

Karen Strambler
Center for Food Safety and Applied Nutrition
US Food and Drug Administration
Department of Health and Human Services
5001 Campus Drive, College Park, MD 20740

To: US Food and Drug Administration

Product: Nutrition Facts Panel (NFP)
Citation: 21 CFR 101 (21 CFR 101.9, 21 CFR 101.36)
OMB Control Number: 0910-0381

This comment is in response to the Food and Drug Administration Docket No. FDA-2017-N-5094. The request for comment seeks input to identify existing regulations and requirements for review, modification, or repeal. A significant body of the FDA's rule docket is implementation of the Nutrition Labeling and Education Act of 1990 (NLEA). Specific changes to food labeling have not been retrospectively reviewed to determine whether their intended benefits were ever realized. For the FDA to meet its public health mission, any regulatory action must show both a significant impact on consumer behavior and improvement to individual health.

The Program for Economic Research on Regulation at the Mercatus Center at George Mason University is dedicated to advancing knowledge about the impact of regulation on society. As part of its mission, the program conducts analyses of the regulatory process from the perspective of the public interest. This comment, therefore, does not represent the views of any particular affected party or special interest group but is meant to assist the US Department of Health and Human Services and the FDA in reviewing its body of regulations.

Review of labeling rules represents an opportunity for the agency to reevaluate the burdens imposed by regulation and the distortionary effect of these burdens on the development of the industries they regulate. Our research has found that the regulatory impact analyses developed in support of packaged food labeling, beginning with the NLEA rules, used flawed models of consumer behavior that resulted in inflated predictions of health benefits from consumer label use.¹ Neither the predicted changes in behavior, particularly for the 1990 NLEA rules and subsequent modifications, nor the resulting improvements in health outcomes have been realized.²

¹ Sherzod Abdulkadirov, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, May 19, 2014), 9; Richard Williams, Michael Marlow, and Edward Archer, "Retrospective Analysis of the Regulations Implementing the Nutrition Labeling and Education Act of 1990" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, April 12, 2016), 3.

² Williams, Marlow, and Archer, "Retrospective Analysis of the Regulations," 2.

CONCERN

Since the inception of nutrition labels in 1973 (for foods with claims), the evidence has failed to support the predictions that labels would positively impact consumer food choices and health outcomes. For example, per capita fruit and vegetable consumption has declined 5.5 percent between 2004 and 2014 (total vegetable consumption is down 6 percent).³ In addition, since the early 1990s, obesity rates have risen from about 28 percent to over 35 percent, and one in six children ages 2 to 19 is now obese.⁴

With the first required nutrition labeling for packaged foods in 1973, former FDA Commissioner Charles C. Edwards noted that the “experience under this new regulation is required before expansion to all foods on a mandatory basis can be considered.”⁵ This advice was not heeded before implementing regulations pursuant to the Nutrition Labeling and Education Act, but now, with more than 40 years of data, it is time to take a broad look at the current approach. In particular, does it really make sense to ask consumers to track and heed individual nutrients, macronutrients, and calories as well as doing the necessary math to make Daily Values work for them?

Below we have addressed some specific questions asked in the request for information.

Is the regulation still current, or is it outdated or unnecessary in some way?

The ideas promoted by current nutrition labeling appear to go beyond scientific consensus on diet-health relationships. For example, at best, the results are mixed as to whether posting calorie counts has public health benefits. In addition, it is by no means clear that added sugars (as opposed to total sugars) information will be useful to consumers, and an increasing number of studies challenge saturated fat guidelines associated with the Nutrition Facts Panel (NFP).

Food labeling standards are ineffective and unnecessary if consumers (1) do not process label information reliably, (2) have little interest in nutritional information, (3) have little concern about health effects that may only be realized decades in the future (i.e., the temporal discounting of alleged health claims), or (4) lack information on the acute or long-term health effects of the labeled product for them personally.⁶

In order for the standards to achieve positive health outcomes, the following conditions must be met:

1. Some percentage of consumers must see the label.
2. Some percentage of those consumers must read the label.

³ *State of the Plate: 2015 Study on America's Consumption of Fruit and Vegetables* (Brentwood, MO: Produce for Better Health Foundation, 2015).

⁴ The State of Obesity, “Obesity Rates & Trends Overview,” accessed December 7, 2017, <https://stateofobesity.org/obesity-rates-trends-overview/>.

⁵ 38 Fed. Reg. 2163 (January 19, 1973).

⁶ W. Kip Viscusi, Wesley A. Magat, and Joel Huber, “Informational Regulation of Consumer Health Risks: An Empirical Evaluation of Hazard Warnings,” *RAND Journal of Economics* 17, no. 3 (Autumn 1986): 351–65.

3. Some percentage of those must understand the label.
4. Some percentage of those must act on the label.
5. The information on the label must be correct.
6. Some percentage of consumers must not use compensation mechanisms to offset the action they take.

There is some percentage (probability) that applies to each of the above steps. Those percentages must be multiplied together to calculate the probability of a positive outcome. If we assume a 50 percent chance for most of them—a generous assumption—then there is only about a 1.6 percent chance (50 percent applied to each) that there will be a positive outcome.

Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

Research subsequent to the enforcement of the NLEA shows that consumers are selective in their use of NFPs, using either front panel claims or information on one or two macronutrients to determine the overall healthfulness of a product rather than making holistic decisions that balance their consumption of all nutrients.⁷ Many consumers who claimed to use nutrition facts were not observed actually using the nutrition facts label when selecting foods.⁸ While many people (65 percent) said in the 1990s that they used the food label to avoid certain contents, that figure has declined through 2006 and dropped to 48 percent in 2013—although this could mean that consumers now knew what they wanted to eat and had no more need for labels.⁹

Have regulated entities had difficulties complying with the current regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.

The difficulty with the proposed labeling changes, for firms, would generally be the costs of complying with the regulations. Such costs would have to be paid for out of retained earnings, as it is difficult to borrow for changes that are not expected to increase sales.¹⁰ These additional costs would be the most burdensome for smaller, less established firms, but all packaged-food product manufacturers would be affected because they would be required to retest their products to update their labels. By its own analysis, the FDA shows that 74 percent of private-label food products, 78 percent of branded dietary supplements, and 84 percent of private-label dietary

⁷ *Qualified Health Claims Consumer Research Project Summary* (Washington, DC: International Food Information Council Foundation, March 2005).

⁸ S. Borra, “IFIC Findings from Ethnographic Research” (presentation, FDA Center for Food Safety and Applied Nutrition, College Park, MD, June 2006).

⁹ Jessica E. Todd and Jayachandran N. Variyam, “The Decline in Consumer Use of Food Nutrition Labels, 1995–2006” (Washington, DC: US Department of Agriculture, Economic Research Service, August 2008); Maggie Hennessy, “How Much Do Consumers Use (and Understand) Nutrition Labels?,” *Food Navigator*, March 4, 2014.

¹⁰ Richard A. Williams, “Helping Small Businesses Comply with Federal Regulations” (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, July 2017).

supplements would require label changes to be in compliance.¹¹ If rules were expanded to require restaurants to provide calorie counts on menus, the number of producers impacted would increase even more.

Longer compliance periods offer higher net benefits and a reduction in regulatory burdens, which would translate into lower food prices for consumers.¹² At a 3 percent discount rate, a four-year compliance option would provide \$500 million in additional net benefits, as opposed to a two-year compliance period.¹³

Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

The only alternatives that have been considered in previous changes to labeling rules are (1) longer periods for firms to become compliant and (2) small changes in the specific levels suggested for a particular nutrient.¹⁴ The FDA should consider alternatives that allow for voluntary standards and innovation in labeling that could produce more useful labeling than the FDA currently produces. There are many voluntary front-of-package symbols that have been privately developed in the US and evaluated in two consensus studies by the Institute of Medicine.¹⁵ One such system has been developed by the American Heart Association (Heart-Check), but the FDA sent out a general warning letter in 2008 telling manufacturers that they must be careful not to make an implied claim.¹⁶ First Lady Michelle Obama urged the FDA to create a national system that would replace the vast number of such voluntary symbols, but such an initiative has yet to be undertaken by the agency.

What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

The FDA should prioritize review of rules that have not been retrospectively reviewed to determine whether their intended outcomes have been realized. Within this body of rules, those that have the

¹¹ US Food and Drug Administration, *Analysis of Impacts* (hereafter referred to as “RIA”), 2014, 21.

¹² Abdukadirov, “Food Labeling,” 2.

¹³ Abdukadirov, 11.

¹⁴ Robert Scharff, “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, & Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; & Technical Amendments” (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, May 19, 2014), 5.

¹⁵ Institute of Medicine, Food and Nutrition Board, Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols, *Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report*, ed. Ellen A. Wartella, Alice Lichtenstein, and Caitlin Boon (Washington, DC: National Academy of Sciences, 2011).

¹⁶ American Heart Association, “Heart-Check Mark Certification,” accessed December 5, 2017, http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Heart-CheckMarkCertification/Heart-Check-Mark-Certification_UCM_001179_SubHomePage.jsp; US Food and Drug Administration, *Guidance for Industry: Dear Manufacturer Letter Regarding Front-of-Package Symbols*, December 2008.

largest compliance cost should be considered first. These include all of the incremental changes to the nutrition facts panel and other food labeling standards that comprise 21 CFR § 101.

PROPOSED SOLUTION

Before any further labeling rules are considered for modification, the FDA must understand the impacts of current rules on consumer health (i.e., heart disease, cancer, obesity, and diabetes). We recommend that the FDA commission a comprehensive study that examines the overall impact of nutrient-based food labeling. Numerous experts agree that labeling of nutrients has been a poor approach since the beginning.¹⁷ Consumers don't eat nutrients, they eat food.¹⁸ Alternatives to current labeling should be considered that are more easily understood by consumers, lead to more holistic decisions about what is healthy for an individual to consume, and better follow the scientific consensus on behaviors that lead to improved individual health.

As discussed above, one alternative to consider might be to replace or supplement current food labels with front-of-package symbols that are easy to understand and are based on the entire food rather than nutrients and macronutrients.

Attached to this letter are three in-depth studies completed on previous labeling rules.

Sincerely,

Richard A. Williams, PhD
Senior Affiliated Scholar, Mercatus Center at George Mason University
Former Employee of the Center for Food Safety and Applied Nutrition, FDA

Catherine Konieczny
Graduate Research Fellow, Mercatus Center at George Mason University

ATTACHMENTS (3)

“Retrospective Analysis of the Regulations Implementing the Nutrition Labeling and Education Act of 1990” (Mercatus Public Interest Comment)

“Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (Mercatus Public Interest Comment)

“Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, & Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (Mercatus Public Interest Comment)

¹⁷ See, for example, Marion Nestle, *Food Politics* (Berkeley, CA: University of California Press, 2007).

¹⁸ This is a phrase brought up at meetings of the McGovern Committee, more formally known as the United States Select Committee on Nutrition and Human Needs, which existed from 1968 to 1977.



MERCATUS CENTER
George Mason University

Bridging the gap between academic ideas and real-world problems

RETROSPECTIVE REVIEW

RETROSPECTIVE ANALYSIS OF THE REGULATIONS IMPLEMENTING THE NUTRITION LABELING AND EDUCATION ACT OF 1990

RICHARD WILLIAMS, PhD

Director of Regulatory Studies Program, Senior Research Fellow
Mercatus Center at George Mason University

MICHAEL MARLOW, PhD

Professor of Economics at California Polytechnic State University, San Luis Obispo
Affiliated Senior Scholar, Mercatus Center at George Mason University

EDWARD ARCHER, PhD, MS

Chief Science Officer, EnduringFX

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that use contemporary economic scholarship to assess existing regulations and their effects on the economic opportunities and the social well-being of all members of American society.

This research investigates, retrospectively, the efficiency and efficacy of regulations from an economic point of view. It has been fairly thoroughly established by now that, despite laws requiring that agencies retrospectively review their regulations, in most cases they fail to do

For more information, contact
Robin Walker, Director of Outreach for Fiscal and Health Care Policy
202-550-9246, rwalker@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Boulevard, 4th Floor, Arlington, VA 22201

so, or when they do make the attempt, the reviews do not result in much action.¹ Thus, the *Code of Federal Regulations* continues to grow without the benefit of rigorous examination of its effects.²

There are several purposes of reviewing regulations: (1) to determine whether an existing regulation (or set of regulations) should be modified, maintained, or eliminated; (2) to determine whether new regulations that address the same problem are likely to be effective; and (3) to determine more generally whether a particular regulatory approach is likely to be effective. Any particular retrospective review provides a great deal of evidence about the first case and is an input in the second and third cases.

INTRODUCTION

The case examined here is the package of regulations that met the initial legal requirements provided by the Nutrition Labeling and Education Act of 1990 (NLEA, Public Law 101-535). This act gave the FDA the authority to require nutrition labeling of most foods regulated by the Agency and to require that all nutrient content claims (e.g., “high fiber” or “low fat”) and health claims be consistent with agency regulations.³ The FDA divided individual regulations into the following categories: (1) mandatory ingredient labeling for standardized foods and certified colors, (2) “voluntary” labeling of raw fruit, vegetables, and fish, and (3) all other labeling regulations, including mandatory nutrition labeling. The regulations became effective for health claims, ingredient declarations, and percent juice labeling on May 8, 1993 (percent juice labeling was subsequently exempted until May 8, 1994). The regulations for nutrition labeling and other provisions became effective on May 8, 1994. Meat and poultry products were not covered, though the US Department of Agriculture proposed similar regulations for voluntary labeling of raw meat and poultry. The regulation also exempted away-from-home foods from mandatory labeling.

A major focus of labeling regulations is the “Nutrition Facts” panel (NFP), which nearly all packaged foods are required to carry. The panel provides information on serving size and servings per package or container, along with per serving amounts and percentages of daily values

1. See, for example, Patrick A. McLaughlin and Richard Williams, “The Consequences of Regulatory Accumulation and a Proposed Solution” (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, February 2014); Stuart Shapiro and Deanna Moran, “The Questionable History of Regulatory Reform Since the APA” (Mercatus Working Paper, Mercatus Center at George Mason University, March 2015); Randall Lutter, “Regulatory Policy: What Role for Retrospective Analysis and Review” (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, March 2013); Michael Mandel and Diana G. Carew, “Regulatory Improvement Commission: A Politically-Viable Approach to U.S. Regulatory Reform” (Progressive Policy Institute Policy Memo, Progressive Policy Institute, Washington, DC, May 2013).

2. Clyde Wayne Crews, “New Data: Code of Federal Regulations Expanding, Faster Pace under Obama,” *OpenMarket*, Competitive Enterprise Institute, March 17, 2014; Patrick A. McLaughlin and Oliver P. Sherhouse, “The Accumulation of Regulatory Restrictions across Presidential Administrations,” Mercatus Center at George Mason University, August 03, 2015, <http://mercatus.org/publication/accumulation-regulatory-restrictions-across-presidential-administrations>.

3. “Guide to Nutrition Labeling and Education Act (NLEA) Requirements,” FDA, last modified December 25, 2014.

of nutrients such as calories, total and saturated fats, cholesterol, and sodium.⁴ For reference, the panel includes a table of recommended daily values of the nutrients for a 2,000-calorie diet.

The FDA published its regulatory impact analysis (RIA) in the *Federal Register* on November 27, 1991, in which it concluded that estimated benefits outweighed estimated costs of the regulation. Total costs, excluding the voluntary supermarket labeling, were estimated to be approximately \$1.5 billion based on estimates that about 17,000 domestic food manufacturers and 257,000 labels would be affected. The regulation was estimated to prevent about 39,100 cases of cancer and heart disease, of which 12,900 would have resulted in death, yielding 80,900 life-years gained over a 20-year period. The estimated monetary value of the benefits (number of life-years saved) was \$3.6 billion (discounted at 5 percent over a 20-year period).

However, the FDA failed to develop an appropriate benefit-cost analysis of the regulation. The FDA's case for mandatory disclosure was inadequate for two major reasons. First, the FDA analysis was based on flawed theoretical models of behavior, and second, it used data and predictive models that were a great deal more uncertain than it acknowledged. Further, since then it has become clear that there is a much more complex relationship between labeling, behavior, and health than was previously assumed. This short comment will focus on just a few of the major problems with this regulation. We highlight shortcomings related to two claims: (1) that mandated nutritional labeling would cause consumers to make more "healthful" eating decisions and (2) that these decisions would actually improve public health. We conclude that a major review of this regulation is in order and that its findings should be applied to any future attempts to improve this label.

More generally, this analysis provides some initial evidence about whether the government can, by providing information, actually improve public health outcomes through the diet-disease relationship. The results suggest that there is a fairly substantial burden of proof that must be overcome prior to any such attempt.

A SHORT HISTORY OF THE NLEA

When Congress passed the NLEA, the Center for Food Safety and Nutrition in the FDA had already been working on many of the proposals that would end up in the law, but one aspect of the requirements—estimation of the benefits and costs of the entire package of requirements—had no preparation. Congress gave the FDA a year to propose what was to become 21 separate regulations and, in order to meet the requirements of Executive Order 12866 (President Reagan's economic executive order), FDA economists had to prepare an RIA that addressed all of these changes. Because of the short time and the interactive nature of these regulations, it was decided that one proposed regulatory impact analysis be prepared that would address all of the labeling changes to food packaging.

4. The 1990 amendments specify that nutrition labeling shall include information on (1) the total number of calories derived from any source, and the number of calories derived from fat; (2) the amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, total protein, and sodium; and (3) any vitamin, mineral or other nutrient required to be placed on the label before October 1, 1990.

The nutrition labeling regime for foods that was established by the NLEA was intended by Congress to address what was then called the “Tower of Babel,” which referred to the perception of numerous confusing and misleading ways that manufacturers were providing nutrition information on packaged products. In enacting the NLEA, Congress wanted to provide consistent nutrition information to “assist consumers in maintaining healthy dietary practices.” There were no models that the economists could draw on, so they needed to create one, particularly for the benefits. The benefits model was entirely new and was built rather quickly. The benefits of the rule were modeled as:

1. Some percentage of consumers will see and read the new NFPs and the new, better-supported health claims.
2. Some percentage of those consumers will understand the information they are reading.
3. Some percentage of those consumers will make some changes in their diets.
4. Those changes will be reflected in reduced cases of coronary heart disease (CHD) and cancer.

Note that all of these probabilities need to be multiplied together so that the estimated amount of changes in the risk of diseases ends up being fairly low. Even despite the theoretical prediction of small changes, it now appears that the changes in health states were overstated.

Creating the model was fairly easy; the real problem was to find valid data. Other agencies in the Department of Health and Human Services that had nutrition experts were contacted, and not one of them agreed to help. These experts regarded the entire exercise as fruitless; that is, they rejected the idea that they could start with a change in information on labels and somehow estimate the health effects the change would exert on all Americans.⁵ In retrospect, perhaps they knew a great deal more than the FDA economists about the perils associated with such a model, but the analysis was, and still is, an executive order requirement.

FDA economists did point out in the analysis that these estimates were a “preliminary investigation into quantification of mandatory information disclosure” and that they recognized that “the benefit estimates provided in both the preliminary and the final RIA are soft because of the many assumptions made and the tenuous support for these assumptions.”⁶

THE FDA’S BENEFIT STUDY

The FDA’s choice of a 20-year window seems to be appropriate; that should have been long enough to evaluate the success or failure of the program and to improve or abandon it

5. This information comes from Richard Williams, who was director of social sciences for the Center for Food Safety and Applied Nutrition during the period that this RIA and the NLEA were implemented.

6. Department of Health and Human Services, Food and Drug Administration, “Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations,” Regulatory Impact Analysis, January 6, 1993.

accordingly. Following the four steps outlined above, we will examine each step in the model for the likelihood that the FDA's analysis was problematic at the time or whether the predictions were borne out.

1. Consumers will notice and read new nutrition information.

The argument that the FDA made was that there was a market failure stemming from a lack of information on nutrition attributes of food products. In effect, the FDA argued that these regulations would correct a market failure. It is true that good information is necessary for markets to allocate resources efficiently. Markets, of course, are imperfect and cannot be expected to fully convey all known information on product attributes or the person-specific health effects of those attributes.

Another imperfection arises when information has “public good” properties whereby product information applies to all businesses within an industry. One firm conducting research must absorb all costs, but other firms “free ride” on benefits without incurring any costs.⁷ It becomes less likely any single firm finds such research profitable, thus private markets provide product information at inefficient levels.

However, the NLEA regulations were unlikely to correct such a market failure. Mandatory food label information promotes economic efficiency only as long as consumers make sound decisions based on information derived from labels⁸ in conjunction with their knowledge of their individual metabolic and behavioral responses to the labeled products. If consumers (1) do not process label information reliably, (2) have little interest in nutritional information, (3) have little concern with health effects that may only be realized decades in the future (i.e., the temporal discounting of alleged health claims) or (4) lack information on the acute or long-term health effects of the labelled product for them personally, mandatory labels may not be particularly effective at fostering better decisions or changing consumer behavior.⁹ In fact, there is a list of characteristics that consumers think are important when choosing food—including price, taste, and ease of preparation—but healthiness is not on the top of virtually anyone's list. Effective labeling must overcome various obstacles to communicating clear and useful information to consumers. Research indicates that some consumers see health claims as useful but prefer succinct wording rather than long and complex claims.¹⁰ Studies indicate that clarity and conciseness are critical as well. Furthermore, consumers might treat standardized and ubiquitous labeling as “background noise” and ignore or dismiss it.

7. Cass R. Sunstein, “Informing America: Risk, Disclosure, and the First Amendment,” *Florida State University Law Review* 20 (1993); Peter S. Menell, “Structuring a Market-Oriented Federal Eco Information Policy,” *Maryland Law Review* 54 (1995).

8. W. Kip Viscusi, “Risk Perceptions in Regulation, Tort Liability, and the Market,” *Regulation* 14 (Fall 1991): 50–57.

9. W. Kip Viscusi, Wesley A. Magat, and Joel Huber, “Informational Regulation of Consumer Health Risks: An Empirical Evaluation of Hazard Warnings,” *RAND Journal of Economics* 17, no. 3 (Autumn 1986): 351–65.

10. Peter G. Williams, “Consumer Understanding and Use of Health Claims for Foods,” *Nutrition Reviews* 63, no. 7 (2005): 256–64.

Subsequent findings on how consumers actually respond to mandatory labeling indicate little support for the FDA theory that this regulation would steer consumers toward “healthier” eating. A Department of Agriculture report examined changes in consumers’ use of nutrition labels on food packages between 1995/96 and 2005/06 and found that, although a majority of consumers reported using nutrition labels when buying food, use had declined for most label components, including the NFP and information about calories.¹¹ The decline in label use was particularly marked for adults less than 30 years old. This finding suggests that the ubiquitous food labels have become background noise for many individuals who grew up with them and that younger individuals in general may be less interested in health-related information than older individuals.¹² This may be compounded by the interaction between person-specific attributes (e.g., age, weight) and information on health claims that may not be realized for many decades (i.e., the temporal discounting of health-related information).¹³

2. Consumers understand the nutrition information they read.

A survey conducted in 2012 by the International Food Information Council Foundation fails to support the FDA’s case that mandatory labeling would encourage “healthier” eating.¹⁴ Most Americans (52 percent) concluded that figuring out their income taxes was easier than knowing what they should and should not eat to be healthier. In fact, interpreting NFPs requires an algorithm. For example, most Americans need more fiber in their diet but may need less saturated fat. How should consumers choose between two foods when one contains somewhat more fiber and somewhat less saturated fat? But, of course, it is much more complex than that. Consumers need to be able to look at all of the levels of the “good” nutrients and ingredients and all of the levels of the “bad” nutrients and ingredients and tone some basis to make a decision.¹⁵ They also need to make individual food choices in light of other things they are eating, their individual health status, genetic make-up, how much exercise they get, and their inherited predispositions.

But research subsequent to the NLEA shows that consumers use either front panel claims or one or two macronutrients from the NFP to determine the overall healthfulness of a product rather than making holistic decisions.¹⁶ For products with claims on the front of the package,

11. Jessica E. Todd and Jayachandran N. Variyam, “The Decline in Consumer Use of Food Nutrition Labels, 1995–2006” (Economic Research Report no. 63, Economic Research Service, US Department of Agriculture, August 2008).

12. Edward Archer, Amanda E. Paluch, Robin P. Shook, and Steven N. Blair, “Physical Activity and the Science of Successful Aging,” *Kinesiology Review* 2, no. 1 (2013): 29–38.

13. Alessia Cavaliere, Elisa De Marchi, and Alessandro Banterle, “Healthy-Unhealthy Weight and Time Preference: Is There an Association? An Analysis through a Consumer Survey,” *Appetite* 83 (2014): 135–43.

14. Jania Matthews, “Americans Find Doing Their Own Taxes Simpler Than Improving Diet and Health,” *Food Insight*, International Food Information Council Foundation, last modified May 23, 2014.

15. It is, of course, much more complicated than good or bad. Most macronutrients have a “U”-shaped dose response curve so that some amount is beneficial for a person but too much is harmful. In fact, many types of compounds have a similar curve where a small amount is beneficial (hormetic dose) and a larger amount is harmful. This is the founding toxicological principle, “the dose makes the poison.”

16. International Food Information Council Foundation, “Qualified Health Claims Consumer Research Project Summary” (March 2005).

consumers often use the existence of these claims involving diet-disease, structure-function relationships, or nutrient content as a signal that a food represents a healthy choice.¹⁷ Consumers tend to overly rely on these claims because of their prior beliefs and their overinterpretation of the meaning of these claims (so-called “halo effects”).¹⁸ Although all the information needed to assess a product’s healthfulness is present on the NFP, consumers have no readily accessible guide to combine the 6 to 30 nutritional factors (with differing levels) into an overall decision about the product.

Thus, because of the complexity of the NFP and the existence of front panel claims, consumers are defining their own rules about how to use nutrition information. Most apparently ignore the FDA’s 5/20 rule.¹⁹ Another problem is that Percent Daily Value seems to be a difficult concept for consumers, and although it was assumed that consumers would learn to use these metrics over time, it apparently will not happen. In fact, an overall problem with the NFP is one that was discovered decades before the NLEA was passed: consumers purchase foods, not nutrients.²⁰

In sum, although most nutrition advice “emphasizes total diet, or overall pattern of foods eaten, rather than any one food or meal,” most consumers use food labels to select individual foods based on comparisons to other foods using simplified heuristics to determine the relative healthiness of individual foods or meals.

3. Some percentage of consumers will use the food label to select healthier foods.

The basic theory was that some consumers would select more nutritious, healthier foods when provided with labeling that clearly stated ingredient and nutrient contents. Consumers were also believed to benefit from the creation of standardized serving sizes and adjectival nutrient content claim definitions (as well as health and structure function claims based on “sound science”) that would help them judge the nutritional aspects of foods.

Consumers are somewhat concerned about their diets. Six out of 10 Americans have given a lot of thought to the foods and beverages they consume (58 percent) and the amount of physical activity they get (61 percent). With respect to this latter point, given that 95 percent of Americans do not meet the current Physical Activity Guidelines,²¹ it is clear that just thinking about beneficial lifestyle behaviors does not necessarily lead to actual beneficial behaviors. Only 20 percent of respondents said their diet was very healthful, and 23 percent described

17. Brian Roe, Alan S. Levy, and Brenda M. Derby, “The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Results from FDA Experimental Data,” *Journal of Public Policy & Marketing* 18, no. 1 (1999): 89–105.

18. Peter Williams, “Consumer Understanding and Use of Health Claims for Foods,” *Nutrition Reviews* 63, no. 7 (2005): 256–64.

19. This rule says to choose foods that contain no more than 5 percent of “bad” macronutrients and more than 20 percent of “good” macronutrients.

20. The McGovern Committee meetings, more formally known as the United State Select Committee on Nutrition and Human Needs, 1968–1977.

21. Richard P. Troiano et al., “Physical Activity in the United States Measured by Accelerometer,” *Medicine & Science in Sports & Exercise* 40, no. 1 (2008): 181–88.

their diet as extremely or very unhealthful. While 90 percent of respondents had given at least a little thought to the ingredients in their food and beverages, taste (87 percent) remained the most significant determinant of food and beverage choices, followed by price, and then healthfulness.

But the FDA had little to no evidence, either theoretical or empirical, to back its prediction that mandatory labeling regulation would change actual behavior and steer consumers toward food decisions that government regulators believe they should make. There was also little to no literature on consumer responses to mandatory labels at the time the FDA estimated the benefits of these regulations. The FDA predicted consumer responses to labels on the basis of data from the Special Dietary Alert program, a special program conducted by the FDA in conjunction with Giant Food, Inc., which measured consumer responses to new nutrition information. This small exploratory study tracked for two years how consumers changed their consumption of fat and cholesterol in response to nutrition information flags on grocery store shelves at various store locations in one metro area. This study served as the basis on which the FDA predicted that consumers would significantly alter their food choices in directions that would improve their health. The FDA simply did not know how looking at small “flags” in supermarket aisles that read, for example, “low fat” would carry over to how people responded to what they saw on packaged food labels. Nor did the FDA know whether the changes observed in the Giant study would persist or whether Washington, DC—where the study was performed—was representative of the country as a whole.

Additionally, it should be pointed out that mere “reading” of labels does not necessarily indicate effectiveness of the regulation since the ultimate goal was to steer purchases toward “healthier” eating and to improve health rather than simply to prompt people to read labels. And while it was assumed that label use and understanding would increase, that did not necessarily happen. Many shoppers who initially described themselves as nutrition facts users were not observed to use the nutrition facts label when selecting foods.²² While many people (65 percent) said in the 1990s they used the food label to check for things they were trying to avoid, that figure dropped to 48 percent in 2013— although this could mean that consumers now knew what they wanted to eat.²³ Consumers who reported “never” using the food label rose from 13 percent in 1994 to 18 percent in 2002. Finally, most consumers did not use the NFP to determine how much they should eat or to plan their daily diet.²⁴

A study conducted by a Department of Agriculture economist concluded that the NFP mandated by the NLEA had no effect on dietary intakes of total fat, saturated fat, or cholesterol,

22. S. Borra, “IFIC Findings from Ethnographic Research,” Presentation at the FDA Center for Food Safety and Applied Nutrition (June 2006).

23. Maggie Hennessy, “How Much Do Consumers Use (and Understand) Nutrition Labels?,” *Food Navigator* (March 2014).

24. C. T. Lin and C. Choiniere, “What Consumers Know about Nutrition—FDA Health and Diet Survey” (Paper presented at the Public Health Professional Conference, Philadelphia, June 6–10, 2005).

thus lending no support for the predicted changes in consumption of these nutrients by the FDA.²⁵ However, the study found that, for consumers who reported using the NFP when buying food, labels led to significantly higher fiber and iron intakes compared with those who rarely or never used the NFP. Nevertheless, a modest boost to public health was argued by the author based on the view that fiber is underconsumed by large proportions of adult Americans and increased iron intake is beneficial for many segments of the population (particularly premenopausal women). The author speculated that labels increased intakes of fiber and iron through promoting the consumption of ready-to-eat breakfast cereals, which are the top source of iron and the fourth major source of fiber in the diets of adult Americans.

Although the author also speculated that increased iron consumption would be beneficial for Americans, this notion is contradicted by the latest biochemical analysis of nutritional status performed by the Centers for Disease Control and Prevention (CDC). The report presented evidence that 90 percent of premenopausal women were not at risk of iron deficiency and that more than 95 percent of children ages 1 to 5 years were not deficient in iron.²⁶ As such, the hypothesized increase in the consumption of iron will have no benefit for more than 90 percent of Americans and is actually a health risk for some populations.²⁷ With respect to fiber, there is some question now as to whether the benefits of fiber have been overstated. For example, a Cochrane Review stated unequivocally, “there is currently no evidence from RCTs to suggest that increased dietary fiber intake will reduce the incidence or recurrence of adenomatous polyps [an antecedent to colon cancer] within a two to four year period.”²⁸ In addition, fiber and iron were clearly not the targets of the NLEA rules, and it is unlikely that any change, especially a clinically irrelevant change, would cause the entire effort to pass a benefit-cost test. This is particularly true of any analysis that considers different options for presenting information.

4. Better food choices will result in better health outcomes.

There are two primary issues to consider when attempting to steer food choices through labeling: (1) the effect of food choices on health is an individual effect, not a population effect, and (2) the relationship between macronutrients and health outcomes remains unclear.

25. Jayachandran N. Variyam, “Do Nutrition Labels Improve Dietary Outcomes?,” *Health Economics* 17 (2008): 695–708.

26. “Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population,” Centers for Disease Control and Prevention, US Department of Health and Human Services, accessed August 20, 2015; Christine M. Pfeiffer et al., “The CDC’s Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population Is a Valuable Tool for Researchers and Policy Makers,” *Journal of Nutrition* 143, no. 6 (2013): 938S–47S.

27. Brian K. Crownover and Carlton J. Covey, “Hereditary Hemochromatosis,” *American Family Physician* 87, no. 3 (2013): 183–90.

28. Tracey K. Asano and Robin S. McLeod, “Dietary Fibre for the Prevention of Colorectal Adenomas and Carcinomas,” *Cochrane Database of Systematic Reviews*, 2002.

INDIVIDUAL RESPONSES TO FOOD CHOICES

One of the major conceptual limitations to the FDA's argument is the failure to acknowledge that the positive or negative health effects of any given food or beverage product are not intrinsic to the product but are the result of the interaction between the properties of the product and the person-specific metabolic and behavioral responses to that food (or beverage). For example, there are substantial inter-individual differences in energy and nutrient metabolism resulting from the consumption of identical foods, beverages, or diets.²⁹ Obviously, information on this interaction cannot be provided via labeling, but it is nonetheless essential for the consumer's behavior via the estimation of the consumer's personal benefits and costs.

There are substantial inter-individual differences in energy and nutrient metabolism resulting from the consumption of identical foods, beverages, or diets.³⁰ These effects are not intrinsic to the food or beverage product, but are the result of the interaction between person-specific attributes (e.g., age, body composition, physical activity levels, and health status) and the components of the consumed product. As such, it would be impossible to convey to a given consumer the physiologic or health effects of consuming a labeled product. For example, African-Americans have greater fluid retention than non-Hispanic whites and therefore take significantly longer to excrete a prespecified water load.³¹ Given the effects of fluid retention on hypertension (i.e., high blood pressure),³² even a product as seemingly innocuous as bottled water may have significant person-specific acute and long-term effects that are not intrinsic to the product but are a result of the interaction of the product's components and the consumer of that product.

Obviously, information on this interaction cannot be provided via labeling but nonetheless is essential to the consumer. As Clare M. Hasler states, "the intent of label claims is to provide consumers more scientifically valid information about the foods they eat to improve their health and well-being. However, evidence to date suggests that this mode of communication has had limited success and in fact may be misleading to consumers with regard to understanding of scientific evidence as well as overall diet choices."³³

29. Frank M. Sacks et al., "Effects of High vs. Low Glycemic Index of Dietary Carbohydrate on Cardiovascular Disease Risk Factors and Insulin Sensitivity: The OmniCarb Randomized Clinical Trial," *Journal of the American Medical Association* 312, no. 23 (2014): 2531–41; David Zeevi et al., "Personalized Nutrition by Prediction of Glycemic Responses," *Cell* 163, no. 5 (2015): 1079–94; Gilbert B. Forbes, "Body Fat Content Influences the Body Composition Response to Nutrition and Exercise," *Annals of the New York Academy of Sciences* 904, no. 1 (2000): 359–65.

30. *Ibid.*

31. Alan B. Weder, Lillian Gleiberman, and Amit Sachdeva, "Whites Excrete a Water Load More Rapidly Than Blacks," *Hypertension* 53, no. 4 (2009): 715–18.

32. Roger G. Evans and Peter Bie, "The Role of the Kidney in the Pathogenesis of Hypertension: Time for a Neo-Guytonian Paradigm or a Paradigm Shift?," *American Journal of Physiology—Regulatory, Integrative and Comparative Physiology* (2015); Arthur C. Guyton, "Dominant Role of the Kidneys and Accessory Role of Whole-Body Autoregulation in the Pathogenesis of Hypertension," *American Journal of Hypertension* 2, no. 7 (1989): 575–85.

33. Clare M. Hasler, "Health Claims in the United States: An Aid to the Public or a Source of Confusion?," *Journal of Nutrition* 138, no. 6 (2008): 1216s–20s.

THE RELATIONSHIP BETWEEN MACRONUTRIENTS AND HEALTH OUTCOMES

The FDA argued that mandatory labeling would decrease rates of cancer, CHD, osteoporosis, obesity, hypertension, and allergic reactions to food. Reductions in the number of cancer cases and early deaths were estimated to occur as a result of reduced total fat intake after a lag of ten years. CHD reductions were estimated to take three years and to result from lowered serum cholesterol as a result of decreases in saturated fat and cholesterol intake. Over the 20-year period the regulation was estimated to prevent about 39,100 cases of cancer and heart disease, of which 12,900 would have resulted in death, yielding 80,900 life-years gained. The estimated monetary value of the benefits (number of life-years saved) was \$3.6 billion (discounted at 5 percent over a 20-year period).

The first issue is that the link from (total) dietary fat to cancer now appears not to exist. The results of a comprehensive study of 50,000 women in the Women’s Health Initiative Dietary Modification Trial “shows no effect on heart disease, breast cancer, colorectal cancer or weight.” The reductions in cancer deaths since the early 1990s are believed to stem from tobacco control efforts, as well as from advances in early detection and treatment. That leaves CHD.

The Scientific Report of the 2015 Dietary Guidelines Advisory Committee found that saturated fat is still “overconsumed by the U.S. population relative to the Tolerable Upper Intake Level set by the IOM.”³⁴ While the validity of those data has been strongly refuted,³⁵ it is clear that over the past three decades deaths from CHD have declined more in some populations than others (e.g., there is higher prevalence of CHD among non-Hispanic blacks than whites).³⁶ From 2006 to 2010, age-adjusted CHD prevalence in the United States declined overall from 6.7 percent to 6.0 percent. Similar declines were observed across age group, sex, and education categories. Among racial and ethnic populations, declines from 2006 to 2010 were observed among whites (6.4 percent to 5.8 percent) and Hispanics (6.9 percent to 6.1percent).³⁷

One study found that reducing the risk (as opposed to treatment) accounted for about 51 percent of the reduced number of deaths from CHD.³⁸ Another study found that the declines in

34. Dietary Guidelines Advisory Committee, “Scientific Report of the 2015 Dietary Guidelines Advisory Committee,” Office of Disease Prevention and Health Promotion, last updated February 21, 2016, Part A: Executive Summary.

35. Edward Archer, Gregory Pavea, and Carl Lavie, “The Inadmissibility of What We Eat in America and NHANES Dietary Data in Nutrition and Obesity Research and the Scientific Formulation of National Dietary Guidelines,” *Mayo Clinic Proceedings* 90, no. 7 (2015): 911–26; Edward Archer, Gregory Pavea, and Carl Lavie, “A Discussion of the Refutation of Memory-Based Dietary Assessment Methods (M-BMs): The Rhetorical Defense of Pseudoscientific and Inadmissible Evidence,” *Mayo Clinic Proceedings* 90, no. 12 (2015): 1736–38.

36. Centers for Disease Control and Prevention, “Morbidity and Mortality Weekly Report, Coronary Heart Disease and Stroke Deaths—United States, 2009.”

37. Centers for Disease Control and Prevention, “Morbidity and Mortality Weekly Report, Prevalence of Coronary Heart Disease—United States, 2006–2010,” October 14, 2011, 1377, 1381.

38. Simon Capewell, C. E. Morrison, and J. J. McMurray, “Contribution of Modern Cardiovascular Treatment and Risk Factor Changes to the Decline in Coronary Heart Disease Mortality in Scotland between 1975 and 1994,” *Heart* 81 (1999): 385.

CHD were from improvements in cholesterol (24 percent), blood pressure (20 percent) and smoking (12 percent) but were attenuated by adverse changes in obesity (8 percent) and diabetes (10 percent).³⁹ There is strong ecological evidence to support the claim that reductions in CHD morbidity and mortality are directly related to reductions in smoking. This result is supported by a large body of evidence for the effects of smoking on CHD.⁴⁰ It is difficult to ascribe causation for CHD to any one particular cause, other than smoking, because as one study notes, the analyses of causation “often end like the Caucus-Race in *Alice in Wonderland*, in which the Dodo Bird, officiating, declared that ‘everybody has won, and all must have prizes.’”⁴¹

However, one piece of evidence points squarely away from the NLEA having positive effects on CHD. Before the NLEA, in the periods from 1976 to 1980 and 1994 to 1998, the prevalence of high LDL cholesterol decreased from 59 percent to 42 percent.⁴² But interestingly, between 1990 and 2000 the age-adjusted decrease in CHD mortality slowed and nearly ceased in younger groups in industrialized countries, including the United States.⁴³ As one author puts it, “in contrast (to previous declines), during the 1990s and the early part of the 21st century, death rates for CHD continued to decline but at a slower rate than in the previous twenty years. Moreover, CHD deaths in-hospital began to decline at a greater rate than those outside hospital, suggesting that improvements in medical care had a relatively greater effect than did public health efforts during the recent period.”⁴⁴ Thus, it is hard to attribute changes in intake of saturated fat from the NLEA to reduced CHD. Success in lowering the incidence of CHD and cancer is most likely the result of factors other than mandatory nutrition labels. In fact, one study found that the percentage of adults who met the guidelines for saturated fat intake in the periods from 1994 to 1998 and 2007 to 2010 remained unchanged.⁴⁵

Another effect, which is still not completely understood, is the relationship between income and health. FDA economists did note in their RIA that this regulation was likely to be paid for by consumers through higher prices—that means it would decrease their ability to spend on other risk-reducing activities, the “health/health” effect. In retrospect, the cost of the NLEA

39. E.S. Ford and S. Capewell, “Proportion of the Decline in Cardiovascular Mortality Disease Due to Prevention Versus Treatment: Public Health Versus Clinical Care,” *Annual Review of Public Health* 32 (2011): 5–22.

40. Caroline M. Fichtenberg and Stanton A. Glantz, “Association of the California Tobacco Control Program with Declines in Cigarette Consumption and Mortality from Heart Disease,” *New England Journal of Medicine* 343, no. 24 (2000): 1772–77; Michael J. Thun et al., “50-Year Trends in Smoking-Related Mortality in the United States,” *New England Journal of Medicine* 368, no. 4 (2013): 351–64; Steven Woloshin, Lisa M. Schwartz, and H. Gilbert Welch, “The Risk of Death by Age, Sex, and Smoking Status in the United States: Putting Health Risks in Context,” *Journal of the National Cancer Institute* 100, no. 12 (2008): 845–53.

41. Lewis Carroll, *Alice’s Adventures in Wonderland* (1865), cited in David S. Jones and J.A. Green, “The Decline and Rise of Coronary Heart Disease: Understanding Public Health Catastrophism,” *American Journal of Public Health* 103, no. 7 (2013): 1207–18.

42. *Ibid.*

43. Simon Capewell et al., “Cardiovascular Risk Factor Trends and Potential for Reducing Coronary Heart Disease Mortality in the United States of America,” *Bulletin of the World Health Organization* (December 8, 2009).

44. “The Decline: Trends in Coronary Heart Disease and Stroke Mortality,” *Heart Attack Prevention*, University of Minnesota, last modified October 15, 2012.

45. Elena V. Kuklina et al., “Trends in High LDL Cholesterol, Cholesterol-Lowering Medication Use, and Dietary Saturated-Fat Intake: United States, 1976–2010” (Data brief no. 117, Centers for Disease Control and Prevention, March 2013).

was probably an order of magnitude larger than what was estimated so that, to the extent this effect is real, there may have been other health consequences.

THE FDA UNDERESTIMATED THE MARKET FOR NUTRITION INFORMATION

Part of the issue for any retrospective review is to determine whether the agency correctly estimated both the current market conditions and the baseline and how markets will change in the future to correct (at least perceived) market failures. In this case, the question is how markets respond to issues associated with the diet-disease relationship.

A widely reported study concludes that 16 of the nation's leading food and beverage companies sold 6.4 trillion fewer calories in 2012 than they did in 2007.⁴⁶ These companies had pledged to lower calories and have so far exceeded their 2015 pledge by more than 400 percent. Clearer evidence comes from a Department of Agriculture study conducted by economist Steve W. Martinez showing rapid growth of new products displaying health claims that are considered evidence of growing awareness of health-related issues.⁴⁷ Health- and nutrition-related claims per product increased from 2.2 in 2001 to 2.6 in 2010, which the author interprets as competition fostering a more complete representation of products' health and nutritional attributes. Claims related to gluten, antioxidants, and Omega-3 fatty acids ranked among the leading health- and nutrition-related (HNR) claims. The study suggests that growing demand for food products that allegedly contribute to overall health beyond basic nutrition provided incentives to manufacturers to supply and promote these products.

The same study finds that voluntary use of HNR claims on new food products was an important component of food companies' marketing strategies. The percentage of new food products carrying HNR claims grew from 25 percent in 2001 to 43 percent in 2010. Claims related to calories, whole grain, fiber, sugar, and vitamins and minerals were important contributors to growth in HNR claims on new products after 2001. Sales of new products introduced in 2009 and 2010 with nutrient content claims exceeded those of all new food products by 8 percent to 28 percent. There is no direct evidence that public health has improved as a result, and as mentioned earlier, consumers tend to use claims as indicators that a product is healthy overall.

A study of Nielsen sales data from 2007 through 2011 from grocery stores, drug stores, and mass merchandisers reports similar results.⁴⁸ Food products by 15 of the largest food and beverage manufacturers were classified into traditional and "better-for-you" (BFY) categories. BFY products included those designated as diet, lite, fewer calories, or zero calorie

46. The companies, acting together as part of the Healthy Weight Commitment Foundation, pledged to remove 1 trillion calories from the marketplace by 2012 and 1.5 trillion by 2015. See "Major Food, Beverage Companies Remove 6.4 Trillion Calories from U.S. Marketplace," Healthy Weight Commitment Foundation (January 8, 2014).

47. Steve W. Martinez, "Introduction of New Food Products with Voluntary Health- and Nutrition-Related Claims, 1989-2010," US Department of Agriculture (February 2013).

48. "Better-for-You Foods: It's Just Good Business," Obesity Solutions Initiative, Hudson Institute, Washington, DC (October 2011).

(e.g., Lean Cuisine, Coca-Cola Zero, Tropicana 50) as well as “good” foods, including whole-grain products and healthier traditional product formulations such as Cheerios, Dannon yogurt, and Nabisco Wheat Thins. Traditional products (i.e., not BFY items, such as Pepsi, Kellogg’s Frosted Flakes, and Hellmann’s mayonnaise) accounted for 61.4 percent of sales, while “lite” and “good” products each accounted for 19.3 percent of sales. BFY products accounted for less than 40 percent of sales but accounted for more than 70 percent of sales growth. Again, there is no direct evidence that public health has changed as a result.

When firms began to make health claims in the 1950s, and when claims increased in the 1980s, the FDA became concerned that the claims were “false and misleading,” although the claims frequently cited authoritative sources such as the American College of Nutrition.⁴⁹ With the NLEA, the federal government mandated that firms make claims only based on its conception of “sound science.” However, one study performed five years after the law noted that “cooking oils with higher levels of saturated fat content and lower monounsaturated fat content gained market share,” the inverse of one of the goals of the regulations.⁵⁰ The author goes on to say, “Evidence suggests that elimination of health claims for cooking oils may have stifled the flow of useful information to consumers, especially less-educated consumers.”⁵¹

Businesses face “market tests” in a world where consumers may reject products that fail to deliver value, and it is entirely possible that consumers would have responded to claims in that manner. Consumers eventually understand whether marketing claims are real or not, with the result that deceptively marketed products are improved or removed from shelves. Ongoing feedback from consumers helps to weed out poor product attributes, including calories, “healthiness,” packaging, taste, and price.

Government policymakers, such as those at the FDA, do not face comparable “market tests” and thus face fewer incentives to critically review misguided policies. Feedback is limited in an environment where ineffective labels do not directly jeopardize jobs or financial viability. As the evidence shows with recent regulatory proposals, the federal government appears to be unlikely to dramatically rethink mandatory label regulation in the face of failure to achieve its predictions that public health would improve as a result. Changes to the existing label, which are limited by the NLEA, are not likely to achieve public health gains.

One serious threat to public health is that FDA-mandated labels “crowd out” market experimentation with voluntary labeling by businesses aiming to profit from marketing products that actually help consumers who are interested in improving their health. There is only so much space on a food package that can be devoted to labeling, and the FDA has clearly monopolized a substantial chunk of packaging space for itself. Moreover, the FDA’s view of the choices of what must be on those labels has also created incentives for businesses to reformulate their

49. Alan D. Mathios, “The Importance of Nutrition Labeling and Health Claim Regulation on Product Choice: An Analysis of the Cooking Oils Market,” *Agricultural and Resource Economics Review* 27, no. 2 (October 1998).

50. *Ibid.*, 166.

51. *Ibid.*

products in ways that make their products look “better” to consumers. But what is certainly the case over the last 23 years is that nutrition information as presented is far too difficult for consumers to use to manage their overall health as it relates to diet. What voluntary labels and product innovations would look like today in the absence of mandated government labels remains an interesting and important question for public health that the FDA has unfortunately ignored.

Recent labeling regulations on away-from-home food—which accounts for a rapidly growing share of food spending—have also met with failure. A related literature on mandatory calorie-labeling laws at restaurants indicates little empirical support for the FDA’s contention that mandatory labels steer consumers toward “healthier” purchases.⁵² Labeling requirements are designed to help individuals who routinely underestimate calories, fats, and other attributes of foods. Studies indicate that labeling improves calorie estimates, but little evidence suggests that labels result in healthier eating.⁵³ A study of New York City’s 2008 law requiring restaurant chains to post calorie counts found no change in calories purchased after the law.⁵⁴ A similar conclusion was reached in a study of menu-labeling regulation in King County, Washington.⁵⁵ A study of the effect of mandatory calorie posting on purchase decisions at Starbucks also reported virtually no change in purchases of beverage calories.⁵⁶ Providing daily, per-meal, or no calorie recommendations to randomized subsets of adult customers entering two McDonald’s restaurants had no effect on purchases in another study.⁵⁷ Calorie labeling did not influence what patrons of a large chain bakery café ordered for lunch in still another study.⁵⁸ As Jonathan Cantor and his colleagues state, “Menu labeling at fast-food chain restaurants, which the Affordable Care Act requires to be implemented nationwide in 2016, remains an unproven strategy for improving the nutritional quality of consumer food choices at the population level.”⁵⁹

CONCLUSION

The FDA’s regulation of food labeling has not achieved the various goals it outlined in its RIA, and given the limitations to its behavioral model, it is unlikely to achieve them. The evidence is

52. Eric A. Finkelstein et al., “Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington,” *American Journal of Preventive Medicine* 40, no. 2 (2011): 122–27; Brian Elbel et al., “Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City,” *Health Affairs* 28 (2009): 1110–21.

53. Brian Elbel, “Consumer Estimation of Recommended and Actual Calories at Fast Food Restaurants,” *Obesity* 19, no. 10 (2011): 1971–78.

54. Elbel et al., “Calorie Labeling and Food Choices.”

55. Finkelstein et al., “Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington.”

56. Brian Bollinger, Phillip Leslie, and Alan Sorensen, “Calorie Posting in Chain Restaurants,” *American Economic Journal: Economic Policy* 3, no. 1 (2011): 91–128.

57. Julie S. Downs et al., “Supplementing Menu Labeling with Calorie Recommendations to Test for Facilitation Effects,” *American Journal of Public Health* 103, no. 9 (2013): 1604–9.

58. Sarah L. Rendell and Charles Swencionis, “Point-of-Purchase Calorie Labeling Has Little Influence on Calories Ordered Regardless of Body Mass Index,” *Current Obesity Reports* (June 26, 2014).

59. Jonathan Cantor et al., “Five Years Later: Awareness of New York City’s Calorie Labels Declined, With No Changes in Calories Purchased,” *Health Affairs* 34, no. 11 (2015): 1893–900.

also consistent with the above review of literature indicating that the science behind informing citizens about various health attributes of products through labels is problematic.

It is not surprising that the labeling did not achieve its goal when it is understood that the FDA relied mostly on a small study that tracked how consumers reacted to various flags (i.e., not nutritional panels on packages) on shelves at several grocery stores in one metro area to predict how shoppers would react to mandated labels. Subsequent empirical evidence indicates that NFP labeling is read by some consumers, but the regulation effects little to no changes in food purchases. Although some consumers still use food labels, they do not and cannot use them in a way that improves their health because they have no way of aggregating the information presented. They also do not have an easy way to relate information on the food label to their personal metabolic and health responses to that product. Further, there is scant evidence that public health has improved overall.

The FDA has engaged in what has recently been termed “heroic policymaking,” which describes ongoing experimentation undertaken by policymakers on citizens.⁶⁰ The FDA should be concerned that its quest to improve and mold citizens’ eating behaviors is based more on ad hoc theorizing than on solid scientific evidence. A major concern remains that, rather than undertaking a critical review of the existing labeling paradigm, the FDA simply revamps existing regulations, either cosmetically or significantly, without credible scientific insight. The heroic assumptions about a simple linear progression from information on individual food attributes to changes in behavior to improved public health outcomes have been shown to be wrong.

At a minimum, the nutrient information as currently presented on the label does not appear to be particularly effective for improving public health outcomes. This suggests that further marginal alterations to this label are unlikely to be helpful as well. But it also suggests, more broadly, that federal interventions in regulating marketplace information deserve much greater scrutiny before such interventions are allowed to go forward.

60. “Randomised Controlled Trials: In Praise of Human Guinea Pigs,” *Economist*, December 12, 2015.



FOOD LABELING: Revision of the Nutrition and Supplement Facts Labels

Docket No. FDA-2012-N-1210-0002

Sherzod Abdukadirov

Research Fellow, Mercatus Center at George Mason University

Department of Health and Human Services, Food and Drug Administration

RIN 0910-AF22

Submitted May 19, 2014

Comment Period Closes June 2, 2014

INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of the proposed rule from an economic point of view. Specifically, it examines how the proposed rule may be improved by more closely examining the societal goals that the rule intends to achieve and by determining whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or by more carefully assessing the actual societal problem.

SUMMARY

Pursuant to the Nutrition Labeling and Education Act (NLEA) of 1990¹ and the Dietary Supplement Health and Education Act (DSHEA) of 1994,² the Food and Drug Administration (FDA) issued regulations requiring food and dietary supplement products to display labels declaring their nutrient content. The regulations specified the format for nutrition labeling as well as the reference values to use in declaring the nutrient content.

1. Pub. L. No. 101-535, 104 Stat. 2353 (1990).

2. Pub. L. No. 103-417, 108 Stat. 4325 (1994).

For more information, contact
Robin Bowen, (703) 993-8582, rbowen@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Boulevard, 4th Floor, Arlington, VA 22201

The FDA now proposes to revise its food labeling regulations in order to improve the nutrition label's accuracy and usability.³ In particular, the proposed Food Labeling rule aims to do the following:

1. Update the nutrition label content based on the latest scientific evidence on health and nutrition captured in the Institute of Medicine (IOM) reports and Dietary Guidelines for Americans (DGA).
2. Update the nutrition label design to improve its use and readability.
3. Prompt manufacturers to reduce added sugars or to reformulate their products in order to maintain health claims under the updated Daily Value (DV) amounts.

The FDA makes an important effort to update its nutrition label content to reflect the best available science. The proposed rule will provide the public with more accurate nutritional information and will help consumers make healthier food choices and ultimately improve their health. With this rule, the FDA follows the principle set out in Executive Order 13563, which requires each agency to “ensure the objectivity of any scientific and technological information and processes used to support the agency’s regulatory actions.”⁴

Unfortunately, the FDA fails to apply this principle consistently. While the FDA makes a strong case that updating DV amounts would help consumers ensure adequate intake of vital nutrients, the agency provides little evidence that the proposed additional mandatory declarations and label format changes will result in consumers making healthier choices. On the contrary, the study commissioned by the FDA shows that a major proposed label change to increase the prominence and font size of calorie information has little impact on consumers’ choices. The FDA failed to test the effectiveness of other proposed label changes as well.

In addition, the FDA uses flawed assumptions to derive the rule’s benefit estimates and bases its calculations on a single unpublished study, casting doubt on its estimates’ validity. Even taking its flawed benefit estimates at face value, the FDA fails to maximize net benefits. The FDA opts for a two-year compliance period, even though the four-year compliance period offers higher net benefits and a fourfold reduction in regulatory burdens, which would translate into lower food prices for consumers.

Before issuing the final regulation, the FDA should take the following steps:

1. Obtain empirical evidence about whether its proposed label changes will have the expected beneficial health impact.
2. Reexamine its benefit estimates using peer-reviewed studies. In estimating benefits, the FDA should rely on the empirical studies clearly demonstrating the health impacts of proposed label changes. It should not simply assume that the proposed rule would produce the same type of benefits as the NLEA rule.
3. Separately estimate the marginal benefits of each proposed change and focus only on changes shown to have a positive impact.
4. Consider a broader range of regulatory alternatives.
5. Opt for a longer compliance period in order to maximize net benefits and to considerably reduce compliance costs.
6. Establish measures to monitor the rule’s health impacts.

3. US Department of Health and Human Services, Food and Drug Administration, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels,” 79 Fed. Reg. no. 41 (proposed March 3, 2014): 11880–987.

4. Executive Order 13563—Improving Regulation and Regulatory Review, 76 Fed. Reg. no. 14 (January 18, 2011): 3821.

MORE EMPIRICAL EVIDENCE NEEDED TO SUPPORT THE RULE

The FDA hopes to achieve three different goals with this rule:

1. Update the nutrition label to provide more accurate nutritional information that reflects the latest IOM and DGA recommendations. The updated label may help consumers make healthier choices and could potentially reduce some chronic disease risks.
2. Improve readability by redesigning the label format. Better label design may make it easier for consumers to understand the nutritional information displayed on the label and increase the likelihood that they would use the nutritional information to make healthier choices.
3. Prompt producers to reformulate products. Given the new definition for fiber and updated DVs for some nutrients, some food manufacturers may reformulate their products in order keep the products' health claims. Similarly, some food manufacturers may respond to the requirement for added sugars disclosure by reducing the added sugars in their products. This would improve the healthfulness of products available to consumers.

Goal 1: Updating Nutrition Label Content

The proposed rule's first goal is to update the nutrition label content based on the latest available science. The FDA last updated the Nutrition Facts label in 2003 in response to the trans fat rule,⁵ and it last updated DVs for nutrients in 1995.⁶ The FDA's current proposal includes changing the definition for dietary fiber and updating DVs for some vitamins and minerals to reflect the latest IOM and DGA recommendations. In addition, the FDA proposes to include a new mandatory nutrient disclosure for "Added Sugars" in the updated nutrition label together with other label format changes. The proposed rule also drops the mandatory declaration requirement for vitamin A and vitamin C, but adds new mandatory declarations for vitamin D and potassium. The FDA identifies the latter as nutrients with potential public health significance, as some populations may be deficient in these nutrients.

Updated DVs for Nutrients

Currently, the label does not incorporate the latest dietary recommendations, which would reflect the changes in public health and the availability of new information about nutrients and reference intake values.⁷ Consequently, the label may be misinforming consumers about the healthfulness of their food choices. For example, the rule updates the DV for fiber based on IOM report recommendations.⁸ The new value is set at the level associated with the greatest reduction in risk of coronary heart disease. Similarly, the rule increases the recommended DV for potassium, which may reduce high blood pressure, and calcium, which may reduce osteoporosis.⁹ Studies indicate a low intake and possibly even a deficiency in these key nutrients in the general population.¹⁰

Since the FDA prescribes the label content, the regulation is necessary to correct the nutritional information. The updated nutritional label would provide consumers with more accurate information, help consumers make healthier food choices, and potentially reduce certain disease risks associated with deficiencies in key nutrients.

5. US Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims," 68 Fed. Reg. no. 133 (July 11, 2003): 41434–506.

6. US Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Reference Daily Intakes," 60 Fed. Reg. no. 249 (December 28, 1995): 67164–175.

7. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Facts Label," 11884.

8. *Ibid.*, 11911.

9. *Ibid.*, 11918–31.

10. *Ibid.*, 11918–19, 11922.

The FDA classifies added sugars as “sugars and syrups that are added to foods during processing or preparation.”¹¹ The added sugars line would be inserted in the label under the line for total sugar content. The agency justifies its decision by claiming that added sugars serve as the main source of calories for youths.¹² The FDA points out that, in contrast to foods with natural sugars, added sugars generally do not provide nutritional value. Further, it claims that added sugars may be displacing other nutrients or leading to overconsumption of calories.

The FDA provides little evidence that adding a separate line for added sugars would yield any health benefits. The IOM Dietary Reference Intakes report states that “added sugars are not chemically different from naturally occurring sugars.”¹³ As the FDA points out, “neither the 2010 DGA nor the IOM macronutrient report concluded that added sugars consumption from all dietary sources, in itself, increases obesity.”¹⁴ Similarly, the 2010 DGA states that added sugars do not increase obesity more than any other source of calories.¹⁵ Consequently, information related to added sugars is not a material fact and there is little reason for the FDA to require disclosure of different types of sugars.

To the degree that sugars add to calorie consumption or increase the risk of dental caries, the nutrition label already provides such information with the “Sugars” line. While it is possible that displaying added sugars may prompt consumers to examine the nutritional value of the product, the FDA provides no evidence that this will be the case. In contrast to other proposed nutrition label modifications, the FDA did not test whether providing information on added sugars would lead consumers to healthier food choices.

Empirical evidence for the potential impact of added sugars disclosure on consumer choices is mixed. Some studies show that negative disclosures lead consumers to switch to healthier choices. For example, in a study predating the NLEA, Edward Russo and his colleagues find that consumers switched to low-sugar versions when the sugar content of cereal was disclosed.¹⁶ In similar studies, which examined the impact of fat and cholesterol disclosures, consumers preferred healthier product versions.¹⁷ However, these studies examined the impact of disclosing previously unavailable nutrition information. In contrast, the requirement to disclose added sugars provides little new information but rather breaks down the source of sugars in food. It is possible that the requirement to show added sugars will not produce health benefits just as including “Calories from Fat” on the nutrition label had no impact on consumer choices.¹⁸

In addition, consumer responses to the disclosure may lead to unintended consequences. For example, several studies found that foods with “low-fat” labels may lead to excess consumption and increased obesity.¹⁹ The perceived healthfulness of the low-fat products reduced guilt associated with excess consumption. It also increased what consumers perceived to be an appropriate serving size. Similarly, consumers opting for products low in added sugars may increase overall consumption, as they would feel less guilty about eating such products. Additionally, consumers focusing exclusively on added sugars may overlook the overall sugar content and fail to constrain total sugar intake.

11. HHS, FDA, “Food Labeling: Revision of the Nutrition and Supplement Fact Labels,” 11902.

12. *Ibid.*, 11903.

13. Institute of Medicine (IOM) of the National Academies, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (Washington, DC: National Academies Press, 2002), 267.

14. HHS FDA, “Food Labeling: Revision of the Nutrition and Supplement Fact Labels,” 11904.

15. US Department of Agriculture and US Department of Health and Human Services, *Dietary Guidelines for Americans*, 2010, 7th ed. (Washington, DC: U.S. Government Printing Office, 2010).

16. J. Edward Russo et al., “Nutrition Information in the Supermarket,” *Journal of Consumer Research* 13, no. 1 (1986): 48–70.

17. Siva K. Balasubramanian and Catherine Cole, “Consumers’ Search and Use of Nutrition Information: The Challenge and Promise of the Nutrition Labeling and Education Act,” *Journal of Marketing* 66, no. 3 (2002): 112–27; Judith A. Garretson and Scot Burton, “Effects of Nutrition Facts Panel Values, Nutrition Claims, and Health Claims on Consumer Attitudes, Perceptions of Disease-Related Risks, and Trust,” *Journal of Public Policy & Marketing* 19, no. 2 (2000): 213–27.

18. Amy M. Lando and Serena C. Lo, “Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Choices,” *Journal of the Academy of Nutrition and Dietetics* 133 (2013): 241–50.

19. Brian Wansink and Pierre Chandon, “Can ‘Low-Fat’ Nutrition Labels Lead to Obesity?,” *Journal of Marketing Research* 43, no. 4 (2006): 605–17; Kelly Geyskens et al., “The Backdoor to Overconsumption: The Effect of Associating ‘Low-Fat’ Food with Health References,” *Journal of Public Policy & Marketing* 26, no. 1 (2007): 118–25.

It is crucial that the FDA ensures that the label's additional content leads to better health outcomes before mandating its inclusion on the nutrition label. Including content that does not help consumers make healthier choices may crowd out the more vital content on the label and confuse consumers about their choices.²⁰ The FDA limits voluntary disclosures on the nutrition label for this reason.²¹

Mandatory Vitamin and Mineral Declaration

While the health benefits of consuming foods rich in mandatorily disclosed vitamins and minerals are not in doubt, the FDA does not consider the option of making these declarations voluntary. Manufacturers of foods rich in these nutrients already have strong incentives to declare the relevant vitamin and mineral content voluntarily. Thus, Athanasios Krystallis and Polymeros Chrysochou find that health claims increase consumer loyalty,²² while Klaus Grunert and Josephine Wills find that health claims increase consumers' positive attitude toward brands.²³ Manufacturers have strong incentives to find ways to educate consumers about the importance of these nutrients and to persuade consumers to increase consumption of nutrient-rich products. Studies by Pauline Ippolito and Alan Mathios and Pauline Ippolito and Janis Pappalardo show that food manufacturers are very effective at communicating to consumers the health information about nutrients through voluntary health claims.²⁴ Ippolito and Pappalardo note that voluntary health claims about calcium and other vitamins and minerals increased post-NLEA.²⁵

It is also important to keep in mind that consumer responses may moderate the impact of vitamin and mineral declarations. Siva Balasubramanian and Katherine Cole show that consumers are more likely to react to negative disclosures than to positive ones.²⁶ After the NLEA rule, consumers reduced their intake of high-fat and high-cholesterol foods (negative disclosure); however, their consumption of vitamin C decreased while calcium consumption remained unchanged (positive disclosures). Similarly, Russo and his colleagues find that consumers changed their purchasing behavior in response to disclosures for sugar content (negative) but not to disclosures for vitamins and minerals (positive);²⁷ Judith Garretson and Scott Burton find that fat content disclosures (negative) affected consumers' perception of the food's disease risks, while fiber content disclosures (positive) did not.²⁸

The FDA should test whether mandatory vitamin and mineral disclosures would have the desired health impacts. In addition, it should examine whether food manufacturers will provide such information voluntarily.

Goal 2: Label Redesign

In addition to updating label content, the rule proposes several changes to the way information is displayed on the label. Four of the proposed 13 changes would modify the content displayed on the label: (1) adding mandatory declaration for added sugars, (2) adding mandatory declaration for quantitative amounts for nutrients, (3) modifying the amount-per-serving declaration, and (4) removing the calories from fat declaration. The remaining changes mostly impact the label's formatting.

20. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Fact Labels," 11888.

21. *Ibid.*

22. Athanasios Krystallis and Polymeros Chrysochou, "Health Claims as Communication Tools That Enhance Brand Loyalty: The Case of Low-Fat Claims within the Dairy Food Category," *Journal of Marketing Communications* 17, no. 3 (2011): 213–28.

23. Klaus G. Grunert and Josephine M. Wills, "A Review of European Research on Consumer Response to Nutrition Information on Food Labels," *Journal of Public Health* 15, no. 5 (2007): 385–99.

24. Pauline M. Ippolito and Alan D. Mathios, "Information and Advertising: The Case of Fat Consumption in the United States," *American Economic Review* 85, no. 2 (1995): 91–5; Pauline M. Ippolito and Janis K. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997*, Federal Trade Commission Bureau of Economics Staff Report (Washington, DC: Federal Trade Commission, 2002), <http://www.ftc.gov/reports/advertising-nutrition-health-evidence-food-advertising-1977-1997>.

25. Ippolito and Pappalardo, *Advertising Nutrition & Health*, 47.

26. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information."

27. Russo et al., "Nutrition Information in the Supermarket."

28. Garretson and Burton, "Effects of Nutrition Facts Panel Values."

Table 1. Proposed Label Changes

Proposed change	Cited research
1. Increase the prominence of calories and the serving size information.	Lando and Lo*
2. Reverse the order of the "Serving Size" declaration and the "Servings Per Container" declaration.	
3. Right-justify the quantitative amounts of the serving size information.	
4. Change the "Amount Per Serving" declaration to "Amount Per ____," filling in the blank with a common household measure, e.g., "Amount Per 2/3 Cup."	
5. Remove the declaration of "Calories from Fat."	Lando and Lo*
6. Change the nutrient declarations and "% Daily Value" declarations on some products for some nutrients.	
7. Declare "Added Sugars" as an indented listing directly beneath the listing for "Sugars."	
8. Change the unit of measure for some nutrients.	
9. Declare the quantitative amounts (in addition to the % Daily Value) of mandatory and, when declared, voluntary vitamins and minerals.	
10. Modify the footnote.	
11. Require that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular type.	
12. Modify the presentation of the "% Daily Value" information by changing its position on the label and separating it from the list of nutrients with a vertical line.	
13. Add a horizontal line directly beneath the "Nutrition Facts" heading.	

* Amy M. Lando and Serena C. Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Choices," *Journal of the Academy of Nutrition and Dietetics* 133 (2013).

Source: US Department of Health and Human Services, Food and Drug Administration, *Analysis of Impacts* (March 3, 2014): 48–49, the other three changes come from the *Serving Size* rule.

The FDA relies on the growing behavioral economics literature to justify some of the proposed label changes. Some FDA-cited studies claim that consumers fail to think through the long-term health implications of their food choices when they purchase highly caloric foods with poor nutritional value.²⁹ They blame consumers' myopic decision-making for the growing obesity problem. The FDA reasons that it is not enough to simply inform consumers; the label format must also persuade them to make healthier choices.

The FDA hopes that, by increasing the salience of the information presented on the label, the proposed rule may help consumers overcome their myopic decision-making and increase their use of nutrition facts. For example, the FDA assumes that making calorie information more prominent would influence consumers to pay attention to the caloric content of the food.³⁰ Similarly, it assumes that disclosing added sugars would alert consumers if chosen foods are high in energy and poor in nutrition, and lead consumers to reconsider their choices.³¹

While the FDA cites some general behavioral economics research, it cites no studies to support its assumption that myopic behavior causes consumers to overlook the current nutrition label. In addition, the agency does not explain how its proposed changes would counter consumers' myopia. If consumers ignore the information presented on the current nutrition label because they fail to account for the long-term impacts of their diets, would they not ignore any additional or reformatted information on the new label?

In fact, the FDA-commissioned study cited in the regulatory impact analysis (RIA) finds that increasing the font size for calories had no impact on consumers' choices.³² Contrary to the FDA's assumption, increasing the prominence of calorie information did not make it more salient to consumers and did not lead to healthier choices. Nevertheless, the FDA decided to proceed with its proposal to increase the prominence of calories on the label.

29. US Department of Health and Human Services, Food and Drug Administration, *Analysis of Impacts* (hereafter referred to as "RIA") (March 3, 2014, available in the docket no. FDA-2012-N-1210 at regulations.gov): 6–8.

30. RIA, 8.

31. RIA, 7–8.

32. Lando and Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling."

The same study finds that removing the “Calories from Fat” statement did not reduce consumers’ ability to judge the product’s healthfulness, as the statement duplicated information already available through total caloric content.³³ Similarly, consumers may ignore the added sugars disclosure, as the information is already contained in the current sugars declaration.

Of the thirteen proposed changes to the label design, only two are backed by cited research. The agency provides no other empirical evidence to support its proposed changes. The FDA justifies the changes by claiming that the improved design would increase label comprehension and use. While it references a product design manual in support of this claim,³⁴ the agency does not test whether its new label actually improves consumers’ comprehension or leads to healthier choices. Similarly, the FDA cites research that shows consumers’ confusion over serving size information, yet it does not test whether its new serving size declaration improves consumers’ comprehension.³⁵

A study by Lauren Block and Laura Peracchio lends support to the FDA’s decision to include quantitative amounts for vitamins and minerals in addition to the “% Daily Value” declaration.³⁶ The study shows that most consumers, including physicians, struggle to transform “% Daily Value” into quantitative amounts, yet physicians typically prescribe vitamin and mineral intakes in milligrams. Quantitative amounts may be particularly useful for at-risk consumers whose recommended vitamin and mineral intake is higher than average. However, the FDA does not cite this or any other study to support its decision.

To improve the rule’s transparency, the FDA should seek out and provide empirical support for each proposed change. Where such evidence is not available, the agency should commission studies that examine the impact of proposed changes. Better documented evidence would allow the general public to make better informed opinions regarding the rule and provide more useful feedback to the FDA regarding the rule.

Goal 3: Product Reformulation

The proposed rule’s third goal is to prompt manufacturers to reformulate their products in response to changes in DVs and the updated dietary fiber definition, as well as the new requirement to disclose added sugars.

The NLEA allows food manufacturers to make health claims about their products if they fulfill specified criteria. For example, some products may claim to be a good source of fiber or calcium if they contain sufficient amounts of these nutrients. As the new rule would change the DVs for fiber and certain vitamins and minerals, it would also change the amount of these nutrients required to continue claiming health benefits for products. Consequently, some manufacturers may have to reformulate their products to contain the newly required amounts of nutrients in order to maintain the health claims with regard to the nutrient or dietary fiber content of their products. Similarly, some manufacturers may decide to reduce the added sugars of their products due to that category’s greater prominence on the label.

Both the benefits and the costs of this portion of the rule depend on the share of products that manufacturers decide to reformulate in response to new label requirements. Yet the FDA simply assumes that 50 percent of manufacturers will reformulate their products to maintain health claims and 5–6 percent of manufacturers will reduce the added sugar content.³⁷ The agency provides no basis for its assumptions.

Better research on how manufacturers would respond to the new label requirements could provide some clues about the share of products that are likely to be reformulated. Such research would include determining the consumer demand for products with health claims and the value of health claims to manufacturers. The more consumers demand products with health claims, the more likely manufacturers are to reformulate their products. For added sugars, the relevant information would be the impact of negative health information disclosures on

33. *Ibid.*

34. RIA, 50.

35. RIA, 50.

36. Lauren G. Block and Laura A. Peracchio, “The Calcium Quandary: How Consumers Use Nutrition Labels,” *Journal of Public Policy & Marketing* 25, no. 2 (2006): 188–96.

37. RIA, 36–38.

consumer choices. The more consumers react to negative health disclosures, the more likely manufacturers are to reduce unhealthy ingredients.

Some studies indicate that food manufacturers value health claims. For example, Krystallis and Chrysochou find that health claims increase brand loyalty.³⁸ Similarly, Grunert and Wills find that health claims increase positive attitudes toward the brand.³⁹ In general, Julie Caswell and her colleagues and Hans van Trijp and Ivo van der Lans show that health claims became an accepted way for food manufacturers to communicate important nutritional information.⁴⁰

However, consumer responses to food manufacturers' decision to reformulate their products may moderate the rule's impact. The FDA assumes that consumers will continue to purchase the same brands even after manufacturers reformulate them. In contrast, Christine Moorman, Rosellina Ferraro, and Joel Huber show that the NLEA nutrition disclosure requirements have actually decreased the nutritional value of brand products.⁴¹ The authors explain the paradox by pointing to the trade-off between taste and nutritional value. They hypothesize that, because consumers value taste over nutritional value, they switch from healthier products to tastier ones, reducing the market share of healthier brands.⁴²

Alternatively, the shift to less nutritious brands may be driven by consumers' sensitivity to prices.⁴³ Only a small fraction of consumers care about nutritional value, while the majority remain neutral to nutrition disclosures. When manufacturers reformulate their products to increase their nutritional value, they incur additional costs, which they pass on to consumers in terms of higher prices. While the few health-conscious consumers may pay higher prices for healthier products, the majority switch to cheaper, less healthy products. Faced with reformulation costs and price-sensitive consumers, many food manufacturers may forgo health claims to maintain lower prices.

Research relevant to added sugars disclosure is similarly mixed. Some studies indicate that consumers react to negative disclosures by switching to healthier versions of products.⁴⁴ The FDA could examine the magnitude of the change to provide some indication for the potential number of products that may be reformulated. On the other hand, Moorman and her colleagues' study shows that higher prices resulting from reformulation costs may actually reduce the demand for products low in added sugars.⁴⁵ In addition, the research showing that the "Calories from Fat" statement had little impact on consumer choices may indicate that few manufacturers would choose to reduce sugar content in response to the mandated added sugars disclosure.⁴⁶

FLAWED BENEFIT ESTIMATES

The FDA arrives at its benefit estimates by assuming that the proposed rule's impact would be similar to the original NLEA regulation that took effect in 1994. Then it calibrates the estimated benefits by accounting for the differences between the proposed rule and the NLEA. The FDA starts with estimated benefits of the NLEA regulation and then adjusts the estimate for increases in population, increased use of nutrition labels, the share of products regulated by the USDA, and the likely smaller impact that the new Food Labeling rule will have compared to the NLEA rule. The FDA acknowledges that the new rule will likely have a smaller impact since it will make fewer changes to the nutrition label.

38. Krystallis and Chrysochou, "Health Claims as Communication Tools That Enhance Brand Loyalty."

39. Grunert and Wills, "Review of European Research."

40. Julie A. Caswell et al., "The Impact of New Labeling Regulations on the Use of Voluntary Nutrient-Content and Health Claims by Food Manufacturers," *Journal of Public Policy & Marketing* 22, no. 2 (2003): 147–58; Hans C. M. van Trijp and Ivo A. van der Lans, "Consumer Perceptions of Nutrition and Health Claims," *Appetite* 48, no. 3 (2007): 305–24.

41. Christine Moorman, Rosellina Ferraro, and Joel Huber, "Unintended Nutrition Consequences: Firm Responses to the Nutrition Labeling and Education Act," *Marketing Science* 31, no. 5 (2012): 717–37.

42. Christine Moorman, Rosellina Ferraro and Joel Huber, "From Consumer Information Regulation to Nutrition Competition: A Response," *Marketing Science* 31, no. 5 (2012): 747–55.

43. Brian T. Ratchford, "Suggestions for Further Research on Firm Responses to NLEA and Other Disclosure Laws," *Marketing Science* 31, no. 5 (2012): 744–47.

44. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information"; Russo et al., "Nutrition Information in the Supermarket."

45. Moorman, Ferraro, and Huber, "Unintended Nutrition Consequences."

46. Lando and Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling."

The FDA's model for estimating benefits takes the following form:

$$B_t = POP_t \times s_t \times \Delta W \times USE \times (1 - USDA),$$

where B_t is the estimated benefit from enacting the proposed Food Labeling rule; POP_t is the adult and adolescent population at time period t ; s_t is the ratio of the benefits attributable to the proposed Food Labeling rule to the benefits attributable to the NLEA rule; ΔW is the estimated gain in welfare resulting from enacting the NLEA rule; USE is the ratio of estimated use of the Nutrition Facts label under the proposed rule to the estimated use of the Nutrition Facts label under the NLEA rule; and $USDA$ accounts for the share of food products whose labeling is regulated by the USDA rather than the FDA.⁴⁷

The variables that have the greatest impact on the estimated benefits of the Food Labeling rule are the estimated welfare gains from the NLEA rule (ΔW) and the expected effect of the proposed rule relative to the effect of the NLEA (s_t). Since the FDA assumes that the proposed rule will have a beneficial health impact similar to the NLEA rule, the greater the estimated NLEA rule benefits, the greater the estimated benefits for the proposed rule. On the other hand, the FDA recognizes that the rules' impacts will not be identical. So it needs to calibrate the estimated benefits for the proposed rule by accounting for its differences from the NLEA rule.

The FDA uses a study conducted by Jason Abaluck to obtain the estimated benefits of the NLEA rule.⁴⁸ In the paper, Abaluck first estimates the changes in consumer purchases that resulted from the NLEA rule.⁴⁹ He then estimates consumers' willingness to pay for this information by estimating the price changes necessary to produce a similar change in consumers' choices.

The FDA accounts for the smaller number of changes that the proposed rule will enact compared to the NLEA rule in order to calibrate for the smaller impact that the proposed rule will likely have compared to the NLEA rule.⁵⁰ The NLEA rule changed 100 percent of the label content to achieve its health impact. The proposed rule would change only 33 percent of the content for single-column labels and 25 percent of the content for dual-column labels. The FDA therefore extrapolates that the proposed rule's impact would be 33 percent of the NLEA rule's impact for single-column labels and 25 percent of the impact for dual-column labels.⁵¹

The rule's benefit estimates have several problems. First, they rely on a single unpublished study. Abaluck's paper is available online as a working paper, but it is yet to be published in a peer-reviewed academic journal. The FDA uses no other studies for its estimates, nor does the agency attempt its own benefit estimates.

Furthermore, after issuing the NLEA rule, the FDA failed to monitor the regulation's impact. Nor did it conduct a comprehensive retrospective analysis on the validity of its original analysis and the effectiveness of the regulation in achieving its stated goals. Despite that, the new Food Labeling rule establishes no plans to monitor the impact of the proposed regulation.

Second, the FDA assumes that the proposed Food Labeling rule and the original NLEA rule will have similar impacts. Thus, it assumes that both rules address the same type of problem through the same type of action. However, the NLEA regulation addressed an information asymmetry problem. The rule increased the proportion of products displaying nutrition labels from approximately 60 percent to almost 100 percent.⁵² In addition, the rule standardized the disclosure information to make it easily comparable across different products. Consequently, the NLEA rule dramatically increased the information available to consumers.

47. RIA, 45–46.

48. RIA, 46.

49. Jason Abaluck, "What Would We Eat If We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling" (working paper, October 17, 2011), http://economics.stanford.edu/files/Abaluck10_28.pdf.

50. RIA, 48–54.

51. To arrive at the mean estimate, the FDA multiplies these ratios by the share of label users and the share of total food products that single- and dual-column labels represent.

52. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information"; Jayachandran Variyam, "Do Nutrition Labels Improve Dietary Outcomes?," *Health Economics* 17, no. 6 (2008): 696–97.

In contrast, the proposed rule adds little new information to the nutrition label. The biggest dietary culprits, such as calorie count, fat, sugar, and cholesterol, are already on the nutritional label. The new label will display updated DVs for carbohydrates, dietary fiber, and some vitamins and minerals. However, the Report of the Working Group on Obesity shows that few consumers use DVs when making food choices.⁵³ The rule's biggest change is to redesign the nutrition label for better readability. It is unlikely that rearranging label information would have the same health impact as disclosing previously unavailable nutrition information.

Third, the FDA assumes that the strength of an impact for a new regulation is proportional to the amount of content rearranged on the label. Yet the FDA provides no support for its assumption. In short, it assumes that all information on the label is equal and all disclosures have the same impact on shaping consumers' choices. Yet consumers generally focus on specific nutrients on the label and ignore the rest.⁵⁴

The FDA should provide better benefit estimates for the proposed changes. It should not base its estimates on the NLEA's impacts since the two rules promulgate qualitatively different labeling changes. While the NLEA regulation dramatically increased nutritional information available to consumers, the proposed rule makes only a few content updates and mostly changes the label's format. Instead, the FDA should empirically test the potential impact of each proposed change. Further, the agency should consider the marginal benefit of each proposed change separately instead of lumping all changes together. This would increase the rule's transparency and present a clearer picture of the rationale behind each proposed change. It would also allow the agency to focus on the changes that provide the greatest benefit and discard those that yield no results.

REGULATORY ALTERNATIVES

Under Executive Order 13563, agencies must consider a range of alternatives including nonregulatory measures and then tailor their regulations to impose the least burden on society.⁵⁵ The FDA fails on both counts.

Few Alternatives Considered

The FDA considers five alternatives including the proposed rule, but these are only minor variations of each other:

1. no federal regulatory action
2. proposed changes with two-year compliance period (selected option)
3. proposed changes with three-year compliance period
4. proposed changes with four-year compliance period
5. proposed changes with a DV for sodium of 1500 mg and 1900 mg

The FDA considers the first option—issuing no new regulation—superficially at best and provides no benefit estimates for continuing with the current nutrition label. The FDA simply assumes that there would be no additional benefits derived from the current regulation. Yet food companies, prompted by increasing consumer demand for healthier food choices, may well continue to improve their offerings under the current regulation.

The next three options differ only in the length of compliance time afforded to food manufacturers. The proposed rule offers manufacturers two years to comply with its requirements. The other two options allow three- and four-year compliance periods. A later compliance date considerably decreases the rule's costs but also delays the

53. US Department of Health and Human Services, Food and Drug Administration, *Calories Count: Report of the Working Group on Obesity* (March 12, 2004), <http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm081696.htm>.

54. Sarah Campos, Juliana Doxey, and David Hammond, "Nutrition Labels on Pre-packaged Foods: A Systematic Review," *Public Health Nutrition* 14, no. 8 (2011): 1501.

55. Executive Order 13563, 3821.

rule’s potential benefits. The final option considers establishing a lower DV for sodium, but claims that evidence for its benefits is insufficient.

Other Alternatives That Should Be Considered

There are other options that the FDA should consider, ones that would yield benefits to consumers while limiting costs to producers. For example, labels could be updated only for DVs for nutrients. Another option is to make all vitamin and mineral declarations voluntary. In addition to providing a wider range of alternatives, these options would allow the FDA and the general public to compare the marginal costs and benefits of the different portions of the proposed rule and evaluate them separately.

The FDA should consider an option of only updating DVs for nutrients. Updating the label’s content to reflect the latest available science is important, and it makes a correction that only regulation can address, because current labeling reflects old regulatory standards. The FDA’s case for label redesign is considerably weaker; the agency presents scant evidence that its proposed label changes would have any impact. Limiting the rule to only DV updates would require manufacturers to make only minor changes to their labels, but it would produce the greatest benefit.

The FDA should also consider making all vitamin and mineral declarations voluntary. Manufacturers of products rich in vital nutrients will likely declare such nutrients without a mandate. They will also communicate the products’ benefits through health claims. Products poor in vitamins and minerals will simply leave the space blank. A less cluttered label would focus consumers’ attention on the other mandatory declarations with regard to calories, fat, and cholesterol.

Net Benefits Not Maximized

The rule should maximize the net benefits for the five regulatory options discussed in the analysis. Even taking the rule’s benefit estimates at face value, the rule fails to maximize net benefits (benefits minus costs). At a 3 percent discount rate, the four-year compliance option would provide \$29.6 billion in net benefits, while the FDA’s preferred two-year compliance option would provide \$29.1 billion in net benefits (see table 2). Yet the FDA does not explain its choice of a shorter compliance time.

Table 2. Summary of Net Benefits by Regulatory Option, 2013–2032
(in billions of 2011 dollars)

Option	Discount rate	Benefits	Costs	Net benefits
1. No new federal regulatory action	3%	\$0	\$0	\$0
	7%	\$0	\$0	\$0
2. Proposed rules, two-year compliance period	3%	\$31.4	\$2.3	\$29.1
	7%	\$21.1	\$2.3	\$18.8
3. Proposed rules, 3-year compliance period	3%	\$30.6	\$1.5	\$29.1
	7%	\$20.5	\$1.5	\$19.0
4. Proposed rules, 4-year compliance period	3%	\$30.2	\$0.6	\$29.6
	7%	\$20.1	\$0.6	\$19.5
5. Proposed rules, DV for sodium of 1,500 mg or 1,900 mg	3%	\$31.4	\$2.4	\$29.0
	7%	\$21.1	\$2.4	\$18.7

Source: US Department of Health and Human Services, Food and Drug Administration, Analysis of Impacts (March 3, 2014): 81.

The FDA's analysis shows that a longer compliance time reduces the rule's costs. Since manufacturers periodically update nutrition labels for their products, the new labeling requirements could be incorporated within these scheduled updates. Including the rule's requirements as part of coordinated updates considerably reduces manufacturers' compliance costs. An uncoordinated label change would cost manufacturers \$6,188 per product as opposed to only \$367 for a coordinated label change.⁵⁶

The longer manufacturers have to comply with the rule, the greater the share of products they can include in coordinated updates. The FDA's analysis shows that, with a two-year compliance time, 74 percent of private label food products, 78 percent of branded dietary supplements, and 84 percent of private label dietary supplements would have to undergo a costly uncoordinated label change.⁵⁷ Given a four-year compliance time, no food products or branded dietary supplements and only 49 percent of private label dietary supplements would undergo an uncoordinated label change.⁵⁸

Translated into dollar amounts, the two-year compliance option would cost \$2.3 billion while providing \$31.4 billion in benefits. In contrast, the four-year compliance option would cost \$0.6 billion while still providing \$30.2 billion in benefits. Thus, a two-year delay in the compliance date could result in an almost four-fold cost reduction, while only marginally reducing benefits.

The FDA should opt for a longer compliance time. Its benefit estimates are highly flawed, based on questionable assumptions and a single unpublished study. The agency provides little empirical support that proposed changes would be effective. Consequently, the rule's actual benefits are likely to be smaller. In contrast, the agency provides considerably better analysis of the proposed rule's costs. The fourfold reduction in costs resulting from a longer compliance time will reduce compliance costs to food manufacturers. Since manufacturers will likely pass on the additional costs to consumers, lower compliance costs will ultimately mean lower prices for consumers.

In addition, the FDA admits that the rule will significantly impact a large number of small businesses.⁵⁹ Under the Regulatory Flexibility Act, the FDA is required to consider flexible approaches to a rule in order to ease small businesses' regulatory burdens.⁶⁰ Similarly, Executive Order 13563 requires agencies to choose "among alternative regulatory approaches, those approaches that maximize net benefits."⁶¹ The four-year compliance option provides exactly the flexibility the Regulatory Flexibility Act requires by both maximizing net benefits and drastically reducing costs.

CONCLUSION

The proposed Food Labeling rule aims to improve the accuracy and usability of the nutrition label but with mixed results. The FDA makes a laudable effort to update the nutrition label information according to the best available scientific evidence. A more accurate nutrition label will allow consumers to make healthier food choices and will encourage adequate intake of vital nutrients. At the same time, the FDA provides little evidence that many of its proposed label format changes would have any beneficial health impacts. In addition, the agency bases its benefit estimates on a single unpublished study and several flawed assumptions, which put the validity of the estimates in doubt. Finally, the agency fails to choose the regulatory option that would maximize net benefits and considerably reduce the regulatory burdens on small businesses, despite being required to do so under the Regulatory Flexibility Act.

Before proceeding with the proposed rule, the FDA should commission studies testing the health impacts of each proposed label change. Further, the agency should reexamine its benefit estimates to reflect the benefits

56. RIA, 25.

57. RIA, 21.

58. RIA, 72.

59. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Fact Labels," 11959.

60. Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980).

61. Executive Order 13563, 3821.

to consumers stemming from the rule's actual impacts. The agency should provide separate estimates for marginal benefits of each proposed change and focus only on changes shown to have a positive impact. The agency should consider a broader range of alternatives, including an option that focuses only on updating DVs and an option that makes vitamin and mineral declarations voluntary. It should opt for longer compliance times to reduce the regulation's impact on small businesses and to reduce the costs passed on to consumers in the form of higher prices. Finally, it should make plans to monitor the rule's progress and impact on public health.



FOOD LABELING: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments
Docket No. FDA-2004-N-0258-0006

Robert Scharff

Associate Professor, College of Education and Human Ecology, The Ohio State University

Department of Health and Human Services, Food and Drug Administration

RIN 0910-AF23

Submitted May 19, 2014

Comment Period Closes June 2, 2014

INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the impact of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of this rule from an economic point of view. Specifically, it examines how the rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

SUMMARY

The Nutrition Labeling and Education Act of 1990 (NLEA) gives the FDA authority to regulate information displayed on food products and describes how a lack of certain types of information would be considered

For more information, contact
Robin Bowen, (703) 993-8582, rbowen@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Boulevard, 4th Floor, Arlington, VA 22201

misbranding.¹ Two rules, sharing one preliminary regulatory impact analysis (PRIA),² have been proposed based on the authority granted by NLEA.³

The first rule covered by the PRIA, titled “Food Labeling: Revision of the Nutrition and Supplement Fact Labels” (NPRM1), includes a laundry list of potential changes that are designed to “assist consumers in maintaining healthy dietary practices.”⁴ The changes required are numerous and involve changes to labels, increases in recordkeeping, and new analytic requirements.

The second rule covered by the PRIA, titled, in part, “Food Labeling: Serving Sizes of Foods” (NPRM2), focuses on labeling changes affecting food packages that hold a small number of servings.⁵ Specifically, NPRM2 requires that foods in packages that contain less than 200% of reference amounts customarily consumed (RACC) must be labeled as single-serving containers, while food packages with 200–400% of RACC must employ a dual labeling format that gives nutrition information for both amount per serving and amount per package. Additionally, the rule defines new RACC for a number of products and gives a new serving size for breath mints, among other smaller changes.

The major provisions associated with NPRM1 and NPRM2 are listed in table 1. Despite the large number of requirements and changes associated with the two rules, the FDA chose to take the unusual step of preparing one PRIA for both rules. Although this can be an acceptable strategy, when using it the FDA must be careful to analyze the costs and benefits of each sufficiently different provision separately. Instead, the PRIA only addressed a limited number of the proposed changes and only evaluated costs and benefits for a much smaller portion of these changes. This approach has contributed to an extremely weak justification for the rule.

Furthermore, the PRIA analyzed an insufficient set of alternatives and did not adequately incorporate uncertainty into the analysis. Most disturbingly, the FDA utilizes a single unpublished article that has not gone through peer review as the basis for benefits estimates for all provisions. This approach makes it impossible to assess benefits for individual provisions, and indeed, to ascertain whether the rules generate any benefits whatsoever. Though information provision has the potential to improve social welfare, the agency has failed to demonstrate that these rules will do so.

Executive Order (EO) 12866 states,

*In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.*⁶

This essentially compels agencies to use regulatory impact analysis as a decision-making tool. In this case, the PRIA is used only as a justification for the rules. I believe the FDA should use the science cited in NPRM1 and NPRM2 as a basis for the benefits estimates in the PRIA and assess the efficacy of each provision separately.⁷ Quantitative risk analysis appears to be an appropriate method of analysis in this case. If the science is not sufficient to support this level of assessment, the FDA should abandon the provisions, make them voluntary (as seems appropriate for the “added sugars” requirement), or conduct original research to close the gaps in the science and assess the value of each provision separately. Doing so will place the agency in compliance with the letter and spirit of EO 12866.

1. Pub. L. No. 101-535, 104 Stat. 2353 (1990).

2. Department of Health and Human Services, Food and Drug Administration, “Analysis of Impacts” (undated), available in the docket at <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0005>.

3. Supplementary authority is also derived from the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

4. Food Labeling: Revision of the Nutrition and Supplement Fact Labels; Proposed Rule, 79 Fed. Reg. 11880, 11880 (proposed March 3, 2014).

5. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Rule, 79 Fed. Reg. 11990 (proposed March 3, 2014).

6. Emphasis added. Exec. Order No. 12866, 58 Fed. Reg. 190 (October 4, 1993) (hereafter cited as “EO 12866”).

7. Benefits from sufficiently related provisions need not be analyzed separately. For example, the requirement to redefine dietary reference value and provide a new set of values and means of calculating dietary fiber can be grouped with associated recordkeeping requirements. Other combinations of provisions might also be validly combined in the analysis, but the agency should make a compelling argument for why it is grouping them.

Table 1. Coverage of Rule Provisions in the Preliminary Regulatory Impact Analysis

Provisions in NPRM1 ("Food Labeling: Revision of the Nutrition and Supplement Fact Labels" rule)
<ul style="list-style-type: none"> • Remove "calories from fat" declaration from the nutrition facts label • Change how calories from saturated fats must be presented • Change how calories from carbohydrates are calculated • Require declaration of "added sugars" (associated recordkeeping required) • Change how caloric values from sugar alcohols are calculated • Redefine dietary reference value (DRV) and provide a new set values and a new means of calculating dietary fiber (associated record-keeping required) • Redefine soluble and insoluble fiber and provide a new means of calculating their amounts as voluntary disclosures (associated record-keeping required) • No longer allow "other carbohydrates" to be reported • Update the reference book for the analytical method of measuring protein • Provide a new DRV for sodium • Allow fluoride and choline to be declared voluntarily • Allow levels of vitamins A and C to be declared on a voluntary basis, rather than the current mandatory basis • Require declaration of vitamin D and potassium • Revise reference daily intakes (RDIs) for most vitamins and minerals • Change how folates are described (associated recordkeeping required) • Change the measurement units used to report folates and vitamins A, D, and E • Change the age categories for infants and children under age four (for labeling) • Require the declaration of added sugars, saturated fat, and cholesterol on the labels of foods consumed by all infants and children under age four • Establish DRVs and RDI values for foods, vitamins, and minerals targeted at infants, small children, and pregnant or lactating women • Require declaration of "% daily value" information on foods targeted at these subpopulations • Allow declarations of multiple nutrients on foods aimed at children under age four • Require dietary supplement labels to include nutrients now required on food labels • Require dietary supplement labels to follow other food label rules (such as order of nutrients and units of measure) • Increase the font size of calories • Change the order of serving size and number of servings • Move "% daily value" information to the left side of the panel • Require declarations of units of vitamins and minerals
Provisions in NPRM2 ("Food Labeling: Serving Sizes of Foods" rule)
<ul style="list-style-type: none"> • Require foods in packages that contain less than 200% of reference amounts customarily consumed (RACC) to be labeled as single-serving containers • Require foods in packages with 200–400% of RACC to use a dual-labeling format • Establish a serving size for breath mints

NEED FOR REGULATION

EO 12866 states that “each agency shall *identify the problem* that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as *assess the significance* of that problem.”⁸ In the PRIA for NPRM1 and NPRM2, the agency notes that “information failure, a well-established type of market failure, can provide an economic rationale for the mandatory disclosure of nutrition information” and that “if the proposed revised labels provide . . . nutrition information, [they] may bring about healthier food choices by reducing uncertainty about the underlying nutrient amounts in prepackaged foods because labels now reflect current science.”

8. Emphasis added.

Though the “need for regulation” section of the PRIA offers a possible explanation of how market failure might occur and how the provision of nutrition information might solve the potential problems, this is not sufficient. As the Office of Management and Budget’s Circular A-4 notes, “Your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information.”⁹ In this case, little more is done.

The agency does provide some evidence that package and portion size have a presumably detrimental influence on consumption. Package size is not directly affected by the rules. Portion size, however, is. In NPRM2 the RACC are updated to conform to current eating habits. In most cases, these values have increased. Thus, the new serving sizes offered by the FDA represent larger portions than before. If consumers use these as anchors for suggested consumption, FDA rules may be creating a market failure rather than eliminating it.

If there are market failures underlying the two rules, the specific science in support of that contention needs to be directly tied to each of the provisions of the rules. NPRM1 and NPRM2 cite a fair amount of science that might be relevant in this case. However, the PRIA does not use the science as a basis for market failure in a meaningful way. For example, given that the agency has noted that there is “a lack of a physiological distinction between added and naturally occurring sugars,” it appears that the required addition of this information does not address a market failure. The PRIA should not assume that all provisions of both rules address market failures just because some might. The FDA should rewrite the relevant section of the PRIA to carefully consider the market failures addressed by the distinct parts of the rules.

In assessing the need for regulation, EO 12866 requires that the agencies also demonstrate the significance of the identified problems. The PRIA provides no discussion of the significance of problems. Circular A-4 notes,

Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation.¹⁰

Thus, even if information is not provided, there may not be a significant advantage to providing that information. Evidence of consequential suboptimal choices needs to be demonstrated. For example, the agency should demonstrate that people are making mistakes that lead to adverse health consequences because nutrition information is on the right rather than the left side of the labels.

EO 12866 also requires that the PRIA examine alternatives to direct regulation. Could the problems that are identified be addressed by nonregulatory information provision, markets, the legal system, or state governments? For example, could the FDA create a user-friendly database with additional nutrition information for the use of interested consumers? These types of alternatives should at least be examined. This was not done.

Summary: The FDA has described a market failure that might exist, but has not demonstrated that it actually does exist.

Recommendation: Use science in the “need for regulation” portion of the PRIA to support the contention that there is, in fact, market failure, and find some way of demonstrating the significance of the problem.

REGULATORY ALTERNATIVES

Circular A-4 lays out the following principles regarding the analysis of regulatory alternatives:

The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, *you should nevertheless explore modifications of some or all of a regulation’s attributes or provisions to identify appropriate alternatives.*¹¹

9. Office of Management and Budget (OMB), Circular A-4, Regulatory Analysis (September 17, 2003).

10. *Ibid.*

11. Emphasis added. OMB, Circular A-4.

The FDA has responded in the PRIA with the following set of alternatives:

1. No New Federal Regulatory Action;
2. The proposed rules that would give manufacturers 2 years for compliance;
3. The proposed rules, but with a 3 year compliance time;
4. The proposed rules, but with a 4 year compliance time; and
5. The proposed rules, but with [daily values] for sodium of 1,500 mg or 1,900 mg.

In reviewing this list of options it is apparent that the FDA did not take seriously the EO 12866 mandate to evaluate alternatives. Option 1 is dismissed in two sentences. This presumes the regulation is necessary, which, as discussed above, is far from clear. The agency would have to perform evidence-based analysis (perhaps based on FDA pilot projects) to demonstrate that option 1 is not the preferred option. The remaining options have measured consequences for costs, but not for benefits. Option 5 only applies to NPRM1, which means that NPRM2 only faces real options for compliance time. Though compliance time is one of the acceptable options, it is not meant to be the only one. Given that this PRIA covers two rules and there is no guarantee that both rules will move forward, at a bare minimum the FDA must include two more options: one in which NPRM1 is not made into a final rule and one in which NPRM2 is not made into a final rule. Also, for a large number of the options discussed in the NPRMs, it appears that the agency is open to change based on comment. The provisions most likely to be changed or with the highest costs should be the ones examined formally. Examples of alternatives that should have been addressed include

1. NPRM1 by itself
2. NPRM2 by itself
3. NPRM1 without the “added sugars” requirement
4. NPRM1 without the “calories from fat” ban
5. NPRM1 without the multiple new labeling requirements for foods, vitamins, and minerals targeted at infants, small children, and pregnant or lactating women
6. NPRM1 without the reformatting provisions
7. NPRM2 without the dual-labeling requirement for packages with 200–400% of RACC
8. NPRM1 and 2 without the requirements for dietary supplements.

The inclusion of these alternatives would provide decision makers with vital information about the relative importance of classes of provisions.

Summary: Too few regulatory alternatives are analyzed. The “no new regulatory action” alternative is not sufficiently examined.

Recommendation: Evaluate option 1 in more depth. Add options that omit provisions most likely to be changed or with the highest costs. Add options that essentially separate the rules as a means of assessing the marginal benefits and marginal costs of the rules.

BENEFITS

Undoubtedly, the weakest part of the PRIA is the estimation of benefits from the two proposed rules. The method used to estimate benefits is both theoretically and empirically flawed. Specifically, the analysis is based on results in a single unpublished paper that estimated the benefits of the introduction of regulations from the NLEA.¹² The results of this study are not sufficiently clear, are not correctly interpreted in the PRIA, and are incorrectly extrapolated to assess benefits from NPRM1 and NPRM2. Most importantly, the analysis fails to convey an understanding that, while NLEA was characterized largely by the introduction of new information, the rules proposed here largely reformat and rescale information.

The Abaluck Study

The cornerstone of the benefits calculations for both rules is a 2011 paper by Jason Abaluck that sought to estimate the benefits to consumers from the adoption of regulations written to comply with the NLEA. The paper assesses the effects of label use on consumption patterns both before and after labeling rules went into effect, finding that consumption of high-calorie foods declined relative to lower-calorie foods following the introduction of labeling. These results are combined with price responsiveness (elasticity) data and an assumption about the accuracy of prior beliefs regarding the calorie content of foods to derive estimates of the change in consumer welfare attributable to NLEA.

There are a number of limitations to this study that were not discussed in the PRIA. First, the paper has not been published or peer reviewed. Next, the sample it uses is limited to women aged 19–50 who are the primary meal preparers in their households. Finally, the results are highly dependent on assumptions regarding prior knowledge and price responsiveness.

For the entirety of its benefits estimates the FDA relies on an unpublished paper that has not been subjected to peer review. This is especially significant because the author used a novel approach to estimate consumers' valuations. I recognize that data limitations will often require the use of a study that has not been through the normal peer-review process, but when an unpublished study is of such importance to a PRIA, the agency should urge the author to publish the study and seek outside reviewers to assess the legitimacy of the paper.

Another limitation of the Abaluck study is the sample that was used. By limiting the sample to women aged 19–50 who are the primary meal preparers in their households, the study introduces a bias into the results. Most notably, a recent study by Nicholas Jay Ollberding, Randi L. Wolf, and Isobel Contento examining National Health and Nutrition Examination Survey (NHANES) 2005–2006 data shows that women are significantly more likely to view nutrition facts panels than men (72.8% vs. 49.5%).¹³ Thus, any effect of labels on calorie consumption is artificially inflated by the choice of sample. Although it might plausibly be argued that men are less likely to be primary meal preparers, some men are primary meal preparers and others make their own food choices for meals and snacks not prepared by the primary meal preparer. The FDA addresses this issue in the PRIA by calculating separate benefits estimates for women only, but these estimates are not then used in the discussion of net benefits.

The results of the Abaluck study are also highly dependent on assumptions about price responsiveness. Changes in consumption figures are converted to dollar values using price estimates from the Continuing Survey of Food Intakes by Individuals and price elasticity (responsiveness) estimates from other studies. It is impossible to assess whether the responsiveness values used are credible or sufficiently tailored to product categories, however, because they are not cited.

Another stage in the calculation of welfare gains from NLEA involves scaling to account for prior knowledge. Abaluck estimates that, pre-labeling, consumers already had knowledge of 20% of the information included on

12. Jason Abaluck, "What Would We Eat If We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling" (working paper, Massachusetts Institute of Technology, 2011), http://economics.stanford.edu/files/Abaluck10_28.pdf.

13. Nicholas Jay Ollberding, Randi L. Wolf, and Isobel Contento, "Food Label Use and Its Relation to Dietary Intake among US Adults," *Journal of the American Dietetic Association* 110 (2010): 1233–37.

NLEA labels. This estimate is cited to a study on Starbucks customers, but no such estimates are given in the cited paper and Abaluck gives no explanation for how the information from the cited paper is used.¹⁴

If the FDA continues to use this study in the PRIA, which I strongly discourage (see below), I urge the agency to contact the author to obtain a better understanding of the paper and to send the paper out for peer review.

Summary: The 2011 Abaluck study that is used as the cornerstone for all benefits estimates is an unpublished, unreviewed work with serious limitations that should have been addressed before it was used in an FDA PRIA.

Recommendation: Replace the study or send the paper out for peer review and make adjustments to account for biases in the population used, unrealistic assumptions made, and any other problems identified in the peer review process.

Extrapolation of Abaluck Results in the PRIA

The Abaluck study is the primary source for benefits for all of the provisions proposed in NPRM1 and NPRM2. Specifically, the FDA uses the following model to estimate benefits:

$$B_t^{\text{label}} = \text{POP}_t \times s_1 \times \Delta W^{\text{label}} \times \text{USE} \times (1 - \text{USDA}),$$

where B_t^{label} is an estimate of the annual national benefits at time t , POP_t is the US population at time t , s_1 is the “ratio of the welfare gain attributable to the proposed rules to the welfare gain attributable to the NLEA,” ΔW^{label} is the change in welfare from NLEA, USE is the ratio of use of proposed rule labels to NLEA labels, and USDA is the proportion of labeled food regulated by USDA.

This is an irredeemably flawed approach for a number of reasons. First, the values taken from ΔW^{label} (from Abaluck) in the PRIA are not complete or accurate, compounding the problems noted in the previous section. More importantly, the means used to scale estimates from the Abaluck study (s_1) are entirely without scientific merit. Additionally, there are questions about the measurement of other components of the analysis. Putting scientific rigor aside, this approach assumes that all the provisions of both rules can be evaluated using one unitary measure, making the assessment of individual provisions nearly impossible.

The FDA uses two estimates of ΔW^{label} —the annual value per person from NLEA labeling—\$40.6 and \$33.4. Updated to reflect current income, the mean annual per capita welfare benefit from NLEA is \$58. The FDA wisely uses the structural equation estimates that Abaluck notes are a better fit, but, without comment, only uses two of the structural models in its analysis, omitting two other models with lower values (\$32.1 and \$28.3).

The welfare change measure, ΔW^{label} , is modified by s_1 to produce a welfare benefit measure for the proposed rules. How this is done is imaginative, but without scientific basis. Essentially, the FDA sets the content in NLEA at 100% (which gives the NLEA a value of \$58) and measures value from any change to the new rule based on the proportion of label content changed. For the single label format, FDA assumes that the label changes between 15% and 50% (mean = 33%), while the change is between 0% and 50% (mean = 25%) for the double label format. Putting aside the obvious (why does adding a second column result in less change?), no attempt is made to describe how proportion changed is measured. Does it include changes that prohibit disclosures or just those that mandate new disclosures? More importantly, this appears to be a measure based entirely on quantity of change, not quality. According to this model, one could replace the nutrition facts label with a label of equal size containing the lyrics for “Dazed and Confused,” resulting in benefits equivalent to those generated by NLEA.¹⁵ Perhaps recognizing the absurdity of this model, the FDA uses the estimates generated from it as an upper bound, with benefits uniformly distributed between zero and the estimated values.

14. Bryan Bollinger, Phillip Leslie, and Alan Sorensen, “Calorie Posting in Chain Restaurants” (No. w15648, National Bureau of Economic Research, 2010).

15. Jimmy Page, “Dazed and Confused,” recorded in 1968 by Led Zeppelin, on Led Zeppelin [LP], London: Atlantic (1969).

There are also unanswered questions about other components of the model. Most notably, the USE coefficient adjusts for supposed increases in label usage over time and as a result of this rule. The PRIA adjusts for changes over time by taking the ratio of post-rule label usage (77% in the 2009–2010 NHANES, plus expected increase due to the rule) to usage soon after NLEA (65%—unreferenced in the PRIA). It is important to note that these two data sources may not be compatible, given that NHANES changed the mode of asking this question after 2006. In NHANES 2005–2006 the question was asked in person and the respondent was shown a nutrition fact panel.¹⁶ Starting with the 2007–2008 collection, the question was asked over the phone without a visual.¹⁷ The result was an increase from 53% to 72% usage in two years (see table 2). This is likely due to question format rather than to actual usage change. If this is being incorporated into the analysis, the FDA is likely overestimating changes in usage. The PRIA also states that “Antonuk and Block (2006) found a 13.9% increase in attention to the label when switching from SCL to DCL format.” This is not true. For non-dieters only, this appears to be the case, but the effect is much smaller for dieters and the difference in both cases is not likely to be significant (though it is not tested).¹⁸

Table 2. Use of Food Labels

NHANES year	Use nutrition facts panel on food label	Use serving size info on food label	Use percentage daily value on food label
2005–06	52.6%	41.2%	N/A
2007–08	72.0%	62.3%	58.3%
2009–10	77.1%	64.1%	60.1%

The FDA model accounts for usage of the nutrition facts panel. Numerous provisions of the proposed rules affect specific parts of the label, such as serving size and percentage of daily value. As data from NHANES in table 1 demonstrate, usage of particular parts of the label is lower than overall label usage. It would be useful for the FDA to tailor its analysis to account for these discrepancies.

It’s easy to let the problems with the model used by the FDA obscure a more fundamental problem with the PRIA. The FDA approach outlined above assumes that all the provisions of both rules can be evaluated using one unitary measure. This makes the evaluation of separate provisions (required by the Office of Management and Budget) nearly impossible. Circular A-4 states,

*You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.*¹⁹

In this case there are dozens of distinct provisions to the rule, but none are explicitly examined. What is the benefit, for example, of requiring “added sugars” to be disclosed on labels? NPRM1 notes that there is a “lack of a physiological distinction between added and naturally occurring sugars,” but this information is being required anyway, so there must be a benefit to requiring it. It is the job of the PRIA to explain what that is. Conversely, what is the benefit of banning “calories from fat” from the label? Abaluck noted, “I estimate a small willingness to pay to avoid calories which appear to be due mostly to a willingness to pay to avoid fat.” This suggests that the removal of this

16. Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey Data (Hyattsville, MD: US Department of Health and Human Services, Centers for Disease Control and Prevention, 2005–2006).

17. Ibid.

18. Citing Beth Antonuk and Lauren G. Block, “The Effect of Single Serving versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food,” *Journal of Nutrition Education and Behavior* 38, no. 6 (2006): 365–70.

19. Emphasis added. OMB, Circular A-4.

label component may adversely affect consumer choice.²⁰ Also, as discussed above, updating RACC may create new anchors for larger portions—leading to increased calorie consumption. This has not been investigated. The point is that the rule provisions, to the greatest extent practicable, need to be assessed in terms of marginal costs and marginal benefits. The PRIA has not done this.

Summary: The FDA has estimated benefits using a model that is irredeemably flawed and does not allow the efficacy of individual provisions to be assessed.

Recommendation: Replace the current benefits model with a model that provides benefits estimates for each provision (or at least for classes of provisions). If the model is not replaced, improve the USE estimates as suggested and use a more scientific basis for scaling Abaluck estimates.

Other Sources of Benefits

In addition to the quantified estimates calculated for the proposed rules, the FDA includes a section on “Other Sources of Benefits.” I believe that the discussion and analysis in most of the subsections of this section are misguided. The analysis here is largely based on the idea that consumers may accrue benefits from the rule that go beyond the benefits they enjoy from making better choices. As the FDA states in the PRIA,

The WTP for better nutrition reflects only the nutrition effects that consumers can internalize, and may not fully reflect their underlying preferences because of time-inconsistent behavior, problems with self-control, addiction, or poor information. However, by reducing the intake of certain nutrients, consumers realize these existing, but uninternalized benefits nonetheless.

This is true, as far as it goes. The problem is that the FDA then adopts the Abaluck approach to reevaluating the benefits estimates to reflect health improvements not captured by the basic model (see tables 14–16 in the PRIA). Abaluck notes that the health and longevity benefits from his revealed preference assessment of the NLEA are lower than an analysis based on expected health losses—measured using value of statistical life (VSL) estimates—would predict and, accordingly, scales his estimates to account for this discrepancy.²¹ The FDA follows suit, presenting quantitative benefits estimates for the VSL discrepancy and qualitative estimates for presumed morbidity benefits that are not internalized by consumers. The problem with this approach is that it completely ignores the hedonic elements of food consumption and assumes that consumers only purchase food for its healthfulness.²² Rational individuals, however, make sensible tradeoffs between health and other pleasurable aspects of life (otherwise it would never make sense to drive to the movies). As Karen Glanz and her colleagues demonstrate, taste is the most important determinant of food consumption, followed by cost and nutrition.²³ As a result, it is possible that the entire discrepancy between the revealed preference and VSL-based estimates is due to a rational tradeoff between taste, cost, and healthfulness, not to uninternalized nutrition benefits.²⁴ It is also possible that *some* of the discrepancy is due to uninternalized nutrition benefits, but the FDA gives no direct evidence to back this claim up. Given that the scope of unintentional nutrition benefits is entirely speculative, use of the Abaluck quantitative estimate (which assumes 100% of the discrepancy is due to unintentional nutrition benefits) is not justifiable.

Summary: Quantitative upward adjustments of estimates to include uninternalized nutrition benefits are not supported by the evidence.

20. The FDA can't have it both ways. If the Abaluck study is used, measured benefits must be reduced due to the ban on the “calories from fat” component.

21. Note that Abaluck uses evidence from a previous study to claim that benefits from a longer life span amount to \$2,000–\$3,500 annually. Without explanation, Abaluck chooses \$3,000 (at the higher end) as his benchmark. Without further explanation, \$2,750 would appear to be a better number, though it would reduce the reevaluated benefits.

22. Abaluck himself notes that his analysis can only answer the following question: “What is the welfare gain implied by the estimated parameters if consumers could continue to eat exactly the same foods, but the nutrient profile of those foods were altered so that it matched that of a much healthier diet?” Abaluck, “What Would We Eat,” 31. The problem, of course, is that you can't make cheeseburgers as healthy as broccoli without fundamentally changing the experience involved in consuming a cheeseburger.

23. Karen Glanz et al. “Why Americans Eat What They Do: Taste, Nutrition, Cost, Convenience, and Weight Control Concerns as Influences on Food Consumption,” *Journal of the American Dietetic Association* 98, no. 10 (1998): 1118–26.

24. The FDA, to its credit, did discuss the possibility that some of the discrepancy may be due to hedonic factors, or “offsetting utility loss,” though apparently only as an afterthought.

Recommendation: Rewrite the section titled “Other Sources of Benefits” to be a qualitative discussion, or provide science to back up the implicit claim that 100% of the discrepancy between VSL and revealed preference estimates is due to uninternalized nutrition benefits.

COSTS

The cost section of the PRIA is generally better supported than the benefits section. That said, there are a few areas that could be clarified or improved. First, there are problems with the categorization of labeling as major or minor. Second, the estimate of universal product code (UPC) counts is dated and insensitive to changes in future UPC counts. Third, reformulation estimates appear to be speculative. Fourth, though labeling and reformulation costs are included, costs associated with likely package resizing/redesign are not included. Fifth, costs to government are not included in the analysis. Finally, a number of explanations of how costs are calculated are not transparent, making it impossible to assess the validity of the analysis.

Minor or Major Label Changes

One of the primary drivers of cost in the PRIA is whether a particular UPC will have to face a minor or major label change. Although the FDA does a good job describing the differences between minor and major changes, the categorization of UPCs by major/minor claim is flawed. It is unclear, but it appears that changes under NPRM1 are minor unless there is a change in health claims, while changes in NPRM2 are major, when they occur.

The provisions of NPRM1 include changing which nutrients are required to be listed on labels, increasing the font size of calories, changing the order of serving size and number of servings, moving “% daily value” information to the left side of the panel, and requiring declarations of units for vitamins and minerals. Each of these changes, by itself, might be minor, but together they constitute a major change to the label. Dietary supplements, as a class of UPCs, will have to make even larger changes to their labels. NPRM1 would require dietary supplement labels to include nutrients that are now only required on food labels and to follow other food label rules (such as the order of nutrients and units of measurement). Finally, the establishment of dietary reference values and reference daily intake values for foods, vitamins, and minerals targeted at infants, small children, and pregnant or lactating women will require label changes to present this information.

For NPRM2, the PRIA anticipates that all changes, if they occur, will be major. This is a fair assessment, but the PRIA incorrectly only includes the conventional foods in its analysis. Based on NPRM1, it appears that dietary supplements must now follow food labeling rules, including those in NPRM2. If this is the case, dietary supplements should be included in the analysis. The new breath mint serving size requirement is also omitted from the analysis. This may be a minor labeling change, but it is a change.

Summary: There is evidence that most or all UPCs affected by NPRM1 will have to make major labeling changes. Dietary supplements, in particular, will likely face the largest changes.

Recommendation: Update the PRIA to classify most, if not all, labeling changes as major.

UPC Counts

Labeling and reformulation costs are both dependent on an accurate count of UPC product codes. In the PRIA, the estimate of UPC counts is dated and insensitive to changes in future UPC counts. This is inconsistent with how population (a similarly critical factor) is treated in the benefits section. While it may be true that the labeling cost model is based on 2008 data, it should be possible to scale costs based on actual and projected growth of UPC labels since 2008. This could be done based on overall growth, or, if possible, growth in particular product categories. In any event, costs and benefits should be scaled equally.

Summary: UPC counts are outdated.

Recommendation: Update UPC counts using more current data.

Reformulation

A number of provisions in the rules provide incentives for reformulation. The FDA identifies three: (1) some products that currently make health claims will lose the ability to do so due to the change in RACC for dietary fiber, (2) producers will want to avoid reporting high added sugars, and (3) the change in daily value for vitamin B12 will leave many cereals with over 100% of recommended daily values. For the first two, the FDA attempts to estimate costs associated with reformulation. The weak link in this analysis is the estimates of reformulation rates. The FDA estimates that changes to daily values for dietary fiber will result in 50% reformulation and 50% relabeling for those that currently make a health claim, but this is just an assumption. Similarly, the FDA assumes that 5–6% of UPCs will reformulate as a result of the added sugar provision. Ideally, the agency should use a science-based estimate. If none is available, the analysis should incorporate the uncertainty of the assumption. In any case, the reasoning for the two estimates should be given for the sake of transparency. The FDA is correct in omitting B12 costs, because any reformulation would be strictly voluntary, without negative repercussions.

The FDA argues that there are conflicting studies that lead to questions about whether the provision requiring calories to be in large, bold font will affect behavior, so any reformulation costs would be speculative. Fair enough, but then why is this provision in the rule?

Summary: Reformulation costs are real, but speculative.

Recommendations: Provide the rationale behind reformulation rates and incorporate uncertainty behind these rates into the analysis. Remove the provision requiring calories to be portrayed in large, bold font from NPRM1.

Package Redesign

NPRM2 requires food packages that contain less than 200% of RACC to be labeled as single-serving containers while foods in packages with 200–400% of RACC must use a dual-labeling format. Given that these labels are expected to shift consumer behavior, it is likely that these provisions will create an incentive for food firms with UPCs in these categories to create new package sizes. For example, if a package of cookies has 350% of RACC, the firm may want to increase the package size to over 400% to avoid the dual-labeling requirement. This is almost certain to occur in some cases, yet the FDA has ignored this important cost.

Summary: The PRIA ignores potentially large package redesign costs.

Recommendation: Provide estimates for package redesign costs.

Costs to Government

An important cost of each regulation is the cost to government from enforcing that regulation. In this case, the FDA did not account for any costs of enforcement moving forward. It may be that it is assumed that all these activities will occur during regular inspections that would otherwise take place. This may be true, but if more tests are added and more records are inspected on each inspection, the length of that inspection will increase, adding a cost to the inspection.

Summary: Government costs are not included in the analysis.

Recommendation: Add government costs to the analysis.

Transparency of Cost Analysis

Throughout the cost section, the FDA makes statements such as the following: “To determine the UPC counts in each product category, the model utilizes 2008 Nielsen Scantrack data. . . . The model allows us to select the types of products that would be covered under any specific regulation, the type of label change (major or minor) that would be required under the regulation, and the compliance period.” Though this statement gives the source of the data and what the data will be used for, it does not explain criteria used to determine the categorization of that

data. Several examples of this sort occur throughout the cost section. This lack of transparency makes it difficult to assess the validity of the cost estimates.

Summary: The validity of cost estimates is questionable given the selective lack of transparency throughout the cost section.

Recommendation: Include detail in the analysis that would allow replication (or at least better understanding) of the analysis.

CONCLUSION

This comment has identified a number of problems with the PRIA for the food labeling rules (NPRM1 and NPRM2) that must be addressed before the agency can claim to have accomplished a proper analysis of the rule under EO 12866. Most importantly, the benefits estimates are completely invalid and should not be used. I urge the agency to read the comment in detail and respond accordingly to each of the suggestions I have made.

I strongly believe that a new PRIA must be made public and available for comment by the FDA before the publication of the final rules. Furthermore, I believe there is a very strong chance that a well-crafted PRIA, if used as intended by EO 12866, will lead to improvements in NPRM1 and/or NPRM2. If these changes are significant enough, the proposed rules should be revoked or resubmitted as new notices of proposed rulemaking.