**Susan Butler/HPM500D Section 1/Fall 2012**

**Federal Health Reform Regulation Project**

***Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments***

**Introduction**

This analysis paper will analyze the regulation calling for nutrition labeling of standard menu items in restaurants, including the need for such regulation, facilitators and barriers related to the implementation of the regulation, benefits and costs, and unintended consequences.

The *Patient Protection &* *Affordable Care Act (ACA)* was signed into law by the U.S. President on March 23, 2010. There are ten Titles of the ACA. Each title has a Subtitle, and each Subtitle has a number of Sections. Title IV is entitled: *Preventing Chronic Disease and Improving Health.* Subtitle C is entitled: *Creating Healthier Communities.* Section 4205 is entitled: *Nutrition Labeling of Standardized Menu Items at Chain Restaurants*. The Notice of Proposed Rulemaking, Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), announced that the rule has the Docket Number of FDA-2011-0172. The FDA published this rule in its Federal Registry of April 6, 2011 and is mandated by Section 4205 of the Patient Protection and Affordable Care Act (Patient Protection & Affordable Care Act, 2010).

The Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Foods (OF) opened a docket to solicit comments on this rule and FDA’s implementation of standard nutrition labeling for menu items at chain restaurants on July 10, 2010. Public comment on the proposed menu-labeling rule ended on June 6, 2011 (FDA, 2012).

This rule applies to restaurants and similar retail food establishments with 20 or more locations doing business under the same name. The purpose of the regulation is to inform the public of specific nutrition information about food sold at chain restaurants, including total calories and calories from total fat, saturated fat, cholesterol, sodium, total and complex carbohydrates, sugars, dietary fiber, and protein (Patient Protection & Affordable Care Act, 2010).

**Need for the Regulation**

Title IV of the Affordable Care Act, entitled Prevention of Chronic Disease and Improving Public Health includes the following phrase:

*“The Act will promote prevention, wellness, and the public health and provides an unprecedented funding commitment to these areas. It directs the creation of a national prevention and health promotion strategy that incorporates the most effective and achievable methods to improve the health status of Americans and reduce the incidence of preventable illness and disability in the United States.”*

In the United States, obesity, type 2 diabetes, high blood pressure, and cardiovascular disease are becoming common, not only among adults, but also among children. According to the National Center for Health Statistics, 33.7% of adults and 16.9% of children and adolescents were obese in the United States (Roger et al, 2012), which is defined as weights that are too high to be considered normal for his or her age, sex, and height (CDC, 2012). According to the American Diabetes Association, approximately 25.8 million children and adults in the United States, or 8.3% of the population, have diabetes. Diabetes is now the 7th leading cause of death in the United States (ADA, 2012). According to the American Heart Association, 76.4 million American adults have been diagnosed with high blood pressure (AHA, 2012). In 2009-2010, about 47% of U.S. adults had uncontrolled high levels of low density lipoproteins (LDL) cholesterol (Fryar, 2012). Food consumed away from home now accounts for over 30% of daily calorie intake and 50% of yearly food spending (Variyam et al, 2005; Harnack et al, 2008; Chu et al, 2009).

An Internet search for public comments in response to this regulation only yielded a few comments from the food service industry, a consumer group, and a few comments submitted to the FDA’s comment website. Below is a sample of the comments, including my comment in response to the regulation (Soenarie, 2012; Consumer Federation of America, 2010; Frumpkin, 2011.

Consumer Federation of America:

*“CFA is a non-profit association of some 280 organizations, with a combined membership of over 50 million Americans. CFA agrees with Congress that healthy eating is a cornerstone of public health. As such, CFA strongly supports national menu labeling and commends the FDA for committing to carrying out the program mandated by the Affordable Care Act.“ “While the amount of information provided is commendable, other information such as trans fats is still not required to be disclosed. However, the ACA gives the FDA the authority to require disclosure of other nutrients to assist consumers in maintain healthy dietary practices.”*

National Restaurant Association:

*“The NRA feels strongly that similar retail food establishments with restaurant-like operations should be required to adhere to the same menu-labeling requirements as restaurants. The proposed regulations currently do not include movie theaters, amusement parks, general merchandise stores, hotels, trains, or planes.”*

Food and Drug Administration’s Public Comment Site:

*“Cover all establishments that sell restaurant-type food, including movie theaters. Theaters’ 1,000-calorie tubs of popcorn should be named so on the menu board. Do not exempt alcoholic beverages from menu labeling. The calorie content of alcoholic beverages can vary widely…”*

*“Americans are facing an obesity epidemic. Diet and exercise are the only solutions. Without the knowledge easily and readily available to make smart diet choices, we will never beat obesity.”*

Author of this Paper:

*“I also think the nutrition labeling needs to include trans fat, but the public needs to be educated on what trans fats are. I believe strongly in educating the public about the food they eat. I always read food labels before I buy food items from the grocery store. I like to know exactly what I am buying. I don’t eat meals from fast food restaurants, but I would like to know what is in the food that I order at a restaurant. However, that is not possible today.”*

**Barriers and Facilitators to Implementation of the Regulation**

While menu labeling has yet to be officially implemented through the ACA, New York City Dumanovsky et al (2011) conducted a cross sectional customer survey in New York City before and after the introduction of calorie labeling in 2007 and 2009 respectively, to collect data on the content of lunchtime purchases from fast food restaurants after the introduction of required calorie labeling. Among 11 fast food chains in New York City during lunchtime, 7309 adults were interviewed. After the implementation of the calorie content, the content of lunchtime purchases declined significantly at three major fast food chains, but not across the entire sample. Energy content increased at one chain when it heavily promoted and advertised large portions. The authors of this study stated that because a clear reduction in energy intake across the full sample was not found, a strong research agenda is needed for nutrition interventions. For example, the authors suggest that there should be a focus on educating consumers on how to interpret and use nutrition information, and assessments of the full impact will require a long term perspective.

A systematic peer- review of seven studies related to restaurant chain calorie labeling since 2008 found that only two out of the seven studies were of good quality (Swartz et al, 2011). These two studies reported a statistically significant reduction in calories purchased by consumers when calorie-labeled menus were implemented. However, they warn that these studies cannot easily be generalized to real world behavior, especially when customers know they are being monitored. However, the authors were impressed with a study conducted by Finkelstein et al (2011) that provided the best evidence regarding the implementation of calorie menu -labeling in a real world setting. In this impressive study, researchers in King County, WA analyzed complete sales data furnished by the restaurant chain during a 13-month period of calorie menu-labeling. The researchers also kept track of total monthly transactions and gathered complete sales data. Swartz et al stated that none of the observational studies could account for environmental factors, such as public education campaigns accompanying the policy implementation. The authors suggest that we need longer-term and rigorous studies to determine whether prolonged exposure to calorie labels has an effect on obesity. Larson et al (2009) and Bleich et al (2010) showed that a majority of U.S. consumers want calorie menu labeling. Swartz et al suggested that we *“proceed with widespread implementation of an unproven policy with social and monetary costs, especially since the effort may detract attention from other effective strategies to combat overweight and obesity or have inadvertent effects”.*

Barriers to implementing the menu labeling regulation include a lack of education among the public about the contents of the menu labeling. The public may not understand what is being presented to them, because there has not been an education campaign about menu labeling. There is also a lack of systematic gathering of data pertaining to the success of menu labeling. Accurate and useful data gathering was reported by only one restaurant chain. Roberto et al, 2009 reported that the restaurant industry has lobbied hard against the proposed regulations. These researchers reported that the restaurant industry sued (without success) New York City, San Francisco, and Santa Clara for attempting to enact labeling requirements.

Facilitators to implementing the menu labeling regulation would be a comprehensive education campaign targeting the different populations that frequent restaurant chains. Roberto et al, 2009 states that the impact of calorie labels on food choices and consumption should first be tested. This research team randomly assigned customers to either a menu without calorie labels, a menu with calorie labels, and a menu with calorie labels and a label stating the recommended daily calorie intake for an average adult. Participants in both calorie label conditions ordered fewer calories than those in the no calorie labels condition.

**Benefits and Costs**

According to the Federal Register from Fall 2011, costs and benefits were examined. The Register stated that chain restaurants would benefit from the nutrition-labeling requirement by having a uniform national standard. The Register reports that some studies have shown that a number of customers consumed fewer calories when information about calorie content was displayed and consumers will also have important nutrition information for the 30 percent of calories consumed away from home (Federal Register, 2011). The Register also suggests that given the high costs associated with obesity, the FDA estimates that if 0.6 percent of the adult obese population reduced their energy intake by at least 100 calories per week, the benefits would be as large as the costs of implementing the rule.

Related to costs, the Federal Registry suggests that the chain restaurants with 20 or more locations will bear the costs associated with adding nutrition information to menus and menu boards. The FDA estimates that the costs of this rulemaking will be approximately $80 million, with an initial cost of about $320 million to set up the initial implementation of the rule (Federal Register, 2011).

**Unintended Consequences**

One unintended consequence of the menu study conducted by Roberto et al was that participants who were furnished with calorie labels believed that they had economized on calories by eating less at the meal under study and believed that they had greater allowance to eat more (Roberto et al, 2009). A situation such as this may have people eating more when calorie labels are provided. Researchers in this particular study suggested that restaurants also need to provide customers with information on daily calorie intake at the point of purchase, and that adding this labeling requirement is essential.

**Summary/Conclusion**

Very few restaurants, as required by the Affordable Care Act, have implemented nutrition labeling of standard menu items sold in certain restaurants. The public debate period with the Food and Drug Administration is now closed. I believe that with the public’s increasing desire to know what they are eating, menu labeling will become commonplace, not only in restaurants, but also in all of the other venues where food is sold to the public.

**References**

America Diabetes Association (ADA). National Diabetes Fact Sheet 2011. Available from <http://diabetes.org/diabetes-basics/diabetes-statistics/html>. [Accessed November 3, 2012].

American Heart Association (AHA). About Blood Pressure. Available from <http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/AboutHighBloodPressure/html>. [Accessed November 3, 2012].

Bleich et al. The public’s understanding of daily caloric recommendations and their perceptions of calorie posting in chain restaurants. BMC Public Health 2010: 10:121.

CDC. Defining Overweight and Obesity. Available from <http://www.cdc.gov/obesity/adult/defining/html>. [Accessed November 2, 2012].

Chu YH, Frongillo EA, Jones SJ, Kaye GL. Improving patrons’ meal selections through the use of point-of-selection nutrition labels. American J of Public Health. 2009: 99:2001-2005.

Consumer Federation of America. Response to Docket No. FDA-2010-N-0298. [Accessed November 3, 2012].

Department of Health and Human Services, Food and Drug Administration. Implementation of Section 4205 of the Patient Protection and Affordable Care Act – Nutrition Labeling. 2012. Available at <http://www.accessdata.fda.gov/FDATrack/track-proj?program=healthcare-reform&id=ACA-4205-Implementation>. [Last Accessed (which included updates) November 2, 2012]

Dumanovsky T et al. Changes in energy content of lunchtime urchases from fast food restaurants after introduction of calorie labeling: cross sectional customer surveys. BMJ. 2011: 343:d4464.

Federal Regiser. Food Labeling: Nutrition Labeling of Sandard Menu Items in Restaurants and Similar Retail Food Establishments. Available from <http://www.FDsys.gov>, [Accessed September 23, 2012].

Fenkelstein et al. Mandatory menu labeling in one fast-food chain in King County, Washington. American J of Preventive Medicine. 2010: 40:122-127.

Frumpkin P. Concerns voiced on menu-labeling proposal. Nation’s Restaurant News. 2011: July 5. Available from <http://nrn.com/article/concerns-voiced-menu-labeling-proposals>. [Accessed November 3, 2012].

Fryar CD, Chen T, Li X. Prevalence of Uncontrolled Risk Factors for Cardiovascular Disease: United States, 1999-2010. NCHS data brief, no 103, Hyattsville, MD. National Center for Health Statistics. 2012.

Harnack LJ, French SA. Effect of point-of-purchase calorie labeling on restaurant and cafeteria food choices: A review of the literature. International Journal of Behavioral Nutrition & Physical Activity. 2005. 5:51.

Larson et al. Menu labeling: Does providing nutrition information at the point of purchase affect consumer behavior. A Research Synthesis, June 2009. Robert Wood Johnson Foundation.

Patient Protection & Affordable Care Act, Pub. L. No. 111-148, Section 4205, 124 Stat.119, 499-502, 2010i

Roberto C. Evaluating the impact of menu labeling on food choices and Intake. American J of Public Health 2010: 100(2):312-318.

Roger et al. Heart Disease and Stroke Statistics – 2012 Update: A Report from the American Heart Association. *Circulation* 2012: 125:e2-e220.

Soenarie A. FDA seeks public’s comments on menu labeling rules. *The Arizona Republic* 2012: July 8.

Swartz et al. Calorie menu labeling on quick-service restaurant menus; An updated systematic review of the literature. International J of Behavioral Nutrition & Physical Activity. 2011. 8:135.

U.S. Department of Health & Human Services. The Health Care Law & You. Washington, DC. Available at <http://www.HealthCare.gov>. [Accessed September 23, 2012].

Variyam JN. Nutrition labeling in the food-away-from-home sector: an economic assessment. Economic Research 2005: Report Number 4.