The FDA's Menu Labeling Regulation: Promoting Change through Shock Value

Rachael Vieder
American University Washington College of Law
COMMENT:

THE FDA’S MENU LABELING REGULATION: PROMOTING CHANGE THROUGH SHOCK VALUE

Rachael Vieder*

I. INTRODUCTION

Chipotle offers a lot to consumers: sizeable servings, a variety of toppings, and a huge burrito bowl to cram in everything. While you may have been aware that you eat more than a couple of calories during this Mexican feast, soon you will be able to confirm exactly how calorie-packed your concoction was, compliments of the new national menu labeling regulation. This regulation attempts to address one of America’s biggest problems—weight. Seventeen percent of all children and adolescents in the United States are obese, an increase of 300 percent from the previous generation. In 2008, obesity-related medical costs for adults in the United States were estimated to be as high as $147 billion, and obese patients’ medical costs, on average, were $1,429 higher than the medical costs of individuals within normal weight ranges.

These staggering numbers have mobilized local and state governments to combat obesity and obesity-related medical costs through multiple types of legislation. One legislative approach that some states and communities have adopted is to require restaurants and other similar establishments to publish caloric and nutritional information about their food items in their menus. With these state and local legislative efforts, chain restaurants provide something more to their customers than sizeable servings and variety toppings: a daily dose of caloric-intake reality.

Aligned with these local efforts, the Patient Protection and Affordable Care Act (PPACA) provides the FDA with the power to regulate menu labeling in chain restaurants. Prior to PPACA, the Food and Drug Administration (FDA) regulated nutritional information printed on food product labels on most foods regulated by the FDA. Section 4205 of PPACA, “Nutrition Labeling of Standard Menu Items at Chain Restaurants,” expands FDA regulatory powers over food product labels to include food sold in certain chain restaurants. Specifically, Section 4205 requires restaurants and other similar establishments that are part of a chain with twenty or more locations to post the caloric content of menu items on menus and menu boards.

As the FDA prepares to publish and implement the final regulation on menu labeling, it is important that the agency address many of the concerns of industry and local and state government groups who are opposed to the new regulation and that it balance those concerns against the public health need to manage the obesity epidemic. This Comment addresses the new relationship between the FDA and the industries affected by Section 4205 and the proposed regulation. Part I provides the relevant background to the proposed regulation, including a brief history of the FDA, obesity issues facing the United States, the FDA’s draft guidance, and the industry’s response to the draft guidance. Part II briefly evaluates the key provisions of the proposed regulation. Part III examines the costs and benefits of the new regulation to the public, industry, and local and state governments and the best way to maximize the benefits and minimize the costs. Part IV concludes by suggesting that the FDA should promulgate a regulation that balances industry concern against the public health need for a useful menu labeling regulation.

II. BACKGROUND

The federal government has taken many steps to regulate different aspects of the food industry before this national menu labeling regulatory effort. From the passage of federal laws governing food manufacturing, to the creation of the FDA, and finally to PPACA, regulatory power over the retail food has steadily been on the rise.

* Rachael A. Vieder is a 2010 graduate of University of Maryland with dual Bachelor of Arts degrees in history and classical languages and literature. As a 2L at American University Washington College of Law, Rachael is dean’s merit scholar, an executive board member of the Moot Court Honors Society, and a senior staff member of the Administrative Law Review.
A. Brief History of the FDA and Nutrition Labeling

Congress passed the Food and Drug Act, or the Wiley Act, in 1906 after a public outcry over the terrible conditions of food product plants and resulting food contamination problems. In 1907, Congress created the Board of Food and Drug Inspection to enforce the Wiley Act; this body became the FDA in 1927. After reporters and consumer protection organizations lobbied for a stronger provision, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938. This law broadened the FDA’s regulatory power to include cosmetics and medical devices and increased the FDA's regulatory control over food products by granting the agency the power to inspect factories and use stronger enforcement tools against noncompliant plants. In the last twenty years, Congress has rapidly expanded the FDA’s authority through the Nutrition Labeling and Education Act of 1990 (NLEA), the Food Allergen Labeling and Consumer Protection Act (FALCPA), and PPACA. Whereas NLEA required that food products have labels, FALCPA expanded upon those requirements and mandated that food labels of food containing major allergens—e.g., peanuts, shellfish, milk—must state the allergen either in the ingredient list or in a statement. Although Section 4205 of the PPACA outlined the basic requirements of a national menu labeling regulation, many of the specific requirements remain for the FDA to decide. Each act gave the FDA increased power over the food industry, culminating with PPACA giving the FDA control over retail food disclosures.

B. Obesity in the United States

The proposed regulation’s goal is to encourage consumers to make more informed and healthier decisions by posting caloric content on menus. “Obese” and “overweight” are both terms describing unhealthy weight. An adult with a body mass index (BMI) between 25 and 29.9 is overweight, whereas an adult with a BMI over 30 is considered obese.

Obesity has been shown to trigger many significant medical conditions, including coronary heart disease; type 2 diabetes; cancer (endometrial, breast, and colon); hypertension; stroke; dyslipidemia; liver and gallbladder disease; sleep apnea; respiratory problems; osteoarthritis; and gynecological issues. Not surprisingly, obesity is one of the leading preventable causes of death. With the new regulation, the FDA has the chance to help consumers make informed decisions, offset the consequences of obesity in a minimally intrusive manner, and provide the industry with a single menu labeling standard to follow.

The FDA cited multiple reasons for the regulation including the public health and economic concerns related to obesity. These considerations were part of the basis for the “Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010.” After posting the draft guidance, the FDA received comments from different industry groups voicing concerns about the direction the FDA seemed to be taking with the menu labeling regulation.

C. The FDA’s Draft Guidance and the Industry’s Response

On August 25, 2010, the FDA first issued the draft guidance on Section 4205, disclosing to affected establishments the preliminary requirements and definitions of the forthcoming regulation. The overwhelming opposition from industry members regarding the draft guidance caused the FDA to change direction in favor of a notice-and-comment rulemaking process. Switching to notice-and-comment rulemaking from the draft guidance increased the likelihood of the industry affecting the regulation successfully and allowed a better platform for the industry to voice recommendations and critiques. The responses to the draft guidance expressed industry concerns, many of which resurfaced later in the notice-and-comment rulemaking comment period.

FDA then published a proposed regulation in the Federal Register on April 6, 2011 for notice-and-comment rulemaking. The proposed regulation detailed terms left open by Section 4205, including the categories of establishments and types of foods that are covered, instructions on how display caloric content, the language for a statement suggesting the daily recommended caloric intake, the availability of additional written nutritional information, and the regulation’s relationship to state and local laws. The comment period for the proposed rule closed July 5, 2011. The responses to the draft guidance came from many different industry representatives potentially affected by the proposed regulation. Comments focused on which establishments the regulation would cover. Many commentators advocated for the FDA to exempt their business from the regulation. Others concentrated on the need for flexible requirements and implementation standards. Comments also discussed the potential burden faced by small businesses and how an inflexible regulation places them at a greater disadvantage compared to their larger chain counterparts. Some of the other major concerns were the definitions of a serving size and requirements for custom and variable orders.

Industry representatives were not the only groups concerned with a national menu labeling regulation. The FDA received comments from state and local governments concerning how the FDA will implement such a sweeping regulation. Local health departments stated that the FDA must clearly communicate federal responsibilities for the regulation and work with local departments in order for the regulation to be effectively enforced. Local departments also expressed concerned about the economic costs of the enforcement requirements.

III. Key Provisions of the Proposed Menu Labeling Regulation

The FDA published the proposed menu labeling regulation on April 6, 2011. It defines many of the terms used in Section 4205 of the PPACA and expands upon these definitions to propose guidelines for affected establishments to follow.

A. Definitions

The proposed regulation defines a covered establishment as (1) a restaurant or similar retail establishment (2) that is part of a chain
with twenty or more locations and (3) offers substantially the same menu items.\textsuperscript{45} An establishment must meet all three requirements to be subject to the requirements of the regulation.\textsuperscript{46} The regulation clarifies that the term “similar retail establishment,” which was hotly contested by industry members,\textsuperscript{47} refers to a place that “offers for sale restaurant or restaurant-type food and its primary business activity is the sale of food to consumers.”\textsuperscript{48} The FDA defines “primary business activity” as either: (1) the establishment presents itself as a restaurant or (2) greater than 50 percent of the establishment’s gross floor area is used for the preparation, service, or consumption of food. The proposed regulation covers grocery stores, convenience stores, chains within larger establishments, multipurpose establishments that present themselves as restaurants, among others.\textsuperscript{49} Adding coverage for chains within establishments includes outlets such as a Starbucks franchise within a Barnes & Noble or fast food chains inside a Walmart under the regulation.\textsuperscript{50}

The FDA filled a potential loophole by specifically including chains within larger establishments. This helps ensure that consumers get the necessary information at every covered establishment. The FDA responded to the comments it received, acknowledging that some commenters desired the inclusion of concession stands, amusement parks, stadiums, and similar venues while others hoped the regulation would be more limited and would exclude establishments selling prepared food.\textsuperscript{51} The agency took a moderate stance, siding with neither extreme in the debate, and reasoned that Section 4205 is not meant to cover all establishments that sell food, but establishments where the “primary business activity” is selling food.\textsuperscript{52}

\textbf{B. Requirements}

The proposed regulation outlines the requirements that a covered establishment must abide by. These requirements include the categories of food covered under Section 4205, the types of information that must be declared, and the compliance standards for self-service food and food on display. Although many of the proposed definitions fulfill PPACA’s basic requirements, some of the regulatory provisions may exceed the FDA’s authority.

\textit{i. What Foods Are Covered under Section 4205}

The proposed regulation defines “covered food” as any item that is a standard menu item or a condiment with more than ten calories per serving.\textsuperscript{53} The FDA defines a “standard menu item” as a “restaurant or restaurant-type food that is routinely included on a menu or a menu board or that is routinely offered as a self-service food or food on display.”\textsuperscript{54} Surprisingly, the proposed regulation focuses less on what foods the requirements will actually apply to and more on what foods will be exempt from the regulation.

The FDA determined that Section 4205 only applied to certain foods and does not pertain to items not listed on a menu or to items offered as daily specials, temporary items, or custom orders.\textsuperscript{55} A “temporary menu item” is defined as an item offered on a menu for less than sixty-days per year, which are not required to be consecutively.\textsuperscript{56} The regulation defines a “custom order” as a food prepared in a specific manner based on the customer’s request,\textsuperscript{57} such as when a customer orders the covered establishment’s standard BLT sandwich but requests that lettuce not be added. Excluding certain menu items helps the industry immensely because of the costs associated with changing the menu every time there is a temporary item. Menu changes and nutritional formula identifications consume business resources that may be used elsewhere to enrich the customer’s experience.\textsuperscript{58} The proposed regulation also tentatively states that the labeling requirements would not apply to alcoholic beverages because the FDA read Section 4205 as not intending to cover alcoholic beverages.\textsuperscript{59} Another area of focus is the information a covered establishment must declare for covered food items.

\textit{ii. Information That Must Be Declared}

The FDA proposes a strict rule regarding the caloric declaration that must be on menus and menu boards. Caloric declarations must: (1) be in the same color or a color as conspicuous as the menu item; (2) have the same contrasting background as the background used for the menu item; and (3) be “clear and conspicuous” and in a font that is not smaller than the associated menu item.\textsuperscript{60} The caloric declaration must be to the nearest five-calorie increment up to and including fifty calories, then to the nearest ten-calorie increment after fifty calories.\textsuperscript{61} The term “calories” or “cal” must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item.\textsuperscript{62}

The FDA proposes that covered establishments must provide a caloric range for items that come in different flavors, varieties, or combinations. An example of a variable item is a pizza with multiple topping choices.\textsuperscript{63} The FDA recognizes that calorie ranges may be wide for these types of items and that it is impractical to require establishments to provide exact information for every possible combination.\textsuperscript{64}

Section 4205 also requires a statement describing suggested daily caloric intake.\textsuperscript{65} This statement helps anchor and contextualize the individual caloric determinations on menus and menu boards. The FDA provides that the statement should say, “a 2,000 calorie daily diet is used as the basis for a general nutrition advice; however, individual calorie needs may vary.”\textsuperscript{66} The statement, like the posted caloric content, must be on the menu or the menu board in a font size no smaller than the smallest type for any caloric declaration and follow the same color requirements as the caloric declarations.\textsuperscript{67} The next major area that the proposed regulation focuses on is self-service food and food on display.

\textit{iii. Self-Service Food and Food on Display}

The proposed regulation has a specific section dedicated to describing requirements for self-service food and food on display.\textsuperscript{68} The covered establishment must provide caloric information adjacent to each offering.\textsuperscript{69} Where the establishment has a sign with the name of the item or the price or both, the caloric determination must appear on this sign.\textsuperscript{70} The caloric declaration needs to be either per item or per serving for food on display or self-service food that is not a single item.\textsuperscript{71} Self-service and display items that also appear on menu boards must comply with the other menu and menu board regulations,\textsuperscript{72} imposing additional strain on establishments.
to fulfill those provisions. An area that the proposed regulation did not discuss in great detail, surprisingly, was the compliance and enforcement requirements for the regulation after its effective date.

C. Compliance and Enforcement

The regulation briefly addresses the effective date along with compliance and enforcement. The proposed effective date for the regulation is six months from the time of its publication. Any failure to comply with the regulation will render the food misbranded under multiple sections of the FDCA. The FDA does not state how it will implement the regulation, but instead looks to the forthcoming comments for suggestions about what would be the most effective method.

PPACA states that the covered establishment “shall have a reasonable basis for its nutrient content disclosures.” The FDA accordingly proposed that a compliant establishment will adhere to a standard where particular nutritional content, including sugar and trans fat, may not be in excess of 20 percent of the declared amount where as other elements, such as protein and fiber, must not be less than 80 percent of the declared value. Establishments must also provide the FDA with “substantiation documentation” to prove that all nutrient disclosures are not false or misleading and have a reasonable basis. Although implementing a menu labeling regulation may seem simple, it has the potential to have a huge impact on multiple sectors of society.

IV. POTENTIAL IMPACT OF THE MENU LABELING REGULATION

This regulation will influence many different groups—the public, the food industry, and local and state governments. Each group has different interests and will likely be both negatively and positively affected by the regulation. An examination of the benefits and costs to each group demonstrates why the FDA should be careful to follow PPACA’s intent and not to overregulate.

A. Costs and Benefits to the Public

Menu labeling laws are one public policy effort employed to combat the obesity epidemic. The theory behind menu labeling laws is supported by studies showing that consumers use food labels on packaged foods to make informed decisions. Currently Americans spend around 48 percent of their food budgets on restaurant foods. Since Americans spend so much of their income and nutritional intake on restaurant foods, menu labeling is a critical step toward informing consumers about what they are truly ordering.

Even before the proposed regulation, retail food chains responded to the forthcoming FDA regulation by adding new, healthier menu items. Although consumers may feel that they have a fair idea of what they are consuming, 90 percent of people, including professional nutritionists, underestimate the caloric content of restaurant foods. Although an individual should be responsible for his or her own choices, it is impossible to expect individuals to choose responsibly if even professional nutritionists do not really know the calorie content of restaurant items. A national menu labeling regulation will hugely benefit consumers by allowing them to know what they are consuming.

The FDA stated that the regulation should be formatted in a manner that is most useful to the consumer and thus based many of the definitions on the consumer's vantage point. By requiring specific font, font sizes, and information placement on the menus, the FDA strived to make the information useful and visible to consumers. Having those provisions helps ensure that a covered establishment actually presents the required information to consumers in a visible and reasonable manner and is less able to hide any undesirable information.

Despite the many positive implications for consumers, there are also a few drawbacks to a national regulation. Not everyone wants caloric information thrown in their face everywhere they go eat. Consumers have many restaurant choices and can choose to frequent an establishment that is known for healthier food. Although the regulation has good intentions, it allows the government to become a disciplinarian, forcing the industry to present certain facts and acting as if consumers will recognize the information and automatically use it to their best advantage, thereby solving the obesity epidemic. Without concrete evidence showing that this kind of measure will help the obesity epidemic, and therefore offset the costs of compliance, the regulation may just work to divert personal responsibility for healthy choices.

Further, acquiring nutritional information can be time consuming and costly. The added costs may deter covered establishments from adding new menu items. For each new item, a restaurant has to run the original nutritional analysis, examine the analysis, potentially change the item formula to make the nutritional analysis appear in a better light, reanalyze the changed item, and then rework the menu or menu board to add the new item and accompanying disclosure. Just one round of this process makes the restaurant pay for nutritional analysis and menu redesign. A large chain restaurant may not want to allocate funding for this extended process, let alone a smaller business that falls under the regulations scope. Given all of the potential costs associated with adding new items, the costliness of menu labeling may deter covered establishments from adding new items, and in turn, give consumers fewer options.

The nutritional analysis and menu redesign costs may also result in consumers having fewer restaurant options. Establishments that are currently below the twenty establishment threshold may not be able to expand their business because of the new costs imposed on establishments with twenty or more locations. Establishments also may strive for the competitive edge by adding new items, but for some, especially the smaller businesses affected by the regulation, the additional costs may make that competitive edge unattainable. Covered establishments will absorb most of the costs of the regulation, and the inability for some of these establishments to expand will result in consumers having fewer new retail food establishment options.

18

Health Law & Policy Brief
Finally, the posted caloric information may be misused by consumers, destroying the effectiveness of the regulation. Instead of using the information as a way to cut down on caloric intake at meals, consumers may think they can eat the high caloric meal in the covered establishment and “cut back” at other points in the day. The menu labeling information is only a guide, and if not used properly, the regulation will address neither the public health nor economic concerns related to food consumption. Industry members will also face the double sided aspects of the regulation.

B. Costs and Benefits to the Industry

A benefit of the proposed regulation for the industry is that there will be a uniform regulation as opposed to many different local and state initiatives. Once the regulation becomes effective, it will preempt any current local and state initiatives. In some cases, the national regulation may also be more lenient than the current local or state initiatives, giving the covered establishment a lower bar to meet. State laws show that there is a movement toward menu labeling regulations and a national regulation brings the benefit of uniformity across state lines.

Conversely, industry members will face the costs of the initial nutritional analysis and then the additional costs of maintaining accurate nutritional disclosures as to not misbrand foods. After running the initial analyses, managers must inform restaurant staff of nutritional contents so that cooks are preparing the food in accordance with disclosures. Later, covered establishments will have to deal with food suppliers reformulating products, which may affect the accuracy of the restaurants’ disclosures. Any food supply changes will require extra maintenance analysis and accompanying costs. Accounting for the cooks and food suppliers adds another layer of complexity for industry members striving to comply with the regulation.

The industry desired flexibility, and the proposed regulation did not strongly reflect a flexible standard. Inflexible standards may hurt the overall effectiveness of the regulation because establishments will have a difficult time complying, which may slow the process of getting the consumer the desired information. Small businesses, such as franchise owners who control only a few locations, may be particularly burdened by an uncompromising regulation. While the parent company may have enough capital to cover expenses, smaller franchise owners do not have the same pool of money to draw from.

Further, the regulation may not even properly address the obesity issue; there is no conclusive evidence on whether menu labeling has an effect on consumer purchases. The regulation places the responsibility of informing customers on the retail food industry as opposed to making the individual responsible for researching desirable information that is not readily available. State and local governments, in addition to industry members, will also bear much of the costs.

C. Costs and Benefits to State and Local Government

A national menu labeling regulation places a great burden on local and state governments. Currently, the FDA does not have a plan for implementing the regulation; this could be particularly distressing to local and state entities that will be the frontline enforcers of the new regulation. The more time the FDA takes to decide on an implementation and enforcement plan, the less time local entities have to adjust and prepare for the influx of work they will take on in connection with the menu labeling regulation. Once a plan is in place, communication will be key to smoothing out implementation and enforcement of the regulation. The FDA must clearly describe to local branches what their role will be during this process. All protocol relating to inspections and violation reports must be easily understandable to any agent enforcing the regulation. Local and state governments will also need contact information and a clear guide on how to report covered establishments in noncompliance. Personnel issues may also become a problem for these branches because sending out inspectors not only costs additional time and money, but also redirects current staff members from other necessary tasks. Because state and local governments are currently dealing with revenue shortfalls, these entities may not have the finances to keep up with a national menu labeling regulation without solid federal support. Financing is a central concern, and without FDA funding, these local groups may experience financial difficulty and be understaffed.

D. Maximizing Benefits and Minimizing Costs

Overall, the FDA should closely follow the spirit of Section 4205 to keep industry members from becoming overburdened, maintain the integrity of the regulation for the public, and not over regulate. The FDA should not include “primary business activity” in the final definition of a covered establishment because by adding that language, the FDA exceeds the authority given in PPACA and acts against congressional intent. The language in PPACA makes no mention of “primary business activity” or any other defining quality related to the business’s revenue or gross floor area. Using “primary business activity” further complicates implementing the regulation because borderline covered establishments may dispute their primary business activity. By taking out “primary business activity,” the regulation is clearer, regarding the meaning or implication of “primary business activity.”

Further, the FDA ought to cover certain establishments currently exempt from the proposed regulation, including amusement parks, movie theaters, and other similar venues. Based on the regulatory definition of “similar retail establishment,” promulgating a regulation that omits amusement parks and movie theaters contradicts the FDA’s own definition and the intent behind PPACA. Amusement parks and movie theaters have food offerings similar to other covered establishments, including candy, hot dogs, and nachos. Removing the “primary business activity” aspect, amusement parks and movie theaters fit under the definition of similar retail establishment. From the consumer standpoint, it is equally important to know what a person is consuming at a convenience store as at a movie theater. Although industry members may have selfish reasons behind the desire to have these other establishments included under the regulation, the regulation should place all restaurants and like
establishments on an even footing for the sake of uniformity and effectiveness. By cutting down on the number of exceptions, the regulation is simplified and the public is acquiring the necessary caloric knowledge at every appropriate venue.

The FDA correctly exempted alcoholic beverages from the proposed regulation and should keep that exemption in the final regulation because the only beverages included in Section 4205 are related to self-service beverages located in a self-service food area.\textsuperscript{100} Whereas individuals can purchase fountain sodas of different serving sizes in self-service locations, alcoholic beverages generally are not purchased in the same way. While Section 4205 does not limit covering alcoholic beverages, the regulation does not specifically mention alcoholic beverages nor indicate intent to cover them. The specific exclusion of alcoholic beverages from Section 4205 is indicative of congressional intent that the regulation should not cover alcoholic beverages, and the FDA correctly followed that intent.\textsuperscript{101}

Additionally, the FDA should reconsider the placement requirement for “calories” or “cal” because while the strict placement requirement may be a good idea in theory, it may ultimately hurt the effectiveness of the disclosures.\textsuperscript{102} Menus and menu boards, depending on how they are redesigned, may look overcrowded and actually detract from the useful purpose of the regulation. It is up to the industry to deal with redesigning menus to include the menu items and caloric disclosures, but it may be more practical to have another method to indicate the caloric content of each item. Instead of the current plan, the FDA should consider having a requirement where next to each menu item is the caloric content, and instead of having “calories” or “cal” by each menu item, putting a unique symbol next to the number. Then, with the same font, type, and size requirements of the disclosure statement, there should be a statement that explains the symbol and how the number and symbol together represent how many calories are in the menu item. If the FDA were to adopt this method, the agency must explain detailed requirements for this system to ensure that establishments do not try to escape noting caloric disclosures. This method still allows for an informed consumer while keeping menus from becoming overcrowded.

The proposed FDA menu labeling requirements for self-service food present even more difficulties than the requirements for menu items located on a regular menu or menu board. Similar to restaurant menus,\textsuperscript{103} requiring that all signs adjacent to menu items contain “cal” and the caloric amount may make the signs overcrowded and confusing instead of illuminating for consumers. Increasing the size of the sign to accommodate all the information creates an even more crowded display and may puzzle a consumer quickly grabbing food. Comments also show concern over these requirements.\textsuperscript{104} The suggestions in the comments, using handouts or information placed in other areas, are not workable options because these methods would allow the information to be too easily missed. If the establishment is just required to set out a handout or have the information on a door, the consumer may easily miss the declaration, defeating the entire purpose of the menu labeling regulation.

Accordingly, the FDA should follow a similar standard for self-service items as it does for restaurant menus and post the caloric declaration with a symbol next to it. There should be highly visible signs by each declaration explaining the number and symbol. The FDA ought to mandate strict requirements for this labeling method to ensure that consumers see the declaration and know what it means.\textsuperscript{105} This method is also helpful to covered establishments because menus and signs are less crowded and compliance is more easily achievable.

In addition, comments about the proposed rule show that six months is not long enough for the industry to comply.\textsuperscript{106} The FDA needs to extend the effective date to at least one year in order for restaurants to have the appropriate amount of time to cope with the new burden. Compliance requires that covered establishments possibly analyze all of their menu items, rework all menus and menu boards, and deal with any extra issues that come up for drive-thru menus. Six months is not a reasonable timeframe to accomplish all of these requirements and become fully compliant. Covered establishments should have enough time to comply with the regulation; this benefits the industry and consumers by allowing time to produce clear menus that incorporate the disclosure requirements.

Also, many of the comments suggested different ways for the FDA to enforce the regulation fairly and effectively.\textsuperscript{107} The suggestions offered by the comments are a suitable basis for the FDA’s enforcement policy and the FDA should base the enforcement policy on those suggestions. There should be a tiered system, including warnings, minor infractions, and serious violations. The FDA should use fines, and if the violation is particularly egregious, the FDA should be able to temporary close a covered establishment that failed to comply. By having a system with different violation definitions and corresponding punishments, the FDA can fairly enforce against multiple covered establishments with differing violations according to their egregiousness. Misbranded food\textsuperscript{108} is a serious violation, and establishments with minor violations should be given a chance to correct their errors before paying serious fines or other potential punishments.

**V. CONCLUSION**

The FDA has had an increasing influence over the retail food industry and the nation’s obesity epidemic provides another justification to further expand the agency’s power. Throughout the process of creating the menu labeling regulation, the FDA presented ideas and received feedback from many sources, including the industry and other groups most affected by the regulation. The FDA took the middle road with respect to many parts of the new regulation and sidestepped industry concerns when necessary. While the industry hoped to influence the regulation, and did in some areas, it is important that the FDA maintained true to the purpose of the regulation and did not overly give in to industry concerns.

Examining the costs and benefits of the proposed regulation shows many of the different groups affected, the positive and negative aspects of the proposed regulation, and areas where the FDA can improve the regulation. Menu labeling in theory is a good idea; it
gives consumers additional knowledge about what they are eating and may spur covered establishments to offer more health conscious choices. However, it also puts a heavy financial burden on the industry, and there is still little concrete evidence that menu labeling will help with the obesity epidemic.

The FDA should finalize the regulation with both the consumer and industry in mind by fulfilling congressional intent but not overburdening the industry with extremely costly requirements that are difficult to implement. Consumers still need to be responsible for their own health choices, and the most that should be expected of covered establishments is that they provide accurate information for a consumer to use.

4 E.g., CAL. HEALTH & SAFETY CODE § 114904 (WEST 2010) (requiring food facilities with nineteen or more facilities under common control to put the caloric content of the menu items on their menus); NEW YORK CITY, N.Y., HEALTH CODE TIT. 24 § 81.50 (2008) (restaurants with fifteen or more outlets nationwide must conspicuously post the nutritional content of each item on their menus); Vt. STAT. ANN. TIT. 18 § 4086 (2011) (restaurants and similar food establishments that are part of a chain of twenty or more locations offering substantially the same menu items must disclose on the menu or menu board the caloric content adjacent to each item and a succinct statement concerning daily caloric intake).
7 See Patient Protection and Affordable Care Act § 4205 (outlining that the requirements will affect restaurants or similar retail establishments that are parts of a chain with twenty or more locations doing business under the same name and offering for sale substantially the same menu items and stating that not later than 1 year after the enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause).
8 See id.
9 See generally Christine Cusick, Comment, Menu labeling Laws: A Move from Local to National Regulation, 51 SANTA CLARA L. REV. 989 (2011) (discussing the possible legal barriers regarding menu labeling laws including free speech, equal protection, and preemption).
11 The obesity epidemic just adds another layer of justification for increasing the FDA’s control over the food industry. See generally Lauren Slive, Note, Closing the Kitchen? Digesting the Impact of the Federal Menu Labeling Law in the Affordable Care Act, 22 U. FLA. J.L. & PUB. POL’y 255, 256-97 (2011) (purporting that allowing the FDA expanded regulatory power over restaurant nutrition labeling will help to effectively combat the obesity epidemic).
13 See id. (giving the government the authority to prevent the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and regulate traffic therein).
14 See Peter Barton Hutt, Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction, 45 FOOD DRUG COSM., L.J. 17, 17–18 (1990) (explaining the how the FDA was formerly known by different titles before it became the “FDA”).
16 See id. (giving the FDA authority to oversee the safety of food, drugs, and cosmetics and defining what is a drug, device, cosmetic, labeling, food additive, and other relevant terms mean in context of the FDA’s authority).
17 See Nutrition Labeling and Education Act of 1990, supra note 6 (giving the FDA authority over nutrition labeling but exempting the restaurant industry).
18 See Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108–282, 118 Stat. 282 (2006) (codified in scattered sections of 21 U.S.C.) (requiring that “a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation”).
19 See Patient Protection and Affordable Care Act, supra note 5 (amending NLEA provisions and extending nutrition labeling to restaurant and similar retail establishment foods).
20 See Nutrition Labeling and Education Act of 1990, supra note 6 (providing the FDA with specific authority to require nutrition labeling on most foods regulated by the Agency).
22 See Patient Protection and Affordable Care Act, supra note 5 (giving the Secretary one year to promulgate proposed regulations to carry out § 4205).
23 See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,202 (Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11 and 101) (explaining that these disclosure requirements will assist consumers in making healthier dietary choices); see also CDC, Obesity, Halting the Epidemic by Making Health Easier – At A Glance 2011, http://www.cdc.gov/chronicdisease/resources/publications/aag/obesity.htm (last visited June 24, 2011) (detailing the costs of obesity which supports the nation’s need to reduce obesity rates and this regulation).
24 Id. BMI is a measure of body fat based on a person’s weight and height. A 5’7 person weighing between 159 lbs. – 190 lbs. would be overweight. The same 5’7 person weighing 198 lbs. or greater would be considered obese. See U.S. Department of Health & Human Services, Body Mass Index Table 1, http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm (last visited April 24, 2012).
26 See WEIGHT-CONTROL INFORMATION NETWORK, NAT’L INST. OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK), Overweight and Obesity Statistics, (June 13, 2011), http://wiv.niddk.nih.gov/statistics/ (estimating that obesity is associated with over 162,000 deaths per year from cancer, cardiovascular diseases, and other diseases); Promoting Healthy Lifestyles: Obesity, American Medical Association (last visited July 14, 2011), http://www.ama-assn.org/a ma/pub-physician-resources/public-health/promoting-healthy-lifestyles/obesity/page (stating that obesity kills more than all cancer, AIDS, and all accidents combined). But cf., Katherine M. Flegal et al., Excess Deaths Associated with Underweight, Overweight, and Obesity, 293 JAMA 1861, 1865 (2005) (discussing how estimated deaths based from obesity is full of variables and the study found that there were less deaths attributed to obesity than previous thought).
27 Cf. David S. Ludwig, MD, Ph.D., State Intervention in Life-Threatening Childhood Obesity, 306 JAMA 206, 206–07 (2011) (suggesting that parents should lose custody of children who are extremely obese because poor parenting led to children with serious medical problems).

28 See CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, OFFICE OF REGULATIONS POLICY AND SOCIAL SCI., FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS NOTICE OF PROPOSED RULEMAKING (Mar. 2011) (recognizing that the regulation will potentially have an economic impact on small businesses, chain retail food and similar establishments, supermarkets, convenience stores, and restaurant franchises). See also Obesity Related Statistics in America, Get America Fit Foundation, http://www.getamericafit.org/statistics-obesity-in-america.html (last visited July 14, 2011) (citing statistics such as $62.7 million spent on doctor visits and $39.3 million workdays lost due to obesity-related problems).


30 See id.

31 Cf. Draft Guidance for Industry; Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance, 76 Fed. Reg. 4,360 (Jan. 25, 2011) (stating that withdrawing for the full note-and-comment rulemaking process will minimize uncertainty and confusion for all parties); see also discussion infra Section II.C. (discussing the various groups that responded and their negative responses).

32 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 22, at 19, 192.

33 See generally id. (detailing the FDA’s definitions of the basic provisions of § 4205).

34 See id.

35 E.g., Comments of signing members, Food Marketing Inst. (FMI), Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (April 6, 2011), http://www.regulations.gov/#/documentDetail?D=FDA-2011-F-0172-0495 (advocating that FDA exceeds its authority by regulating operations within a retail food establishment unless the whole establishment is similar to a restaurant and Congress did not intend to regulate supermarkets); Comments of The Nat’l Connection for Local Pub. Health (NACCHO), Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 6, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0318 (urging the FDA to consider the effect the regulation will have on local and state health departments).

36 E.g., Comments of Randy Davis, Senior Vice President of Gov’t Relations & Safety Servs., Int’l Ass’n Of Amusement Parks And Attractions (IAAPA), Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0338 (advocating that amusement parks should not be included under covered establishments); Comments of FMI, supra note 35 (discussing how the supermarket industry was not intended to be included under the regulation).

37 Compare Comments of Lori Otto Punke, Director, Government and Civic Affairs, Starbucks Coffee Co., 75 Fed. Reg. 39,206 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0337 (recommending flexibility regarding the format and location of the suggested daily caloric intake statement, the required font size and type of the caloric listings on the menu, and the location of nutritional brochures), with Comments of John D. Barker, Senior Vice President and Chief Comm’r Officer, Wendy’s Arby’s Group, Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0330 (suggesting the FDA not require a specific font size for caloric disclosures and allow ample time to fix outdoor menu boards so they comply with zoning laws).

38 See Comments of FMI, supra note 35 (presenting the potential regulatory financial burden on small businesses); accord Comments of Sam Graves, Ranking Member of the Small Bus. Comm., U.S. H.R., Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0359 (urging the FDA to allow flexibility for small businesses trying to comply with any national menu labeling regulation because of the associated costs).

39 Compare Comments of Starbucks Coffee Co., supra note 37 (suggesting that the regulation should not have the same strict requirements because Starbucks offers over 87,000 kinds of custom drinks), and Comments of Julie Fields, Dir., Govt. Relations, Nat’l Assoc. of Convenience Stores (NACS), Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0329 (suggesting that the regulation should consider convenience store food like a custom order rather than a variable item because customers tend to specifically tell store employees how to prepare the individual food), with Comments of the Pizza Indus. Coal., Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0336 (suggesting that the definition of a serving size should be provided by the slice because consumers typically do not eat an entire pizza at one time and need to be able to calculate nutritional intake for what they consume).

40 See, e.g., Comments of NACCHO, supra note 35 (voicing the concerns of the nation’s local health department regarding the national menu labeling regulation).

41 See id. (citing the potential for conflict with a national regulation because the regulation will replace local provisions and the local health departments will be responsible for ensuring a smooth transition).

42 See id.

43 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 23, at 19,192.

44 See generally Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 23 (explaining the proposed definitions and requirements fulfilling § 4205).

45 Id. at 19,195.

46 Id.

47 Compare Comments of Randy Davis, IAAPA, supra note 36 (discouraging the inclusion of amusement parks under the regulation and specifically noting the franchise requirements), and Comments of Erik R. Liberman, Regulatory Counsel, FOOD MKTG. INST. (FMI), Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0343 (advocating that supermarkets should be exempt from the law because the legislative history does not support that supermarkets should be regulated), with Comments of Joseph B. Perea, Vice President and Gen. Counsel, Drury Hotels, Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010), http://www.regulations.gov/#/documentDetail?D=FDA-2010-N-0298-0352 (requesting that hotel chains be exempt from the regulation).

48 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 23, at 19,196.

49 Id. at 19,197.

50 Id.

51 Id. at 19,196 (discussing the comments the FDA received regarding what establishments should be covered and why the FDA chose to go with what is listed in the proposed regulation); see Comments of Judith Thorman, Int’l Franchise Ass’n, FDA-2011-F-0172 (Proposed Rule: Nutrition
Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (76 Federal Register 19192 (April 6, 2011)), http://www.regulations.gov/#/documentDetail;D=FDA-2011-F-0172-0395 (stating that the IFA believes that the regulation arbitrarily excludes certain kinds of establishments that sell "restaurant-type" food and that the exclusion is contrary to public policy goals); Comments of Tom Harkin, Sen., FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), (on file with author) (writing that the proposed definition is narrower than Congress intended because the phrase "and similar retail establishments" was specifically used to ensure that not just restaurants were affected. Congress intended for PPACA to have a broad aim and not confined to establishments that primarily sold food). Contra Comments of Lisa Mullings, NATSO, FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), http://www.regulations.gov/#/documentDetail;D=FDA-2011-F-0172-0467 (agreeing that the definition of covered establishments should be limited by the primary business activity).

52 See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,197 (disclosing the primary business activity aspect is important because primary business activity evidences a retail food chain or similar establishment and not an establishment that just happens to sell food).

53 Id. at 19,204–05 (reasoning that a condiment with more than 10 calories per serving has an effect on the overall nutrition of the menu item).

54 Id. at 19,204.

55 See id. at 19,205 (defining each term and stating why they are not included under the regulation).

56 Id.

57 Id. at 19,204.


59 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,203.

60 Id. at 19,206.

61 Id. at 19,207; if the caloric content of an item was 4 calories, the restaurant must post the caloric content as 5 calories and if the caloric content were 53 calories, then restaurant must post the caloric content as 50 calories.

62 Id. at 19,206.

63 See id. at 19,207 (giving an example such as milkshakes or self-made sandwiches or pizza).

64 See id. at 19,209 (asking for comments on whether this method is appropriate and not misleading); see also Comments of the PIZZA INDUS. COAL. (Sept. 7, 2010), supra note 39 (describing how there are thousands of ways to order a single pizza).

65 See Patient Protection and Affordable Care Act, supra note 5 (stating that there must be a statement but the specifics will be decided by the Secretary through the proposed menu labeling regulation).

66 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,210.

67 Id.

68 Self-service refers to buffet style, whereas food on display includes salad bars, cafeterias, and establishments such as delis. In the latter, the customer sees the food, but a food-service employee puts together the meal and serves it to the customer.

69 Id. at 19,215.

70 Id.

71 Id.

72 Id.

73 Id. at 19,219.

74 See The Federal Food, Drug, and Cosmetic Act of 1938, supra note 15 (listing the specific provisions regarding misbranded food and that noncompliance will be handled under those regulations).

75 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,220 (giving a general call for comments on how to implement the regulation).

76 See Patient Protection and Affordable Care Act, supra note 5 (namimg that a reasonable basis includes nutrition databases, cookbooks, laboratory analyses, and other reasonable means).

77 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,218.

78 Id. at 19,219.


80 See id. (citing multiple studies that researched the eating habits of the general public and how the public has increased the frequency they eat out of their homes).

81 E.g., Lisa Jennings, BJ's the Latest to Go Low-Cal, NATION'S RESTAURANT NEWS (May 9, 2011), http://www.nrn.com/article/bj%E2%80%99s-lates go-low-cal (citing the retail food chain BJ's as one chain that started offering more lower calorie items after the announcement of a pending FDA menu labeling regulation); Restaurants Redo Menus Ahead of New Regulations, NACSONLINE (June 24, 2011), http://www.nacsonline.com/NACS/News/ Daily/Pages/ND0621144s.aspx (reporting that retail food chains across the nation are adding more lower calorie items before the menu labeling regulation goes into effect).

82 Pomeranz, supra note 79, at 1578.

83 See FDA Proposes Menu Labeling Regulations, UPI.COM (April 1, 2011), http://www.upi.com/Health_News/2011/04/01/FDA-propses-menu labeling-regulations/UPI305431301720715/ (describing how consumers do not realize that appetizers may have over 1,000 calories and movie theaters serve 400-calorie drinks).

84 See generally Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1 (introducing the regulation and explaining certain requirements as needed for the consumer's benefit).

85 Id. at 19,206; See discussion, supra Section III.B.ii. (discussing the declaration requirements for menus and menu boards).


87 See generally William H. Dietz & Alicia S. Hunter, Legal Preparedness for Obesity Control and Prevention: The Public Health Framework for Action, 37 J.L. MED. & ETHICS 9, 9–11 (2009) (summarizing the early public policy efforts employed by the national government to combat obesity with a focus on the CDC’s efforts); Demetrios L. Kouzoukas, Legal Preparedness for Obesity Prevention and Control: The Structural Framework and the Role of Government, 37 J.L. MED. & ETHICS 24, 26 (2009) (listing three areas that must be kept in mind while formulating any national agenda: (1) preventing obesity also requires decisions about personal behavior, (2) open markets express collective individuals’ opinions, and (3) obesity is not like smoking and the same avenues cannot be used for both).

88 See Anita Jones-Muller, How to Tackle Menu Labeling, Nation’s Restaurant News (Mar. 28, 2010), http://www.nrn.com/article/how-tackle menu-labeling (listing that costs can range from $5,000 to $35,000 for a menu, depending on the number of items on the menu and the complexity of the items); Julie Steurgeon, QRSR ponder Cost of Menu labeling Laws, QRWeb.c om, http://www.qrweb.com/article/102239/QRSRs-ponder-cost-of menu-labeling-laws (describing the costs and challenges of implementing a
nation—wide menu labeling system).


90 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19, 193.

91 E.g., CAL. HEALTH & SAFETY CODE § 114904, supra note 4 (outlining the more encompassing requirements of the California menu labeling law which affect chains of nineteen or more).

92 See Robert Wood Johnson Foundation, Menu Labeling: Does Providing Nutrition Information at the Point of Purchase Affect Consumer Behavior?, http://www.rwjf.org/pr/produce.jsp?id=45408 (last visited July 5, 2011) (summarizing that some sources found that menu labeling information led to consumers choosing healthier items while other sources found that some population subgroups, such as college men, may use it to get higher energy meals, and finally summarized the need for studies on the impact of diverse demographic groups); accord Tamara Schulman, Comment, Menu Labeling: Knowledge for a Healthier America, 47 HARP. J. ON LEGIS. 588, 598 – 602 (2010) (discussing a New York study that compared the use of menu labeling in New York City and in Newark, New Jersey and stating that the results were inconclusive and potentially flawed because the study was too short ranged and the subjects were biased because they already ate at fast-food restaurants); compare Lisa J. Harnack & Simone A. French, Effect of Point-of-Purchase Calorie Labeling on Restaurant and Cafeteria Food Choices: A Review of Literature, 5 INT’L J. OF BEH NUTR. & PHYSICAL ACTIVITY, 51 (2008), available at http://www.ibjnpa.org/content/5/1/51 (concluding that more research is needed on the subject because of mixed findings and that there needs to be larger studies that examine various demographics in more areas of the country), and Tamara Dumanovsky et al., Consumer Awareness of Fast-Food Calorie Information in New York City After Implementation of a Menu Labeling Regulation, 100 AM. J. OF PUB. HEALTH 2520, 2520 (2010) (concluding that posting of caloric information increases the number of people who use the information), with Eric A. Finkelstein et al., Mandatory Menu Labeling in One Fast Food Chain in King County, Washington, 40 AM. J. OF Preventive Med. 122, 122 (2011) (concluding that menu labeling did not promote healthier food purchasing behavior).

93 See The Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, 109 Stat. 48 (2006) (codified in scattered sections of 2 U.S.C.) (aiming “to curb the practice of imposing unfunded Federal mandates on States and local governments” and defining a mandate as “any provision . . . that would impose an enforceable duty on state, local, or tribal governments. . . or that would reduce or eliminate the amount of funding authorized to cover the costs of existing mandates”); see also Molly Ramsdell & Jeff Hurley, Mandate Monitor Overview, NAT’L CONF. OF STATE LEGS. (last visited August 15, 2011) (listing the mandates that exceeded the UMRA threshold, including minimum wage increases and preemption of various state taxes).

94 See Patient Protection and Affordable Care Act, supra note 5 (stating that the general requirements for a covered establishment are: (1) a chain with twenty or more locations, (2) doing business under the same name, and (3) offering substantially the same menu items).

95 See Comments of Lisa Mullings, NATSO, supra note 51 (arguing that the primary business activity of truck stops and truck plazas is not food sales but diesel food sales so truck stops should not be subject to the regulation).

96 Cf. Comments of Elliot Burg, Assistant Att’y Gen., STATE OF VT., FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), http://www.regulations.gov/# !documentetail;D=FDA-2011-F-0172-0404 (advocating that the FDA get rid of the “primary business activity” distinction because the approach is arbitrary, hinges on how an establishment describes itself, and PPACA does not run against the broader construction).

97 Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, supra note 1, at 19,196 (defining a similar retail establishment as a place that “offers for sale restaurant or restaurant-type food and its primary business activity is the sale of food to consumers”).

98 See Patient Protection and Affordable Care Act, supra note 5, at 574 (describing the requirements for self-service food and noting “self-service beverages or food that is on display”).

99 But see Comments of Joana Rusu, Regulatory Counsel, CONSUMERS UNION, FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), http://www.regulation. s.gov/#!documentDetail;D=FDA-2011-F-0172-0451 (stating that since restaurants often list alcoholic beverages and other drinks on menus, the covered establishment should be required to list the caloric content).

100 Food Service Warehouse, Menu Design, Food Warehouse Website (suggesting that for a menu to be an effective marketing tool, a restaurant should not overcrowd its menu).

101 See discussion infra Section IV.D. (suggesting that restaurants should place a symbol next to the caloric declaration and have a required notice in large, bold font stating what the symbol and number mean).

102 Accord Comments of Carin Nersesian, NACS, FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), http://www.regulations.gov/#!documentDetail;D=FDA-2011-F-0172-0468 (stating that the proposed requirements are unworkable and the FDA should allow caloric declarations to be on the same table or counter as a buffet or door to the self-service space); see Comments of Lisa Mullings, NATSO, supra note 51 (discussing the difficulty for truck stops because consumers pick both what they will eat and the amount of each item they will take. Also noting the space issue and advocating for a more flexible requirement, like a handout).

103 Cf. Kathryn M. Sharpe & Richard Staelin, Consumption Effects of Bundling: Consumer Perceptions, Firm Actions, and Public Policy Implications, 29 PUB. POL’Y & MARKETING 170, 170 (2010) (summarizing their study where the researchers found that customers purchase more food when they are in bundles than individually, showing the importance of visual cues); Suzanne Burns, How to Increase Food Sales, Ehow.com (Dec. 9, 2010), http://www.ehow.com/how_7471178_increase-food-sales.html (describing ways to increase food sales by using different graphics to draw attention).

104 See Comments of Lisa Mullings, NATSO, supra note 51 (stating that the proposed six month effective date is not enough time to properly review the final rule, analyze covered items, and become compliant); see also Comments of Comments of Cicely D. Simpson, DUNKIN BRANDS, FDA-2011-F-0172 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011)), http://www.regulations.gov/#!documentDetail;D=FDA-2011-F-0172-0457 (advocating for at least one year for implementation because six months will not be enough time to implement the requirements nationwide).

105 E.g., Comments of Carin Nersesian, NACS, supra note 104 (suggesting that the FDA should issue warning letters, utilize a tiered penalty structure so as to distinguish minor violations from serious violations, issue Guidance documents to the industry to clarify expectations, and permit stores to have points of contact in order to address any issues with enforcement); Comments of Judith Thorman, IFA, supra note 51 (suggesting that the FDA provide explicit guidance on the requirements before enforcing against any establishment out of compliance).

106 See The Federal Food, Drug, and Cosmetic Act of 1938, supra note 15 (defining misbranded food as “false or misleading label. If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which Section 350 applies, its advertising is false or misleading in a material respect or its labeling is in violation of Section 350(b)(2)”).

107 See Comments of Lisa Mullings, NATSO, supra note 51 (arguing that the primary business activity of truck stops and truck plazas is not food sales but diesel food sales so truck stops should not be subject to the regulation).