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RETROSPECTIVE REVIEW

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

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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

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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.