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PUBLIC INTEREST COMMENT

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

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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 of 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

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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.

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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)
• 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)
• 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:

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

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.

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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.