Public Interest Comment\(^1\) on
The Food and Drug Administration’s Proposed Rule:
Food Labeling: Revision of the Nutrition and Supplement Facts Labels
Docket ID No. FDA 2012-N-1210
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Ian Smith, Visiting Fellow\(^2\)

The George Washington University Regulatory Studies Center
Retrospective Review Comment Project

The George Washington University Regulatory Studies Center strives to improve regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration’s proposed rule, inter alia, implementing new labeling regulations for conventional foods and dietary supplements does not represent the views of any particular affected party or special interest, but is designed to evaluate whether the proposal incorporates plans for retrospective review, pursuant to Executive Order 13563.

\(^1\) This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center’s policy on research integrity is available at [http://regulatorystudies.columbian.gwu.edu/policy-research-integrity](http://regulatorystudies.columbian.gwu.edu/policy-research-integrity).

\(^2\) Ian Smith is a Visiting Fellow at the George Washington University Regulatory Studies Center, 805 21st St. NW, Suite 609, Washington, DC.
**Introduction**

According to the Food and Drug Administration (FDA), the proposed regulation would provide “updated nutrition information on the label and improve how the nutrition information is presented to consumers, in light of current scientific evidence, dietary recommendations of most recent consensus reports, and public comments received in response to advance notices of proposed rulemaking.”\(^3\) This latest update in nutrition labeling since it became mandatory in 1990 includes the addition of new nutrients for mandatory declaration, the reformatting of labels with increased emphasis on calories and percent daily values and changes to serving size requirements.\(^4\)

With the new labeling, the agency seeks to “assist consumers in maintaining healthy dietary practices.”\(^5\) The proposed rule seeks to increase understanding of nutritional science by creating new requirements on manufacturers to declare “added sugar,” potassium and Vitamin D content, change the daily values for sodium, dietary fiber and Vitamin D, and remove “Calories from Fat” due to new research showing the type of fat is more important than the amount.\(^6\)

In order to help consumers accurately identify the number of calories in a product the proposed rule also requires that packaged foods “that can reasonably be consumed at one eating occasion” declare their calorie and nutrient information for the entire package.\(^7\)

FDA also states in its separate Preliminary Regulatory Impact Analysis (PRIA) that the new labeling requirements would “potentially prompt industry to reformulate products to maintain health claims and nutrient claims, and reformulate products that may appear less attractive to consumers under the provisions of the proposed rules.”\(^8\)

As a part of its ongoing Retrospective Review Comment Project, the Regulatory Studies Center examines significant proposed regulations to assess whether agencies propose retrospective review as a part of their regulations, and submits comments to provide suggestions on how best to incorporate plans for retrospective review. To facilitate meaningful retrospective review after the promulgation of a final rule, multiple government guidelines instruct agencies to incorporate retrospective review plans into their proposals during the rulemaking process.

\(^3\) 79 FR 11880.
\(^5\) 79 FR 11881.
\(^6\) 79 FR 11880.
\(^8\) FDA Preliminary Regulatory Impact Analysis, [www.regulations.gov](http://www.regulations.gov) (Docket No. FDA-2012-N-1210) at 43.
Incorporating Retrospective Review into NPRMs

Through a series of Executive Orders, President Obama has encouraged federal regulatory agencies to review existing regulations “that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” On January 18, 2011, President Obama signed Executive Order 13563, Improving Regulation and Regulatory Review, which reaffirmed the regulatory principles and structures outlined in EO 12866. In addition to the regulatory philosophy laid out in EO 12866, EO 13563 instructs agencies to consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.9

This ex-post review makes it possible for regulatory agencies and the public to measure whether a particular rule has had its intended effect. In his implementing memo on retrospective review, former Administrator of the Office of Information and Regulatory Affairs, Cass Sunstein, stated the importance of designing regulations to facilitate their evaluation:

With its emphasis on “periodic review of existing significant regulations,” Executive Order 13563 recognizes the importance of maintaining a consistent culture of retrospective review and analysis throughout the executive branch. To promote that culture, future regulations should be designed and written in ways that facilitate evaluation of their consequences and thus promote retrospective analyses and measurement of “actual results.” To the extent permitted by law, agencies should therefore give careful consideration to how best to promote empirical testing of the effects of rules both in advance and retrospectively.10 [Emphasis added]

This emphasis is repeated in Sunstein’s June 14, 2011 memo, “Final Plans for Retrospective Analysis of Existing Rules.” In its 2013 Report to Congress on the Benefits and Costs of Federal Regulations, the Office of Management and Budget (OMB) states that such retrospective analysis can serve as an important corrective mechanism to the flaws of ex ante analyses. According to that report, the result of systematic retrospective review of regulations:

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should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations. A large priority is the development of methods (perhaps including not merely before-and-after accounts but also randomized trials, to the extent feasible and consistent with law) to obtain a clear sense of the effects of rules. In addition, and importantly, *rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects.*

**Retrospective Review Requirements**

To evaluate whether FDA’s proposal was “designed and written in ways that facilitate evaluation of [its] consequences,” we measure it against five criteria:

- Did FDA clearly identify the problem that its proposed rule is intended to solve?
- Did FDA provide clear, measurable metrics that reviewers can use to evaluate whether the regulation achieves its policy goals?
- Did FDA commit to collecting information to assess whether the measurable metrics are being reached?
- Did FDA provide a clear timeframe for the accomplishment of the stated metrics and the collection of information to support its findings?
- Did FDA write its proposal to allow measurement of both outputs and outcomes to enable review of whether the standards directly result in the outcomes that FDA intends?

**Identifying the Problem**

The first of the “Principles of Regulation” outlined by President Clinton in EO 12866 makes it clear that, as a first step, agencies must be able to identify the problem that justifies government action through regulation:

> 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.

This step is crucial to the formulation of any policy. Without knowledge of the problem that the agency is trying to address, the public cannot assess whether the policy or regulation at hand has had the intended effect, which is key in retrospectively evaluating regulation. In its PRIA, FDA observes that “information failure, a well-established type of market failure, can provide an economic rationale for the mandatory disclosure of nutrition information.”

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With the goal of providing information to consumers to help them maintain healthy dietary practices, the proposed rules would affect consumers by: (i) better aligning the information provided in the Nutrition and Supplement Facts labels with new data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic diseases, (ii) improving the design and content of the Nutrition Facts label such that relevant information is more salient and easy to understand for the purpose of informing consumer consumption decisions, and (iii) by potentially prompting industry to reformulate products to maintain health claims and nutrient content claims, and to reformulate products that may appear less attractive to consumers under the provisions of the proposed rules.\(^\text{12}\)

According to FDA, the new labels proposed under the rule are “consistent with current data on the associations between nutrients and chronic diseases or health-related conditions (and) reflect current public health conditions in the United States.”\(^\text{13}\) The agency assumes several causal linkages between its new proposed requirements and its goal of improved consumer dietary practices. Again, from its PRIA:

Overall, major predicted elements of the consumer and industry response to the nutrition labeling proposed rules include:

- Increased knowledge of the nutrient content of packaged foods, which may help consumers make healthier food choices;
- Increased ease of nutrition label use from the decreased need to do arithmetic for products that bear DCLs [dual-column labeling];
- Greater disclosure of the nutrient content of existing packaged foods, which may give firms an incentive to provide additional items with healthier formulations; and,
- Potential reformulation of products to reduce added sugars or change amounts of added vitamins and minerals based on current recommendations.

The effects together would help reduce the information failure and increase the salience of the information on food packages, assisting consumers to make healthy decisions in their diet.\(^\text{14}\)


\(^\text{13}\) 79 FR 11880.

Measurement Criteria

In order to measure the success of this rule following implementation, it is necessary for FDA to define what constitutes a “success.” Any stated metrics of success should be linked to the problems identified, to show the proposed requirements are effectively solving the problem at hand. Of course, not all positive outcomes can be directly measured; however, many can be, and the proposed rule stage is the perfect time to introduce a plan to measure the rule’s effects to gauge its efficacy.

According to FDA, the benefits of the proposed rule far outweigh the costs. It estimates the one-time cost to industry of labeling, reformulation, and initial recordkeeping at $2.3 billion, with a small cost associated with ongoing recordkeeping. The benefits over a 20 year period are projected to be between $21.1 billion to $31.4 billion, depending on the discount rate used. To calculate these estimated benefits, FDA used an academic study of “willingness-to-pay for nutrient content.”

To quantify the benefits of the proposed rules, FDA extrapolated from the welfare effects estimated in a retrospective study on the impact of [the Nutrition and Education Act] by [Jason] Abaluck. Abaluck measured the consumer welfare gains as the willingness-to-pay (WTP) for nutrient content based on revealed preference data, i.e., food consumption and prices.

The causal logic implied in FDA’s proposed rule is that the new labeling will increase consumer knowledge of healthier dietary practices and lead to better consumption choices and a better public health profile overall. Further, the proposed rule seeks to have the complimentary effects of increased production of healthier products on the part of industry.

FDA should commit to measuring these causal linkages if the rule is finalized. For example, it should identify and commit to collecting information on:

1. The usefulness of the new labeling and its effects on consumer knowledge.
2. Whether products were reformulated to maintain health and nutrient content claims.
3. Changes in consumer purchasing behavior.
4. Consumer welfare gains (perhaps as measured by the willingness-to-pay for nutrient content based on revealed preference data, i.e., food consumption and prices.)
5. The number and or rate of change of diagnoses of chronic diseases nationally.

Information Collection

In order for retrospective review to be effective, FDA should identify how it will gather information to assess whether it’s stated metrics are being accomplished. Consistent with the requirements of the Paperwork Reduction Act, the agency should commit to collecting the information needed to measure the rule’s success.

FDA generally does commit “to continue to perform research during this rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label.”18 The overall goal of these efforts, according to the agency, is “to assess a consumer’s ability to use the Nutrition Facts label and assess a consumer’s preferences related to proposed modifications of the Nutrition Facts label format.”19 This is important, and should be continued if the rule is implemented. In addition, the agency should commit to ascertaining the extent to which products have been reformulated in response to the new dietary guidelines, and the effect of any product changes on consumer decisions.

Also, given the proposed rule’s wide impact on industry and consequently consumer prices, the agency should commit to tracking whether the proposed rule proves to be more or less burdensome than anticipated. FDA estimates costs to manufacturers of $2.3 billion.20 It should take advantage of the feedback opportunities facilitated by the Paperwork Reduction Act to evaluate the accuracy of those estimates. For instance, it projects “minor” costs to manufacturers of having to keep written records to verify their declarations should be monitored.21

Timeframe

The text of the proposed rule does not include a timeframe for retrospective review. In the final rule, FDA should commit to measuring some of the above stated metrics and verify the assumptions underlying its estimated benefits on a regular basis to provide timely feedback on the rule’s outputs, outcomes, costs and unanticipated consequences.

Some measures, such as consumer understanding and response to the labels, can begin as soon as the provisions of the rule become effective, or 60 days after the final rule is published.22 Other outcomes, such as changes in product formulation and ultimate public health outcomes, will require a longer time period to be observed. Pursuant to the Paperwork Reduction Act, FDA

18 79 FR 11887.
19 Ibid.
22 79 FR 11883.
must seek OMB approval of the information collection requirements every 3 years, and this provides a reasonable time period for evaluating the burdens and utility of the information.

Measure Linkages

FDA’s goal is for the new labeling requirements to increase consumer knowledge in order to change their dietary behavior so they can make better food choices and enjoy better health. It recognizes, however, that consumers may offset any reduction in their consumption of unhealthy items with consumption of unlabeled or unhealthy meals or snacks. Consumers substitute between nutrient sources when attempting to modify their food choices foods in response to the labeling changes, the benefit estimates in this analysis may over- or understate the effects realized if we finalize the nutrition labeling proposals as proposed."

Further, the agency admits that rates of chronic disease have increased in the face of two previous rulemakings. FDA states that “the public health profile of the US population has changed” noting a dramatic “increase in obesity” since its last update in 2003. Elsewhere the agency notes that “[b]etween 1976 and 1980 and 2007 and 2008, obesity rates increased more than twofold (from 15 to 34 percent) in adults and more than threefold (from 5 to 17 percent) among children and adolescents.”

As FDA commits to measuring the effects of its rule, it should also be aware of mediating factors that may have accomplished or undermined the stated metrics absent the rule. Determining linkages between the rule and the measured outcomes is necessary to ensure that the policy itself resulted in the desired outcomes, rather than other factors beyond FDA’s control. For example, it should consider whether the costs of implementing the requirements will affect consumer prices, and lead to unintended behavior changes.

It is also possible that unintended consequences could derail the agency’s stated goals. Label requirements, due to their mandatory elements, prohibition of certain information, and space limitations that preempt other information, necessarily lock in information based on today’s science, and slows responsiveness to new information as it develops.

FDA also recognizes that consumers may not make choices experts think they should, even when informed:

24 79 FR 11884.
25 79 FR 11885.
We note that the behavioral economics literature suggests that distortions internal to consumers (or internalities) due to time-inconsistent preferences, myopia or present-biased preferences, visceral factors (e.g., hunger), or lack of self-control, can also create the potential for policy intervention to improve consumer welfare.26

As stated above, the agency fails to expressly link through evidence the prospect of increased health benefits and new nutrient labeling. Further, the overlap it discusses between the nation’s worsening health profile and its initial rulemaking on label requirements raises questions about the link between health benefits and nutrient labeling. Committing to conduct measurement needed for retrospective review may help to clarify the rule’s effects, in terms of consumer knowledge, manufacturer practices and costs, and public health.

**Recommendations**

If FDA proceeds with this rule, given the uncertainty in the causal linkages between the nutrition labeling changes and public health benefits, it should commit to measuring both public health outcomes and the intermediate effects it assumes. As discussed above, this could include information on consumer understanding of the nutrition content of covered foods, product formulation changes, behavioral change with respect to dietary choices, and measures of public health. FDA should also examine any unintended consequence associated with higher food prices, or constrained ability to respond as new information on nutrition and health emerges.

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