

FDA MISSES THE MARK WITH FOOD LABELING RULES

There is little evidence that the new labels will improve Americans' health.

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As the battle to trim American waistlines heats up, the U.S. Food and Drug Administration has joined in the fray with not one, but two rules aimed at improving the nation's diet. The rules constitute the biggest change to the Nutrition Facts label in over two decades. Despite the comprehensiveness of the effort, the fact that the rules were built on poor analysis makes it unlikely they will curb obesity or improve public health. Like the whole grain biscuits and unappetizing vegetables that are being forced onto the lunch trays of unhappy schoolchildren, the FDA's efforts should end up in the trash (or at least a recycling bin).

The FDA proposed the rules based on the authority granted by the Nutrition Labeling and Education Act of 1990 (NLEA) to regulate how information is displayed on food products. The first of the proposed rules, the Food Labeling rule, includes a laundry list of potential changes that are designed to "assist consumers in maintaining healthy dietary practices." The changes required are numerous, involving both formatting and content changes to labels, increases in recordkeeping, and new analytic requirements.

The second rule, the Serving Size rule, focuses on labeling changes affecting food packages that hold a small number of servings. Specifically, the rule requires that foods in packages that contain less than 200 percent of "reference amounts customarily consumed" (RACC)—that is, small packages that are nonetheless larger than a traditional serving size—must nonetheless be labeled as single-serving containers, while food packages with 200–400 percent 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 small changes.

Together, the two rules result in major changes in how nutrition information is conveyed to the American public, resulting in billions of dollars in new costs, much of which will ultimately be passed on to consumers. It is disturbing that the agency made only a halfhearted—and ultimately failed—attempt to determine whether those costs are justified by corresponding benefits to the public.

WHY REGULATE?

The FDA gives two reasons to justify the proposed regulations. First, the FDA argues that it needs to update the Nutrition Facts label requirements with regard to recommended Daily Values (DV) and serving sizes. This is a laudable goal given the advancements in nutritional science over the last two decades. For example, the rule updates the DV for fiber based on a recent Institute of Medicine (IOM) "Dietary Reference Intakes" report. The new value is set at the level associated with the greatest reduction in risk of coronary heart disease. Similarly, serving sizes are updated to reflect amounts that people consume today, as opposed to what was consumed in decades past.

Second, the FDA claims that food labels are not currently designed to promote ideal healthy behaviors. The agency points out that while many consumers report using the label, they find some of its information confusing. Consequently, the FDA claims that improving the label's design could potentially improve consumers' ability to understand and use the label, which, if successful, would ultimately lead consumers to make healthier food choices.

On their face, these appear to be sensible changes. A nutritional label updated to reflect the most recent science would provide consumers with more accurate information, help consumers make healthier food choices, and potentially reduce certain disease risks associated with deficiencies in key nutrients. Nevertheless, the science supporting the many provisions of these rules is uneven and, in some cases, nonexistent. Further, there is no effort to assess whether the benefit from each provision is justified by its cost.

Changing the label design / The Food Labeling rule proposes numerous changes to the way information is displayed on the label. In the accompanying regulatory impact analysis (RIA), the FDA relies on the growing behavioral economics literature

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

The FDA hopes that, by increasing the salience of the information presented on the label, the proposed rule may help consumers to improve their decisionmaking and increase their use of nutrition facts. For example, the FDA assumes that making calorie information more prominent would influence consumers

to pay attention to the caloric content of the food. Similarly, it assumes that disclosing added sugars would alert consumers if chosen foods are high in energy and poor in nutrition, and lead consumers to reconsider their choices.

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

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

Beyond that single study, the agency cites no empirical evidence in support of the remaining label changes. The FDA justifies the changes by claiming that the improved design would increase label comprehension and use. While it references a product design manual in support of this claim, the agency does not test whether its new label actually improves consumers' comprehension or leads to healthier choices. Similarly, the FDA cites research that shows consumers' confusion over serving size information, yet it does not test whether its new serving size declaration improves consumers' comprehension.

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Demonizing added sugar / One of the most prominent changes to the Nutrition Facts label proposed by the FDA is the requirement for mandatory declaration of “added sugars.” The FDA classifies added sugars as “sugars and syrups that are added to foods during processing or preparation.” The added sugars line would be inserted in the label under the line for total sugar content. The agency justifies the requirement by claiming that added sugars serve as the main source of calories for youths. The FDA points out that, in contrast to foods with natural sugars, foods with added sugars are generally not good sources of vital nutrients. Further, it claims that added sugars may be displacing other nutrients or leading to overconsumption of calories.

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

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

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

It is crucial that the FDA ensures that the label’s additional content leads to better health outcomes before mandating its inclusion on the nutrition label. Including content that does not help consumers make healthier choices may crowd out more vital content on the label and confuse consumers about their choices.

WHERE ARE THE BENEFITS?

In 1994 President Bill Clinton issued Executive Order 12866 requiring regulatory agencies to assess the costs and benefits of major rules in RIAs. This was a sensible measure designed to ensure that each major provision of enacted regulations improved social welfare. Of course, reliable benefits estimates for each rule provision are necessary if these types of analyses are to have any value. In the case of the labeling rules, the benefits estimates are completely without merit. Thus, it is impossible to assess the value of the rule, both as a whole and in its parts.

The FDA’s method used to estimate benefits is both theoretically and empirically flawed. Specifically, the analysis is based on results from a single unpublished paper that estimated the

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benefits of the introduction of regulations from the NLEA. The results of this study are not sufficiently clear, are not correctly interpreted in the RIA, and are incorrectly extrapolated to assess benefits from the proposed rules. Most importantly, the analysis fails to convey an understanding that, while the NLEA was characterized largely by the introduction of new information, the rules proposed here largely reformat and rescale information.

Use of a flawed study / The cornerstone of the benefit calculations for both rules is a working paper by Jason Abaluck titled, “What Would We Eat If We Knew More? The Implications of a Large-Scale Change in Nutrition Labeling.” The paper 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. It derives estimates of the economic value of those changes in nutrient consumption.

There are a number of limitations to this study that were not discussed in the RIA. First, the study, which is the source of the FDA benefits estimates, is unpublished and has not been subjected to peer review. This is especially significant because the author used a novel approach to estimate consumers’ valuations. Data limitations 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 an RIA, the agency

should urge the author to publish the study or seek outside reviewers to assess the legitimacy of the paper.

Second, the Abaluck study introduces a bias into the results by limiting the sample to women aged 19–50 who are the primary meal preparers in their households. Yet, a recent study by Nicholas Jay Ollberding, Randi Wolf, and Isobel Contento shows that women are significantly more likely to view nutrition facts panels than men (72.8 percent vs. 49.5 percent). 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, it is also undoubtedly true that some men are primary meal preparers and others make their own food choices for meals and snacks.

Additionally, the study makes a number of assumptions without documented support in its effort to derive estimates of economic benefits from the NLEA. As a result, it is impossible to assess the validity of the study conclusions. The reliance of the FDA on such a flawed study does not instill confidence. Still, the problems with the Abaluck study are minor relative to problems with the FDA's use of data from the study.

Faulty extrapolation of results in the RIA / The biased and flawed Abaluck study is the primary source for the estimated benefits used to justify both proposed labeling rules. To work this minor feat of magic, the FDA assumes that the proposed rules' impact would be similar to the original NLEA regulation. The agency then calibrates the Abaluck study's estimates by accounting for the differences between the proposed rules and the NLEA. The FDA acknowledges that the new rules will likely have a smaller effect because they will make fewer changes to the nutrition label.

This is an irredeemably flawed approach for a number of reasons. First, the Abaluck study estimates used in the RIA 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 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 the annual monetized benefit per person from NLEA labeling—\$40.60 and \$33.40. Updated to reflect current income, the mean annual per-capita welfare benefit from the NLEA is \$58. However, the FDA omits without comment two other Abaluck model estimates with lower values—\$32.10 and \$28.30—potentially inflating the proposed rules' benefit estimates.

The RIA then scales the Abaluck study estimates to produce the benefit estimates for the proposed rules. How this is done is imaginative, but without scientific basis. The FDA starts with the assumption that the NLEA rule changed 100 percent of the label content to achieve its health effect valued at \$58. The agency then estimates that the proposed rules would change 33 percent of the

physical content for single-column labels and 25 percent of the content for dual-column labels. The FDA therefore extrapolates that the proposed rule's effect would be 33 percent of the NLEA rule's impact for single-column labels and 25 percent for dual-column labels.

Putting aside the obvious question of why adding a second column would result in less change, no attempt is made to describe how the proportion changed is measured. Does it include changes that prohibit disclosures or just those that mandate new disclosures? More importantly, the FDA uses 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 from Led Zeppelin's "Dazed and Confused," resulting in benefits equivalent to those generated by the NLEA. 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. The lower bound benefits estimate of zero, however, is the only estimate with any basis in reality.

Marginal benefits of the rule's distinct provisions / It is easy to let the problems with the model used by the FDA obscure a more fundamental problem with the RIA. The FDA approach outlined above assumes that all the provisions of both rules can be evaluated using one unitary measure. In fact, that makes the evaluation of separate provisions (required by the Office of Management and Budget) nearly impossible.

There are dozens of distinct provisions to the rule, but none are explicitly examined. For example, as noted above, the RIA fails to explain the benefits of requiring "added sugars" to be disclosed on labels. The Food Labeling rule notes that there is a "lack of a physiological distinction between added and naturally occurring sugars," but the added-sugar information is being required anyway. Conversely, the RIA fails to explain the benefit of removing "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 label component may adversely affect consumer choice. Also, updating serving size may create new anchors for larger portions, leading to increased calorie consumption. Failure to assess the rules' provisions in terms of marginal costs and marginal benefits makes it impossible to determine which of the large number of individual provisions have benefits that justify their costs.

The costs associated with these rules are substantial, amounting to \$2.3 billion according to the FDA. The methods used to estimate this figure, however, are not transparent, with many apparently speculative assumptions used for major cost categories. Furthermore, several cost categories are simply omitted. Not included in the FDA's estimates are costs to government for enforcing the rule, costs to industry from changing package sizes in response to the rule, and recordkeeping costs to suppliers of ingredients that have added sugars included. There is also no indication that the FDA considered the larger changes required of labels for dietary supplements.

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ARE THERE ALTERNATIVES TO REGULATION?

In its proposal, the FDA considers four other policy alternatives to the proposed rule, but the proposals are largely just minor variations of each other. In reviewing this list of options, it is apparent that the FDA did not take seriously EO 12866's mandate to evaluate alternatives.

The first option—issuing no new regulation—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 issuing no regulation would not be preferable.

The remaining options, which differ primarily in compliance time, have measured consequences for costs but not for benefits. While differences in compliance time represent important policy alternatives, there surely are other policy alternatives that the FDA could have considered. Moreover, given that this RIA covers two rules and there is no guarantee that both rules will move forward, at a bare minimum the FDA must evaluate the two rules separately.

In addition, for a large number of the provisions discussed in the proposed rules, 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. The inclusion of those alternatives would provide decisionmakers with vital information about the relative importance of classes of provisions.

Beyond the narrow range of alternatives, the rule fails to maximize the net benefits for the five regulatory options discussed in the analysis. At a 3 percent discount rate, the four-year compliance option would provide \$29.6 billion in net benefits, while the FDA's preferred two-year compliance option would provide \$29.1 billion in net benefits. Yet the FDA does not explain its choice of a shorter compliance time.

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

The longer manufacturers have to comply with the rule, the greater the share of products they can include in coordinated updates. Consequently, the two-year compliance option would cost \$2.3 billion while providing \$31.4 billion in benefits. In contrast, the four-year compliance option would cost \$0.6 billion while still providing \$30.2 billion in benefits. Thus, a two-year delay in the compliance date could result in an almost four-fold cost reduction, while only marginally reducing benefits.

The FDA should opt for a longer compliance time. Its benefit estimates are highly flawed, based on questionable assumptions and a single unpublished study. The agency provides little empirical support that proposed changes would be effective. Consequently,

the rule's actual benefits are likely to be smaller. In contrast, the agency provides considerably better (though by no means ideal) analysis of the proposed rules' costs. The four-fold reduction in costs resulting from a longer compliance time will reduce compliance costs to food manufacturers. Because manufacturers will likely pass on the additional costs to consumers, lower compliance costs will ultimately mean lower prices for consumers.

CONCLUSION

The proposed rules aim to improve the accuracy and usability of the nutrition label, but there is reason to be skeptical of that intended outcome. Provision of more and better information to consumers is a preferred strategy to improve consumer choice in the marketplace. Specifically, a more accurate nutrition label will allow consumers to make healthier food choices and will encourage adequate intake of vital nutrients. Nevertheless, while the FDA makes a laudable effort to update the nutrition label information according to the best available scientific evidence, it provides little evidence that many of its proposed label changes would have any beneficial health effects (as opposed to the concrete costs associated with the rules). This lack of scientific evidence makes benefits measurement impossible. Undaunted by this impediment, the agency constructs benefits estimates based on a single unpublished study and uses several flawed assumptions, all of which put the validity of the estimates in doubt. Finally, the agency fails to choose the regulatory option that would maximize net benefits and considerably reduce the regulatory burdens on small businesses.

Before proceeding with the proposed rules, the FDA should ensure that each of the provisions being required has tangible and measurable benefits. If no such benefits can be identified, the provisions in question should be put on hold pending further study. For those that do have tangible benefits, the FDA should revise the RIA to provide empirical support for the health effects of each proposed label change. Further, the agency should reexamine its benefit estimates using peer-reviewed studies. In estimating benefits, the FDA should rely on the empirical studies clearly demonstrating the health effects of proposed label changes. It should not simply assume that the proposed rule would produce the same type of benefits as the NLEA rule. It should also opt for longer compliance times to reduce the regulation's effect on small businesses and reduce the costs passed on to consumers in the form of higher prices. Finally, it should make plans to monitor the rule's progress and effect on public health.

The FDA has a chance to improve the public health by increasing consumers' comprehension and use of the nutrition label. Unfortunately, the flawed analysis in the proposed rules makes it unlikely the FDA has chanced upon an optimal labeling rule. Without better analysis, the proposed rules will likely only add pages to the *Code of Federal Regulations* but fail to shed pounds from the waistlines of American consumers. R

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