provision was slipped into the legislative package that ultimately was enacted as the Patient Protection and Affordable Care Act (ACA). The provision, Section 4205, marked a profound change to our nation's nutrition labeling laws—one of comparable significance to the Nutrition Labeling and Education Act of 1990 (NLEA), which required standardized nutrition labeling on packaged foods. Section 4205 established a federal menu labeling requirement which mandated that chain restaurants list calorie content and written nutrition information for food and beverage items on menus, menu boards, foods on display, and self-service items.

The provision was supported by the restaurant industry, which sought to have a single national standard that would preempt the patchwork of various state and municipal menu labeling laws which regulated them. The provision was also supported by public health organizations, which favored expanding menu labeling requirements to all fifty states. While restaurants were plainly included within the scope of the law, its application to other types of establishments was not entirely clear.

In April 2011, the U.S. Food and Drug Administration (FDA) issued a sweeping proposed rule that regulated not only restaurants, cafeterias, and coffee shops, but extended the scope of the law to supermarkets and convenience stores. The federal rule diverged from every state and local menu labeling regulation in this aspect. The expanded scope of the rule has been estimated by the supermarket industry to place a regulatory burden on supermarkets that exceeds $1 billion dollars. FDA has acknowledged that the law does not require them to impose this burden on supermarkets.

Several months before the rule was published, President Obama issued Executive Order 13563 (E.O. 13563), requiring agencies to promulgate rules only upon a determination that the benefits of a regulation exceed its costs. In spite of the executive order, FDA failed to quantify a single benefit resulting from implementation of the rule and overlooked many of its biggest costs.

Did FDA overreach in issuing its menu labeling rule? An examination of the text of the law and its legislative history indicate that the agency did. It is also apparent that FDA failed to meet its obligations under E.O. 13563.

POLICY RECOMMENDATIONS

FDA should:

- Abide by the authority granted to FDA in Section 4205 of the ACA and exclude supermarkets from the scope of menu labeling regulations.
- Reanalyze the regulatory costs and public benefits of menu labeling.
- Adhere to the principles of Executive Order 12866 and 13563 in the menu labeling rulemaking.

II. BACKGROUND

Over the past several decades, obesity rates have climbed in the United States significantly and policymakers have sought to find a solution to address them. Education, exercise promotion, labeling, taxation, and even prohibition of high calorie items have all been considered by policymakers, and many of these strategies have been attempted. Despite these efforts, obesity rates have continued to rise precipitously. Between 1995 and 2010, the obesity rates in 39 states increased by 80 percent or more.

The increase in obesity rates parallels a concurrent rise in the proportion of meals and food consumed away from home in restaurants. Americans are eating out more and preparing fewer meals from items purchased at supermarkets. Between 1970 and 2010, the percentage of Americans' food budget spent on food away from home increased by 60 percent.[1] Increased quantities of food consumed away from home have been linked to increased obesity,[2] and studies have demonstrated that fast food consumption is correlated to obesity rates.[3]

In 1994, the NLEA was enacted, requiring food manufacturers to place a standardized nutrition label on virtually all packaged foods. The law generally excluded restaurants from the requirement to label menu items; however, for menu items in which nutrient content or health claims were made, FDA mandated in the regulations that additional nutrition information must be provided.[4] The NLEA captured the vast majority of foods sold in grocery stores; more than 95 percent of food items in the typical supermarket are required to be labeled under the NLEA.[5]

Largely because of concerns related to the consumption of restaurant food and obesity, policymakers began efforts to require the labeling of menu items in chain restaurants. The first menu labeling requirement was enacted by the New York City Board of Health in December 2006. Several other states and municipalities followed New York with similar laws and regulations including California; Oregon; New Jersey; King County, Washington; and Suffolk County, New York.[6] None of these laws or regulations applied to supermarkets.

As a consequence of the state and local activity on menu labeling, the National Restaurant Association worked with public health organizations, including the Center for Science and the Public Interest, to motivate Congress to enact a federal menu labeling standard that would preempt the patchwork of state and local laws and regulations its members were subject to.[7] Enacted as part of the ACA, the provision directed FDA to issue proposed menu labeling regulations which were published in the Federal Register on April 6, 2011.[8]

The proposed rule regulated supermarkets in a very broad fashion. All grocery chains with 20 or more stores were covered, and essentially every item of food not already required to bear labeling in stores under the NLEA was now subject to menu labeling. For grocery retailers, this meant that hundreds to thousands of bakery, deli, cut produce, and prepared food items within their retail outlets were now required to be analyzed, marked with new signage, and documented with reams of records.

Although FDA decided to subject supermarkets to menu labeling, it did acknowledge that Section 4205 did not require them to do so, and offered a regulatory alternative that would exclude food retailers from the scope of the law and greatly reduce the overall burden of the rule.[9]

The agency's decision to regulate menu labeling in such a broad manner was controversial. Following the publication of the rule, several members of Congress wrote letters to FDA urging it to adopt the alternative, which narrowed the range of establishments regulated.[10] The House Agricultural Appropriations Subcommittee also weighed in with report language expressing concerns over the rule.[11]

Several months before the rule was published, President Obama issued Executive Order 13563, which reiterated the principles of Executive Order 12866 stating that each agency must: (1) issue regulations only upon a reasoned determination that the benefits justify the costs; (2) tailor regulations to impose the least burden on society; and (3) select approaches that maximize net benefits. The Administration has been called upon to ensure these principles are applied to the menu labeling rule.[12]

The supermarket industry has estimated that food retailers face a greater than $1 billion regulatory burden in the first year of compliance with the proposed rule, and hundreds of millions of dollars annually thereafter.[13] The implications of whether the FDA has authority to regulate supermarkets as restaurants are immense. The manner in which the Administration enforces Executive Order 13563 has similarly high stakes.

III. ISSUES IN DISPUTE

The rise in obesity rates has been linked to increased fast-food consumption, among other contributors.[14] In response to concerns over rising obesity rates, states and municipalities implemented menu labeling regulations for chain restaurants. A single federal standard was promoted by the restaurant industry to preempt the patchwork of state and municipal regulations they faced. The federal standard was ultimately passed as part of the ACA. Despite the fact that no state or municipality chose to regulate grocery stores, FDA took the language of the statute and extended it to supermarkets in a very broad manner. Questions have emerged regarding FDA's aggressive approach and whether the agency acted within its authority. The rule has also spurred debate as to the costs and benefits of menu labeling. These issues are discussed below.

A. FDA Authority to Regulate Establishments Under Section 4205

Does the law apply only to restaurants and other firms whose primary business is the sale of food for immediate consumption, or does it apply to a wider range of establishments including grocery and convenience stores? This is one of the core questions FDA is grappling with in its rulemaking. Section 4205 requires restaurants and "similar retail food establishments" that are part of a chain with 20 or more locations to provide calorie and other nutrition information for standard menu items. However, Congress left the term "similar retail food establishments" undefined, leading FDA to create the following definition:

"Restaurant or similar retail food establishment" means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment's primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption or storage of food.[15]

On its face, FDA's definition appears counterintuitive. Establishments are subject to the regulation on the basis of floor space dedicated to all food sold, including packaged foods already required to be labeled under NLEA. Under this definition, a food retailer that sells nothing but boxes of cereal and dinner rolls is considered a restaurant the instant it offers a consumer a bag of rolls portioned at the shopper's request.[16] The definition thus captures all supermarkets, which the agency has acknowledged.[17] The agency has, however, proposed an alternative definition, "Option 2," that would regulate businesses on the basis of floor space dedicated to restaurant or restaurant-type food.[18] This definition is rational; it would generally exclude supermarkets while greatly reducing the overall burden of the rule.

FDA notes that "the statutory text focuses explicitly on restaurants and retail food establishments that are 'similar' to restaurants, rather than on all establishments where food is sold (often incidentally to or quite separately from the establishment's primary purpose)."[19] However, the definition the agency adopted in the rule makes no distinction between retail food establishments and retail food establishments that are similar to restaurants. Section 4205 requires the agency to do so.

B. The Costs and Benefits of Menu Labeling

It has been estimated by industry that the costs of extending menu labeling to supermarkets will exceed $1 billion in the first year of compliance alone, and hundreds of millions of dollars annually thereafter.[20] Meanwhile, the evidence that menu labeling has any significant impact on public health is scant. Indeed, of the studies FDA cites in the rule, most demonstrate that menu labeling has little to no effect on purchasing habits. Furthermore, no study shows any link to reduction of obesity rates, the purported benefit which FDA used to justify the menu labeling regulation.

While the Office of Management and Budget has recognized the menu labeling rule as one of the biggest new paperwork burdens imposed on businesses in 2011,[21] FDA failed to account for any quantitative benefits of the proposed rule.[22]

The agency has also downplayed the costs the rule will impose on supermarkets. FDA estimated that supermarkets have on average approximately one-half the number of menu items of an average restaurant, or 40 menu items.[23] Because the rule requires virtually every food item in a supermarket to be labeled that is not required to carry nutrition labeling under the NLEA, supermarkets actually have from 6 to hundreds of times more menu items than that of an average restaurant. Supermarkets have reported that anywhere from 500 to 15,000 items are covered.[24]

FDA has estimated that the average cost of a full nutrition analysis is $269 per item. The agency, however, neglected to consider that grocers will need to enlist the help of outside laboratories and labeling firms to comply with the requirement. These firms generally charge $500-$1,000 per item.[25]

The agency also vastly understated the number of grocery stores subject to the rule. FDA estimated that only 11,200 grocery establishments will be affected by the rule because the Census Bureau's 2007 Economic Census data reported that only 36 percent of total establishments report sales of "meals or beverages for immediate consumption."[26] This estimate misses the mark because it fails to consider that the rule regulates stores that not only sell food for immediate consumption,[27] but also restaurant-type food not sold for immediate consumption.[28] In reality, virtually every supermarket outlet will be regulated—more than 35,000 establishments. While FDA has estimated a cost to the entire supermarket industry of only $3 to $17 million, the industry has estimated a cost of over $1 billion.[29] The agency, thus, has missed the mark in its estimate of the burdens of Section 4205 and should reanalyze its assessment.

C. Executive Orders 13563 and 12866

In January 2011, President Obama issued Executive Order 13563, which directed agencies to minimize regulatory burdens. Executive Order 13563 states:

Our regulatory system . . . must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends . . . As stated in (Executive Order 12866) . . . each agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs . . . (and) tailor its regulations to impose the least burden on society.[30]

FDA has acknowledged that Section 4205 does not obligate it to regulate supermarkets, but decided to do so in the proposed rule without justifying the decision.

E.O. 13563 requires agencies to "take into account benefits and costs, both quantitative and qualitative," as well as contemplate the cumulative burdens of regulations on entities.[31] FDA has not quantified any benefits of the proposed rule[32] in spite of E.O 13563 and the fact that the expanded scope of the rule is estimated by the supermarket industry to impose a greater than $1 billion burden on supermarket industry in the first year of compliance alone, nor has it considered the cumulative regulatory burdens faced by the grocery industry.

IV. RESEARCH AND RESPONSE

A. FDA did exceed its authority under the menu labeling law in regulating supermarkets and should exclude them from the scope of the final rule.

Because FDA has failed to give any meaning to the term "similar" or make a distinction between supermarkets, convenience stores, and restaurants, the agency has failed to stay within its mandate under Section 4205.

An examination of the term in the context of the statute Section 4205 modifies, 21 U.S.C. S. 343(q), is instructive as to the scope of the law. Within paragraph (q), the term "food retailer" is used to describe entities that are subject to nutrition labeling of meat and fish, and this term is generally understood, and has been construed, to apply to supermarkets. Also within paragraph (q), the term "retail establishment" is used to describe certain foods that are exempt from the NLEA.[33] Supermarkets certainly fall within the definition of retail establishments. Instead of using these terms, however, Congress chose to use the term "similar retail food establishment."

It is always appropriate to assume that Congress knows the law.[34] The United States Supreme Court has stated that "[w]here Congress includes particular language in one section of a statute, but omits it in another it is generally assumed that Congress acts intentionally.[35] It is apparent that Congress did not intend for "similar retail food establishments" and "food retailers" or "retail establishments" to have the same meanings.[36]

The law requires FDA to make a distinction between supermarkets and restaurants, and to give meaning to the term "similar." The definition FDA has included in its rule does not. "Similar" means "comparable" or "nearly corresponding."[37] The agency acknowledges that supermarkets are generally covered under the regulation. "It is an elementary rule of construction that effect must be given, if possible, to every word, clause and sentence of a statute," the United States Supreme Court has stated.[38] A statute should be construed so that effect is given to all its provisions, where no part will be inoperative or superfluous.[39]

The mandatory country of origin labeling statute for agricultural products covers supermarkets, but exempts restaurants and similar establishments. It contains a definition of "food service establishment" that should instruct FDA in determining the scope of menu labeling. "The term 'food service establishment' means a restaurant, cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, or other similar facility operated as an enterprise engaged in the business of selling food to the public."[40]

An examination of the text of Section 4205 and the legislative history makes clear that Congress intended for the law to be narrower in scope than FDA has applied it.

The heading of Section 4205, entitled "Nutrition Labeling of Standard Menu Items at Chain Restaurants," must inform the agency's rule. Because the heading refers only to restaurants, FDA should construe the term "similar retail food establishment" narrowly.[41] FDA acknowledges that the term ". . . is ambiguous." It is possible to imagine a range of interpretations of this term, calling for relatively narrow coverage (including only restaurants and those establishments that are closely analogous to restaurants) or relatively broad coverage (including a range of establishments that sell food at retail.)"[42] The title and heading of sections in an act, however, can shed light on an ambiguous phrase.[43] In this case, the heading instructs the agency to read the term narrowly.

In addition, the primary champion of menu labeling in the Senate, Senator Tom Harkin, has repeatedly held up supermarkets as the model for providing nutrition information to consumers.[44][45] As the sponsor of the bill that served as the basis for Section 4205, the MEAL Act (S. 1048), Senator Harkin's statements are particularly probative in determining Congress's legislative intent.[46] In his floor statement introducing the MEAL Act, Senator Harkin stated: "Consumers say that they would like nutrition information provided when they order their food at restaurants, yet, while they have good information in supermarkets, at restaurants they can only guess."[47] Furthermore, Senator Harkin cited several laws, initiatives, and municipalities in his statement—none of which regulate supermarkets.[48] Nowhere in the legislative history is there an indication that Congress contemplated regulating supermarkets under Section 4205.

It is also important to consider that Section 4205 is modeled after Section 81.50 of the New York City Health Code.[49] Section 81.50 does not regulate supermarkets. "Where a meaning of a statute is in doubt, reference to legislation in other states and jurisdictions which pertains to the same subject matter . . . may be a helpful source of interpretive guidance."[50] Where courts look to another jurisdiction for clarification or guidance, the phraseology and language of similar legislation in other jurisdictions deserves special consideration not only in the interests of uniformity but also for the purpose of determining the general policy and objectives of a particular course of action.[51] The New York Code was the first—and most extensively discussed—law cited by Senator Harkin in introducing the MEAL Act.

In addition, the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Subcommittee Reports for the fiscal year 2012 and 2013 Agriculture and Related Agencies funding bills include report language expressing concern about the scope of the Proposed Rule. "[W]hile the views of subsequent Congresses cannot override the unmistakable intent of the enacting one, such views are entitled to significant weight, and particularly so when the precise intent of the enacting Congress is obscure."[52]

The text of Section 4205 and its legislative history indicate that Congress intended for the law to be narrower in scope than FDA has implemented in the rule. The agency has overreached with its menu labeling regulation.

B. Studies on menu labeling show little to no benefit while costs of labeling are high.

Studies on the effects of menu labeling are inconclusive. Some show a modest reduction in calorie content of consumer choices while others show no impact.

Several studies have been conducted on the New York City menu labeling regulation. A study by Ebel and colleagues of the New York labeling regulation's impact on children and adolescents found "no statistically significant differences in calories purchased before and after labeling and no evidence that labeling influenced adolescent food choice or parental food choices."[53] Another study of the New York regulation conducted by Ebel and colleagues found no impact on menu selections of lower income populations.[54] Dumanovsky and colleagues found no overall decline in calories purchased after implementation of the New York regulation, but did observe significant reductions in calories purchased for several major chains.[55] A study by Bollinger and colleagues of purchases at Starbucks did observe a six percent decrease in calories consumed per transaction, largely due to a decline in accompanying food purchases. [56]

A study conducted on the King County menu labeling regulations found no impact on purchasing behavior. Researchers concluded that mandatory labeling did not promote healthier food purchasing behavior.[57] The United States Department of Agriculture (USDA) researchers have noted that "findings suggest that diners may pay less attention to nutritional information when eating out than when shopping for the week's meals."[58]

Down and colleagues' study showed that menu labeling had a modest impact in leading consumers to select lower calorie items, but in some circumstances led consumers to purchase items with a higher calorie content.[59] A study performed by Yamamoto and colleagues concluded that calorie information had little effect on adolescent fast food choices.[60]

No significant evidence exists to link menu labeling to a reduction in obesity rates. Absent such evidence, FDA cannot justify expanding the scope of the rule under Section 4205 beyond what is required under the law.

The costs, on the other hand, can be ascertained with much more certainty. The supermarket industry has estimated that 150 chains[61] will be impacted, with an average of 1,500 food items covered. The cost of obtaining the nutrition information initially is estimated to be at least $225,000,000 for the industry. Menu boards and signs are projected to cost $1,000,000 for each retailer, for a total of $150,000,000. New scale/software investments are estimated to be $1,500,000 per retailer, or $225,000,000 total. Training store level associates and developing training materials is expected to cost $150,000,000 across the industry. Recordkeeping is estimated to cost $2,000,000 per chain annually, for a total of $300,000,000. The total burden on the industry is expected to be more than $1 billion for the first year alone. Ongoing costs are estimated to amount to the hundreds of millions of dollars.[62]

Supermarkets also face a number of challenges with menu labeling that restaurants do not. A much larger variety of items is subject to the rule in the typical supermarket. Every loaf of bread, roll, cake, bagel, and pie made within the store must be labeled. Even items that are not prepared within the store, but are portioned at the customer's request, are all covered.

While a restaurant manages a limited set menu under the control of a chef or sous chef, a retail supermarket merchandises foods in a variety of formats—full service, self-service, cold or hot—in various departments throughout the store. The types of foods offered can vary throughout the year depending on season, holiday, or promotions. There is also not a set menu used by all stores within a supermarket chain.

Supermarkets have a greater variety of items not only in terms of the number of different items offered for sale, but also in how the items are displayed. For example, the same cake and pie may be displayed whole, sliced in half, or sliced in quarters. All of these items would have to be labeled separately.

Many retailers add hundreds of new items to their product mix each year. Many of these items will be covered under the menu labeling rule because they are ready to eat and require some retail processing.

In addition, ingredients for store-prepared items are less standardized than those found at chain restaurants. Unlike a chain restaurant with prescribed recipes and ingredients, many retailers give stores the flexibility to adapt recipes to the local regional taste profiles. For example, there may be multiple formulas of potato salad in a single chain that are sold throughout the different regions.

Unlike restaurants, stores often serve as their own suppliers for prepared foods. The meat department supplies the meat, the produce department supplies fresh fruits and vegetables, and packaged foods may also be used in creating prepared items. Stores have discretion in using these ingredients based on availability, unlike chain restaurants. Each ingredient change may impact the calorie or nutritional values of the finished product. Items may vary across divisions, regions, and even by store, as offerings are customized based on customer demographics and trade area profile. A great deal of variation can occur based on ingredient availability, demographics and seasonality.

Supermarkets have far more signage and displays which will be affected than restaurants. The lineal footage of display cases and menu boards for each department far exceeds any restaurant operation. While restaurants typically identify their offered foods and pricing through a single menu board and/or menu, supermarkets typically identify and price offered products through individual product shelf tags or product signs. Each and every one of these individual product shelf tags and product signs for items covered under the rule would have to be changed to incorporate the required nutrition information.

C. The agency has failed to meet its obligation under Executive Order 13563.

Executive Order 13563 requires agencies to: (1) use the least burdensome tools to achieve regulatory ends; (2) consider quantitative benefits and costs; and (3) tailor regulations to impose the least burden on society while accounting for the costs of cumulative regulations, among other things.

FDA has not utilized the least burdensome tools to achieve regulatory ends:

FDA has acknowledged that Section 4205 does not obligate the agency to regulate supermarkets. FDA has proceeded to do so in the rule but is considering an alternative "Option 2" that would generally exclude supermarkets from the scope of the law. According to the agency, the alternative would reduce the compliance costs of the rule by more than 12.5 percent, while the proportional dollar sales of restaurant or restaurant-type food not covered by the menu labeling would drop by only 5 percent. For every dollar of restaurant food not covered, FDA would save the economy $2.50 in compliance costs, according to the preliminary regulatory impact analysis conducted by the agency.[63] The industry has estimated that the savings will be nearly ten times of that calculated by FDA. Consistent with E.O 13563, the alternative is the least burdensome tool FDA has expressed in the Proposed Rule that would permit the agency to achieve its regulatory ends.

No accounting for quantitative benefits:

E.O. 13563 requires agencies to "take into account benefits and costs, both quantitative and qualitative."[64] FDA has not quantified a single benefit of the rule in spite of E.O. 13563. The agency has failed to meet its obligations under the executive order.

Burden of cumulative regulations not considered:

E.O. 13563 reaffirms the principles governing regulatory review that were established in E.O. 12866, which require each agency to "tailor its regulations to impose the least burden on society . . . taking into account . . . the costs of cumulative regulations."[65] In May, President Obama issued Executive Order 13610, which further emphasized the importance of considering cumulative burdens. Supermarkets face a profoundly larger array of regulations than restaurants. Compliance staff at supermarket firms are already being stretched thin to cope with these existing rules, and the burden imposed by menu labeling rule will impact them disparately.

Supermarkets are already subject to the following rules, which restaurants are not: country of origin labeling,[66] statement of identity labeling,[67] net quantity of contents labeling,[68] ingredient and allergen labeling,[69] safe handling instructions,[70] nutrition labeling of raw meat and poultry,[71] labeling of artificial flavors and colors and chemical preservatives,[72] and Bioterrorism Act recordkeeping[73], to name a few.

FDA has failed to consider the challenges of adding a new regulatory burden on top of the existing ones that supermarkets face, but is required to make such a consideration pursuant to E.O. 13563.

V. IMPACT OF POLICY RECOMMENDATIONS

Section 4205 does not grant FDA carte blanche authority to regulate establishments that are not restaurants. If the agency tailors the final menu labeling rule to fit within its authority under the law, then it must exclude supermarkets from the scope of the regulation. FDA has proposed this option in the rule and a reexamination of the statutory text should lead them to adopt the alternative. Adopting the alternative will save the economy hundreds of millions of dollars in regulatory costs, allowing supermarkets to create or retain thousands of jobs.

Even if the agency believes it is acting within its authority to regulate supermarkets as restaurants, it still has an obligation to reassess the costs and benefits of the rule. The costs of the rule have been severely underestimated, while not a single benefit of the rule has been quantified. A reappraisal of the costs and benefits should lead the agency to conclude that the costs of expanding the scope of the rule vastly exceed any benefits.

Executive Order 13562 requires FDA to use the least burdensome tools to achieve regulatory ends and tailor regulations to impose the least burden on society. The agency has acknowledged that Section 4205 does not require them to regulate supermarkets and has proposed an alternative that would exclude supermarkets from the scope of the rule. This alternative is the least burdensome option proposed by the agency that would allow it to achieve its regulatory ends. Pursuant to E.O. 13562, FDA must adopt this alternative.

VI. CONCLUSION

Though enacted with little fanfare, Section 4205 of the ACA changed our nation's nutrition laws in a manner nearly as significant as the NLEA itself. Enacted for the purpose of preempting the patchwork of state and local menu labeling laws with a single national standard, FDA has used the law to regulate supermarkets and convenience stores. These establishments were not subject to the state and local menu labeling laws which the federal law sought to preempt. Given that there is no legislative history indicating that Congress intended to, or even contemplated, regulating supermarkets and no statutory language that requires a relatively narrow reading, FDA has exceeded its authority under the statute by extending the scope of the law to supermarkets.

The costs of extending menu labeling to supermarkets are clear, while not a single benefit of menu labeling has been quantified by FDA. The agency has proposed an alternative that would exclude supermarkets from the scope of the rule. E.O. 13562 requires the agency to adopt this alternative, which would greatly reduce the burden of the rule while allowing grocers to create and retain thousands of jobs.

ABOUT THE AUTHOR

Erik Lieberman is the regulatory counsel for the Food Marketing Institute and represents the food retailing and wholesaling industries before federal agencies ranging from FDA and USDA to the Department of Labor and Department of Justice. Lieberman works with federal agencies in the rulemaking process and assists the industry in complying with federal rules. Previously he served as the Majority Regulatory Counsel for the House Small Business Committee. From 2004-2007, Lieberman was Director of Government Affairs at the National Grocers Association. Prior to that, he served as a legislative assistant to U.S. Senator Bob Graham. Lieberman has been featured in the Wall Street Journal, Businessweek and the Washington Post and regularly appears in trade and industry publications. He is a graduate of the University of Florida and the University of Pennsylvania Law School.

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6. Brent Bernell, *The History and Impact of the New York City Menu Labeling Law,* 65 Food Drug L.J. 839 (2010).

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9. Dina ElBoghdady, *Pizza chains band together over proposed menu-labeling plan,* Washington Post, June 19, 2012*; http://www.washingtonpost.com/business/economy/pizza-chains-band-together-over-proposed-menu-labeling-plan/2012/06/19/gJQAxcf3oV_story.html.*

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[1] USDA, Economic Research Service, Chart of Food Away From Home as Share of Food Expenditures, http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/Expenditures_tables/table10.htm (last visited June 21, 2012).
[2] *See* Gayaneh Kyureghian, et al., *Food Away from Home Consumption and Obesity: An Analysis by Service Type and by Meal Occasion*, http://ageconsearch.umn.edu/bitstream/9690/1/sp07ky01.pdf (last visited June 21, 2012).
[3] *See* Mark Pereira, et al., *Fast-food Habits, Weight Gain, and Insulin Resistance (The CARDIA Study): 15-Year Prospective Analysis*, The Lancet (2005); Janet Currie, et al., *The Effect of Fast Food Restaurants on Obesity and Weight Gain*, *Working Paper No. 14721*, National Bureau of Economic Research (2009).
[4] 21 C.F.R. §101.10.
[5] The average store in the industry carries about 39,000 stock keeping units according to FMI's survey, the Food Retailing Industry Speaks (2011). 10- 15 percent of those items are non-food items. Assuming an average of 12.5 percent for non-food items, the typical chain supermarket carries 34,125 food items. Of these, 700-1500 will not be labeled with nutrition labeling, which equates to 2-4 percent of food items. Certain retailers carry significantly higher SKUs and proportionately more food items are not labeled. Many of the items in bakeries and delis are already labeled. All par baked items, defrosted cakes, and deli items in consumer packages must be labeled.
[6] *See* Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons From Local Experience,* 65 Food Drug L.J 901 (2010).
[7] Press Release, National Restaurant Association, *National Restaurant Association Says Nutrition Information Provision Is Win for Consumers and Restaurants* (March 22, 2010), http://www.restaurant.org/pressroom/pressrelease/?id=1910 (last visited June 21,2012) ; Press Release, National Restaurant Association, *National Restaurant Association Backs Bipartisan Senate Agreement To Empower Consumers Nationwide with More Nutrition Information* (June 10, 2009), http://www.restaurant.org/pressroom/pressrelease/print/index.cfm?ID=1820 (last visited June 21, 2012).
[8] 76 Fed. Reg. 19192 (April 6, 2010).
[9] *Id.* at 19199.
[10] *See* Letter from Rep. Robert Latta, et al., to Commissioner Margaret Hamburg (July 26, 2011); *see also* Letter from Sen. Jerry Moran, et al., to Margaret Hamburg (July 25, 2011).
[11] H.R. Rep. No. 112-101 at 53 (2011).
[12] Letter from the Food Marketing Institute to Hon. Cass R. Sunstein (Nov. 21, 2011), http://www.fmi.org/docs/newsletters-comments/omb-menu-labeling---omb-review-pursuant-to-executive-order-12866-and-13563.pdf?sfvrsn=2 (last visited June 21, 2012).
[13] FMI Comments to FDA on Proposed Menu Labeling Rule (July 5, 2011). http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-0172%29.pdf?sfvrsn=2 (last visited June 21, 2012).
[14] *See* Pereira, et al., *supra. See* Currie, et al., *supra.*
[15] 76 Fed. Reg. 19233 (April 6, 2011).
[16] 76 Fed. Reg. 19197 (April 6, 2011) ("Restaurant-type food is defined as 'food of the type described in the definition of 'restaurant food' that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment"); *see* FDA Guidance for Industry: A Food Labeling Guide, October 2009, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/UCM064904#away (last visited June 21, 2012) (FDA considers "processed and prepared" in a very broad fashion in the retail context: "To meet the criteria for being 'primarily processed and prepared on-site,' the food must be augmented on site in a manner that changes the nutrient profile of the food [i.e., filling, icing, enrobing]. Washing and garnishing with nuts, onions or seeds would fall under the definition of 'primarily processed and prepared' if the added foods change the nutrition profile of the finished product. Custom cakes are exempt . . . Foods which are not prepared on premises and that are portioned to consumer specifications on-site are not required to have nutrition labeling [e.g., 1 lb of potato salad; 2 lb cheese, 1 lb assorted cookies, 5 rolls]").
[17] 76 Fed. Reg. 19198 (April 6, 2011).
[18] *Id.*
[19] 76 Fed. Reg. 19197 (April 6, 2011).
[20] FMI Comments to FDA on Proposed Menu Labeling Rule 16 (July 5, 2011).
[21] 2011 Information Collection Budget of the United States (November 2011) http://www.whitehouse.gov/sites/default/files/omb/inforeg/icb/2011_icb.pdf (last visited June 21, 2012).
[22] 76 Fed. Reg. 19223 (April 6, 2011).
[23] Department of Health and Human Services, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis (March 2011). http://www.fda.gov/downloads/Food/LabelingNutrition/UCM249276.pdf (last visited June 21, 2012).
[24] FMI Comments to FDA on Proposed Menu Labeling Rule (July 5, 2011).
[25] *Id.*
[26] Dept. of Health and Human Services, Preliminary Regulatory Impact Analysis, *supra.*
[27] *See* 76 Fed. Reg. 19233 (April 6, 2011) ("*Restaurant or similar retail food establishment* means a retail establishment that offers for sale **restaurant or restaurant-type food** (emphasis added), where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment's primary business activity if the establishment

presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption or storage of food.")
[28] *See id.* ("Restaurant-type food is defined as "food of the type described in the definition of "restaurant food" that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment").
[29] FMI Comments, *supra.*
30 Exec. Order No. 13563 (January 18, 2011).
[31] *Id.*
[32] 76 Fed. Reg. 19223.
[33] 21 U.S.C. § 343(q)(5).
[34] *See Cannon v. University of Chicago*, 441 U.S. 677 (1979) ("It is always appropriate to assume that our elected representatives, like other citizens, know the law"); *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329 (1998) (quoting *Miles v. Apex Marine Corp.*, 498 U. S. 19, 32 (1990)) ("The Court presumes Congress is aware of existing law when it passes legislation").
[35] *See Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). *See also United States v. Ahlers, 305 F.3d 54, 60* (1st Cir. Me. 2002).
[36] *See Bailey v. U.S.*, 516 U.S. 137 (1995) ("If Congress uses one term in one place and a different term in another place, the court presumes that each term has a distinct meaning").
[37] *See U.S. v. Stanko*, 491 F.3d 408 (8th Cir. 2007) ("The term 'similar' indicates an intent to limit the business practices clause's reach to offenses which are 'comparable' or 'nearly corresponding' to the enumerated offenses").
[38] *See Plaut v. Spendthrift Farm, Inc*., 514 U.S. 211 (1995).
[39] *See ErieNet, Inc. v. Velocity Net, Inc*., 156 F. 3d 513 (3d Cir. 1998) (quoting *Pennsylvania Medical Soc'y v. Snider*, 29 F.3d 886, 895 (3d Cir. 1994)).
[40] 7 U.S.C. § 1638.
[41] *See* Sutherland Statutes §21.4, 7th Edition, Vol. 1A (2009) citing *U.S. v. Buckand*, 277 F. 3d 1173 (9th Cir. 2002) ("Although a heading is not part of a statute, it may be relevant to the legislative history if it was present in the bill during the legislative process"); *see also id.* citing *Lazaro v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1203 (M.D. Fla. 2001) ("Even though a section heading is not part of the law, it can aid interpretation when an ambiguity exists").
[42] 76 Fed. Reg. 19196.
[43] *See Brotherhood of R.R. Trainmen v. Baltimore & O.R. Co*., 331 U.S. 519 (1947).
[44] *See* Press Release, Senator Tom Harkin, "Harkin Introduces Restaurant Labeling Initiative" (June 8, 2006), http://harkin.senate.gov/press/release.cfm?i=256693 (last visited June 21, 2012) ("It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally in the dark when they go to a restaurant for dinner").
[45] *See* Senator Tom Harkin, "Statement of Senator Tom Harkin on Ruby Tuesday's Decision to Provide Nutrition Information" (April 27, 2004), http://harkin.senate.gov/press/release.cfm?i=256693 (last visited June 21, 2012), "[I]nformation is lacking in our restaurants. Even though consumers have ready access to nutritional information at grocery stores, they are left to guess and estimate when they go out to eat").
[46] *See Nat'l Woodwork Mfgs. Assn. v. NLRB*, 386 U.S. 612, 640 (1967) ("It is the sponsors that we look to when the meaning of the statutory words is in doubt" [quoting *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384 (1951)]); *NLRB v. St. Francis Hosp. of Lynwood,* 601 F.2d 404, 415 n. 12 (9th Cir.1979) ("[W]e would look to the language of the sponsors of the bill as being more demonstrative of the congressional intent rather than the other comments made on the Senate floor"). *See e.g. Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 178 (1989) (relying on the statement of the Age Discrimination in Employment Act sponsor, Senator Javits, when interpreting the statute).
[47] 155 Cong. Rec. S5522 (May 14, 2009) (statement of Senator Harkin).
[48] *Id.*
[49] "The measure was modeled after one that has already taken effect in New York City . . ."
http://www.foodconsumer.org/newsite/Politics/32/health_care_legislation_calories_restaurant_menus_2703100932.html
[50] *See e.g.* Sutherland Statutes §52.3; *Jamison v. Encarnacion*, 281 U.S. 635 (1930); *Taber v. Maine*, 45 F. 3d 598 (2d Cir. 1995).
[51] *See Overstreet v. North Shore Corp*., 318 U.S. 125 (1943).
[52] *Seatrain Shipbuilding Corp. v. Shell Oil Co*., 444 U.S. 572 (1980).
[53] Brian Elbel, et al., *Child and adolescent fast-food choice and the influence of calorie labeling: a natural experiment*, 35 International Journal of Obesity 493-500 (April 2011).
[54] Brian Elbel, et al., *Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City*, 28(6) Health Affairs 1110-1121 (October 2009).
[55] Tamara Dumanovsky, et al., *Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labeling: cross section customer surveys*, BMJ Research (July 2011).
[56] Bryan Bollinger, et al. *Calorie Posting in Chain Restaurants* (January 2010).
[57] Eric Finkelstein, et al., *Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington*, 40(2) American Journal of Preventative Medicine 122-127 (February 2011).
[58] Rosanna Mentzer Morrison, et al., *Will Calorie Labeling in Restaurants Make a Difference?* USDA Economic Research Service, Amber Waves, Volume 9, Issue 1 (March 2011).
[59] J.S. Downs, et al., *The Psychology of Food Consumption: Strategies for Promoting Healthier Food Choices*, 99(2) American Economic Review: Papers & Proceedings, 159-164 (2009).

[60] J.A. Yamamoto, et al., *Adolescent Fast Food and Restaurant Ordering Behavior with and without Calorie and Fat Content Menu Information*, 37 Journal of Adolescent Health 397-402 (November 2005).
[61] Progressive Grocer, 78th Annual Report of the Grocery Industry, April 2011; 2011 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains.
[62] FMI Comments to FDA on Proposed Menu Labeling Rule (July 5, 2011).
[63] Department of Health and Human Services, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis (March 2011).
[64] Exec. Order No. 13563 (January 18, 2011).
[65] *Id.*
[66] 7 C.F.R. pt. 60.
[67] 21 C.F.R. § 101.3.
[68] 21 C.F.R. § 101.105.
[69] 21 C.F.R. §§ 101.4.
[70] 21 C.F.R. § 101.17.
[71] 9 C.F.R. §§ 317.300-345 and 381.400-445.
[72] 21 C.F.R. § 101.22.
[73] 21 C.F.R. § 1.327.