October 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir and Madam:


The Sugar Association (Association) represents United States sugar cane farmers and refiners and sugar beet farmers and processors. Association members account for over 90% of sugar/sucrose production in the United States. Founded in 1943, our mission is to monitor nutrition science, to provide science-based information on sugar to consumers and health professionals and to ensure that Federal nutrition and food policy regarding sugar is based on the preponderance of scientific evidence. The foundation of our efforts to support and promote sugar in moderation as a safe and useful part of a balanced diet and healthful lifestyle is grounded in the totality of high-quality scientific evidence. As such, the

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Association offers these comments on this unprecedented proposal which, if enacted, would have significant impact on our member companies.

We understand that the Food and Drug Administration (FDA, the Agency) seeks to ensure that product labeling will “assist consumers in maintaining healthy dietary practices.” However, we contend FDA has not provided scientific evidence to justify requiring “added sugars,” a non-statutory nutrient, to be included on the Nutrition Facts Label (NFL). Further, FDA has not provided the scientific evidence to uphold its statutory requirement that “added sugars” labeling and a daily reference value (DRV) for “added sugars” is “necessary to assist consumers in maintaining healthy dietary practices.”

The scientific justification put forth by the Agency to support its proposals raises serious concerns it is compromising its well-established scientific principles. In this rulemaking effort, FDA has openly admitted it has deviated from “factors traditionally considered for mandatory declaration” of nutrients on the NFL and the record shows that the Agency has arbitrarily selected from general dietary guidance, science of low evidentiary value and selective reports to support its proposal for “added sugars” labeling and to set a DRV.

We offer the following comment on the quality of scientific evidence and the irregularities in this rulemaking process used by the Agency to support its proposal to require an “added sugars” declaration in the NFL and to set a DRV and require the declaration of percent daily value (DV) for “added sugars.”

Summary of Key Points

- FDA arbitrarily selected from general dietary guidance, science of low evidentiary value and selective reports such as the 2015 Dietary Guidelines Advisory report to support its proposal for “added sugars” labeling and to set a DRV for “added sugars.”

- FDA is bypassing its traditional reliance on the Institute of Medicine to set Dietary Reference Intakes, which provide the scientific basis for the development of food guidelines in both the United States and Canada, to make its DRV proposal for “added sugars.”

- USDA Food Pattern modeling mathematical construct does not have the scientific underpinning to support “added sugars” intake recommendations or as a basis for setting a DRV.

- Until the food pattern modeling itself is tested, “empirical” evidence for its efficacy does not exist. In the interim, such creative methods of portraying the science to
support “added sugars” intakes as official science-based recommendations undermines the credibility of FDA’s efforts to set a DRV for “added sugars.”

- Comparing current “added sugars” intake to USDA Food Patterns, Healthy U.S.-Style, Healthy Mediterranean-Style, and Healthy Vegetarian Patterns is not scientific evidence for setting a 10% DRV for “added sugars.”

- FDA asserts that a public health endpoint now exists for requiring “added sugars” labeling and setting a DRV for “added sugars” based on the 2015 DGAC concluding a strong association between dietary patterns and increased risk of cardiovascular disease. Despite the fact that the majority of dietary pattern index studies cited by the DGAC to reach this conclusion did not include “added sugars” criteria.

- FDA links “added sugars,” to serious disease outcomes without scientific evidence of verifiable biological mechanisms that show causation to support this assertion.

- FDA cited the World Health Organization (WHO) commissioned meta-analysis as a basis for the 10% DRV despite the fact WHO grades its own evidence for free sugars (added sugars) intake and body weight for both adults and children to be of moderate quality, at best.

- The extraordinary contradictions and irregularities in this rulemaking process and the use of scientific evidence of such low evidentiary value to propose “added sugars” labeling and a DRV is unprecedented for the Food and Drug Administration.

- The Food Drug and Cosmetic Act gives FDA the responsibility to ensure “labeling is not false or misleading in any particular” however, FDA’s own consumer research shows that should FDA move forward with its “added sugars” labeling proposal it will mislead consumers.

The scientific evidence FDA relied on to set a DRV for “added sugars” and to assert a link between “added sugars” intake to an increased risk of cardiovascular disease

We are addressing FDA’s questions regarding “new information” from the 2015 Dietary Guidelines Advisory Committee (DGAC) report regarding “added sugars” and the proposal to establish a DRV for “added sugars,” as well as FDA’s proposal to require the declaration of the percent DV for “added sugars” on the Nutrition Facts and Supplement labels.

FDA’s scientific justification for setting a DRV and asserting a strong link between “added sugars” and cardiovascular disease risk includes, USDA Food Pattern modeling, current “added sugars” consumption, the published meta-analysis on sugar and body weight and the Nutrition Evidence Library (NEL) review “Dietary Patterns and Health Outcomes Systematic Review Report.” We address each of these justifications below.
**USDA Food Pattern modeling does not have the scientific underpinning to support “added sugars” intake recommendations or as a basis for setting a DRV.**

In the preamble to the Supplemental Proposed Rule (Supplemental) FDA states, “The 2015 DGAC examined the relationship between dietary patterns and health outcomes more extensively than did earlier DGAC reports, through the use of a food modeling approach using USDA Food Patterns.”

FDA's use of the 2015 DGAC USDA Food Pattern modeling as a scientific basis for labeling a non-statutory nutrient, or any nutrient, raises serious concerns. First, regardless of whether the 2015 DGAC examined the relationship of dietary patterns, or one of its components, and health outcomes more extensively than previous DGACs, the mathematical construct of USDA Food Pattern modeling does not have the scientific underpinning upon which to purport a link between a dietary component and a health outcome. Food pattern and menu-modeling serves the purpose of developing a pattern of eating to meet (already established) nutrient requirements. In no way does this exercise provide evidence to determine a nutrient requirement, a nutrient intake limit, or provide the basis to determine the relationship between a nutrient or food group and a health outcome. Such determinations require actual experimental evidence.

Accordingly, this was FDA’s previous position, cited in its March 3, 2014, Proposed Rule, as to why the use of USDA Food Pattern modeling for setting a DRV for “added sugars” is inappropriate:

> “The solid fats and added sugars limit at each calorie level in the USDA Food Patterns is determined by calculation through food pattern modeling rather than on any biomarker of risk of disease or other public health endpoint.”

It was also FDA’s position, in the March 3, 2014, Proposed Rule, when the Agency did not rely on menu modeling to set a DRV for saturated fat. FDA concluded:

> “Menu modeling, by its very nature, would not permit the selection of DRVs that are based on scientific evidence related to actual public health outcomes.”

The “extensive” effort by the 2015 DGAC was simply an attempt to validate USDA Food Pattern modeling without actually testing the patterns in a clinical study, or several clinical studies, that would be required for such validation. The 2015 DGAC sought to validate the USDA Food Patterns by plotting the USDA food groups against those found in published hypothesis-based dietary patterns studies on a graph. The 2015 DGAC stated, “The data from the intervention trials and the cohort studies provide empirical data that the USDA
Food Patterns provide an evidence-based guide to food consumption.” The graphs provided by the DGAC to support this assertion raise several red flags. The table below quantifies the information provided in these graphs Appendix 1 Figures 1-5 that depict the correlation between intakes in cited dietary pattern studies and USDA Food Pattern recommendations.

<table>
<thead>
<tr>
<th>Dietary Component</th>
<th>Studies</th>
<th>Within USDA Food Pattern Range</th>
<th>Intakes Outside USDA Food Pattern Range</th>
<th>Lower</th>
<th>Higher</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetables</td>
<td>23</td>
<td>9 (39%)</td>
<td>14 (61%)</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Fruit</td>
<td>23</td>
<td>5 (22%)</td>
<td>18 (78%)</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Dairy</td>
<td>19</td>
<td>6 (32%)</td>
<td>13 (68%)</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Red &amp; Processed Meat</td>
<td>20</td>
<td>1 (5%)</td>
<td>19 (95%)</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Seafood</td>
<td>20</td>
<td>5 (25%)</td>
<td>15 (75%)</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

We question how the USDA Food Pattern, when compared to the actual serving data from these studies, depicted in the above chart, demonstrates empirical evidence (as stated by the 2015 DGAC) that USDA Food Patterns are evidence-based guides for food consumption. The quantified table shows that, in fact, the majority of food group intakes from the USDA Food Pattern do not actually fall within the range of intakes in these published dietary pattern studies recommendations, as asserted by the 2015 DGAC. Additionally, because the majority of dietary pattern index studies used for this exercise did not include “added sugars” criteria (as is evidenced by omission of “added sugars” in this chart), the 2015 DGAC certainly did not provide “empirical evidence” to support the “added sugars” intake recommended in the USDA Food Patterns or evidence that “added sugars” consumption is associated with a negative health impact.

FDA pointed out in 2014, the “added sugars” recommendations in USDA Food Pattern modeling are not evidence-base but are simply the remainder of calories left when all food groups are accounted for in the model. In the case of the 2015 DGAC, they arbitrarily assigned 45% of these discretionary calories be allotted to “added sugars.” Such a calculation in no way is an indication of how this amount of “added sugars” is associated with disease risks or health outcomes.

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In fact, the 2010 Dietary Guidelines for Americans clearly state that the USDA Food Pattern is but one example of suggested eating patterns and that the USDA Food Patterns “have not been specifically tested for health benefits.”

Despite the 2015 DGAC’s plotting the pattern against published dietary pattern studies, the fact remains that the USDA Food Pattern modeling is still based on a mathematical construct in which determination of servings and micronutrient requirements in the pattern lack standardization and can be subjective. Micronutrient requirements in the USDA Food Pattern are not always based on established intakes i.e., the USDA Food Patterns calcium intakes can range from 110% of the RDA at the lower calorie range to 138% of the RDA at the highest, the RDA range for iron is 110% to 265%. As caloric levels increase there is a disregard for the percent adequacy of micronutrients. Further, with few exceptions, the USDA food modeling does not take into consideration fortification in the food supply, which could dramatically reduce the number of food servings in the USDA Food Patterns and increase the calories designated as leftover. The unscientific concept of leftover calories available for solid fats and “added sugars” intakes would completely change based on one addition or deletion of a serving of food. The multitude of subjective variables in USDA Food Patterns and the fact that it cannot be used to identify biomarker of risk of disease or public health endpoints raises serious questions about its use as a platform for intake recommendation or setting a DRV for “added sugars.” (Emphasis added)

Therefore, until the food pattern modeling itself is tested, “empirical” evidence for its efficacy does not exist. In the interim, such creative methods of portraying the science to support “added sugars” intakes as official science-based recommendations undermines the credibility of FDA’s efforts to set a DRV for “added sugars.” [Emphasis added]

Comparing current “added sugars” intake to USDA Food Patterns, Healthy U.S.-Style, Healthy Mediterranean-Style, and Healthy Vegetarian Patterns is not scientific evidence for setting a 10% DRV for “added sugars.”

In the Supplemental Proposed Rule FDA states:

“The 2015 DGAC reviewed the current science, status and trends in dietary patterns of intake in the U.S. population compared to a “Healthy U.S. –style Pattern” a

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“Healthy Mediterranean style Pattern”, and a “Healthy Vegetarian” pattern associated with health benefits. The report found that current U.S. population intake is high across all age groups and genders with nearly 90 percent of the population “exceeding the recommended daily limits.”

There are several issues with this statement. First, the notion that the 2015 DGAC found that the U.S. population is “exceeding the recommended daily limits,” for “added sugars” is predicated on the contention that USDA Food Patterns are official intake recommendations and provide established science-based intake “limits,” which is certainly not the case.

Second, this statement also implies that the 2015 DGAC provided new scientific evidence to support its contention that the “Healthy U.S. –style Pattern” “Healthy Mediterranean style Pattern”, and “Healthy Vegetarian Pattern” are associated with health benefits. There is no new scientific evidence to support the “added sugars” intake recommendations put forth in Table D6.1, See Appendix 1, Table 1 nor is there new evidence to support the 2015 DGAC’s assertion that this table provides evidence that 10% of calories from “added sugars” is associated with health benefits.

The 2015 DGAC asserted their “patterns take into account food group intakes from studies using a Med-diet index to assess dietary patterns” but fail to disclose that not one of the Mediterranean dietary pattern studies cited by the DGAC had a sugars or “added sugars” criterion. Further, we reiterate that the majority of dietary pattern index studies cited by the DGAC did not include “added sugars” criteria. See Appendix 1 Table 2.

Thus, the suggested intakes in Table D6.1 are based on criteria set by the DGAC that resulted in patterns that provide a value for the hypothetical concept of leftover calories. The DGAC’s untested and unsubstantiated patterns create leftover calories assigned to levels of solid fats and “added sugars” intakes. The cited studies did not incorporate this methodology. We reiterate it is untested and therefore not validated.

The “Healthy U.S. –style Pattern,” “Healthy Mediterranean style Pattern”, and “Healthy Vegetarian” patterns are not based on a validated evidence-based methodology for determining health outcomes. The 2015 DGAC provided no new scientific evidence to support its patterns in Table D6.1, its contention that these extremely low “added sugars” intakes will improve health outcomes or that the results of its food modeling support a recommendation to consume less than 10% of energy from “added sugars.”

Third, we also question the scientific validity of using hypothesis-based dietary pattern scores for determining health outcomes. The DGAC described its evaluations below:
“These patterns are defined using dietary quality/adherence indices, [e.g., Healthy Eating Index (HEI)], based upon data-driven approaches (e.g., cluster or factor analysis), or may be self-identified patterns (e.g., vegetarian).”

However, the use of adherence scores, cluster or factor analysis as a science-based measure for predicting health outcomes is flawed and not an accepted scientific methodology. A February 3, 2014 study “Added Sugar Intake and Cardiovascular Diseases Mortality Among US Adults” published in *The Journal of the American Medical Association Internal Medicine*, used hazard risk ratios to evaluate risks of cardiovascular disease mortality. The analysis of diets based on the HEI scores found that individuals with a higher adherence to the HEI ≥Top 50% (2.96) compared to individuals with lower adherence ≤ Top 50% (1.80) actually had an almost 300% *increased* chance of dying from cardiovascular disease.  

We continue to question why a science-based agency, such as FDA, is not requiring rigorous scientific evidence to promulgate “added sugars” labeling regulations and instead using untested food modeling and dietary pattern studies as its almost sole scientific justification.

**FDA asserts that a public health endpoint now exists for requiring “added sugars” labeling and setting a DRV for “added sugars” based on the 2015 DGAC concluding a strong association between dietary patterns and increased risk of cardiovascular disease.**

As part of the rationale for “added sugars” labeling and setting a DRV, FDA identified new evidence from the 2015 DGAC report to support a public health endpoint of cardiovascular disease, CVD. In the Supplemental, FDA states, “Specifically, there is evidence of a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD.” It is hard not to question whether FDA actually reviewed the scientific literature forming the basis for this Supplemental as there are several flaws to this rationale, which are outlined below.

First, as with the evidence for dietary pattern modeling, we strongly question the scientific validity of using primarily-observational dietary pattern studies, grounded in hypothesis-based indexes, as evidence to link a dietary pattern, let alone its components, to disease outcomes. To use hypothesis-based research to establish cause and effect relationships between dietary components and disease outcomes that have not yet been established by more traditional, experimental science, is inconceivable by a trusted agency such as FDA.

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The methodologies used in these dietary patterns studies do not, and cannot, accurately isolate the positive or negative effects of individual components of the dietary pattern, nor can they adequately control for the numerous confounders known to be associated with higher diet quality. In this highly subjective methodology, certain components of a dietary pattern are pre-assigned negative scores based on the presumptions they are detrimental, resulting in outcomes that are biased and predetermined. We contend that this methodology is not objective science and is not appropriate for use in making evidence-based recommendations or to validate a public health need to require “added sugars” labeling.

Second, the conclusions of the DGAC, subsequently cited by FDA in the Supplemental, do not accurately reflect the findings from the 55 studies that went into making this conclusion. This raises the question as to whether FDA just relied on the DGAC’s conclusions instead of actually reviewing the studies that went into forming this conclusion. Pertinent to FDA’s rationale for the “added sugars” label and a DRV, the Supplemental specifies “The 2015 DGAC report, in its analysis of added sugars as part of a dietary pattern among the U.S. population, found strong association with that pattern of intake to an increase in CVD risk, in comparison to healthier dietary patterns with lower added sugars intakes.” It is important to note that of the 55 dietary pattern index studies reviewed by the DGAC, only 18 were studies of the U.S. population. Of these 18 studies using various hypothesis-based indexes to score dietary patterns, 12 did not include any assessment of “added sugars.” This means that 66% of the studies used to inform this “strong” conclusion did not include anything regarding the “added sugars” intakes of the study’s participants when concluding the patterns relationship to CVD risk.

Of the six (of 18) studies that did include a dietary index containing an “added sugars” criterion, four of them only assessed sugars-sweetened beverage intake (with two of the four including fruit juice in this criterion) with no assessment of intake of sugars-containing foods. Additionally, of the six studies, two found no association between the dietary pattern measured and CVD risk, leaving only four studies to base the determination of the role of “added sugars” as part of a dietary pattern associated with CVD risk. To continue, in two of these four studies (Fung et al. 2008 and Fitzgerald et al. 2012), while the authors found an association between increasing adherence to the dietary pattern index score (a composite of all dietary component criteria) and decreased CVD risk, the “added sugars” scores did not differ across quintiles of dietary pattern index adherence. Therefore, “added sugars” intake was not a factor in the observed differences in CVD risk.

In summary, only two of the 18 studies that are the basis for the “public health endpoint” being used by FDA, actually provide data to support that a dietary pattern lower in “added sugars” is associated with CVD risk. While it is problematic that FDA relied upon the DGAC
report’s conclusions, what is more confusing is the low level of evidence that FDA is using to determine a public health outcome, particularly when the agency has a long history of stringent scientific protocols. Even if there were more than two studies to inform the role of “added sugars” in these patterns linked to CVD, there are several limitations that are inherent to this dietary patterns research, making it incomprehensible how this type of evidence could all of the sudden be acceptable to form any conclusion, let alone significant policy decisions. Some of these limitations are noted below:

- The observational data used in these studies, and the way that they are analyzed, make the findings highly subjected to residual confounding. Even with adjustment for confounders, residual confounding cannot be eliminated from observational studies. Specifically, as stated in a large number of these studies,
  - Higher/better dietary index scores were associated with a number of factors, such as higher education, increased physical activity, non-smoker, multi-vitamin use, hormone therapy (women), married vs. single.
- The dietary indexes themselves are inherently biased, and based on a priori determinations made by “scientific consensus or proposed by investigators.”
- The dietary patterns are not uniformly defined. This hampers cross-study comparisons and limits reproducibility.
- Food groups are categorized differently across the dietary indexes (e.g., potatoes, fruit juice, dairy). Additionally, fats and oils are spread across food groups, making them difficult to account for,
- Use of Food Frequency Questionnaires to estimate dietary intake poses several issues:
  - They are not designed to assess absolute intakes of foods.
  - When used only at baseline, the assumption is that intake does not change over several years, when health outcome is measured.
  - Self-reported data introduces report bias.
  - They are not validated measures of dietary patterns.
  - They provide little to no information on how food is prepared.
- Some studies not only had self-reported dietary data, but also self-reported health outcome data.
- The scoring algorithms used to evaluate adherence differ, often resort to qualitative descriptions of dietary patterns (i.e. higher vs. lower).
- The patterns may be population specific and therefore not generalizable.
- The NEL systematic review project fails to mention all of the individual components that they tested that had no effect on CVD (“added sugars”, for example)
- Additionally, dairy’s impact is inconsistent, highlighting how imprecise this methodology is.
• The NEL project based its conclusions only on those studies where score adherence was associated with decreased CVD risk, leaving all of the studies showing no effect out of the analysis.

Further, additional analyses of 20 studies were conducted. In the report it states “Twenty studies assessed the association between individual food components of a dietary pattern score and CVD endpoint outcomes”\(^\text{10}\) Only three studies of the 20 included an “added sugars” scoring component and no association between “added sugars” intake and CVD risk were found in all three studies. See Appendix 1 Table 2. In fact, in the report it identifies “key findings” and the only reference to “added sugars” simply states, “Certain scores also included sugars or sugar-sweetened beverages as negative components.”\(^\text{11}\) It is inconceivable that FDA would infer that there is evidence of a strong association between “added sugars” and CVD risk based on a “key finding” that “added sugars” were scored as a negative component in these studies.

Therefore, we find it particularly egregious to link “added sugars,” or any food category, to serious disease outcomes without scientific evidence of verifiable biological mechanisms that show causation to support this assertion.

To reiterate, the majority of dietary pattern index studies cited in this DGAC report did not include total sugars or “added sugars” criteria. Yet, somehow the conclusions made by those that conducted this NEL review, which was then endorsed by the 2015 DGAC and now FDA, conclude that the studies in this report show there is strong evidence of a strong association between “added sugars” intake and CVD risk.

Further, one must question why FDA ignored the 2015 DGAC’s Added Sugars Working Groups NEL review on the direct relationship between “added sugars” and cardiovascular disease. This is not surprising though, given the “moderate” evidence associating “added sugars” and CVD, the DGAC’s conclusion would not provide FDA the support it needed to declare CVD as a public health outcome, as required for a non-statutory nutrient. This is further evidence of FDA’s subjective selection of science from the 2015 DGAC report to support its agenda to require “added sugars” labeling on the NFL.

We continue to be mystified as to why FDA would use science of such low evidentiary value to determine a substance/disease relationship. FDA would never consider such evidence as acceptable for a food manufacturer to claim a positive association between a

\(^{10}\) A Series of Systematic Reviews on the Relationship between Dietary Patterns and Health Outcomes, Page 88 available at http://www.nel.gov/vault/2440/web/files/DietaryPatterns/DPRptFullFinal.pdf

\(^{11}\) A Series of Systematic Reviews on the Relationship between Dietary Patterns and Health Outcomes, Page 81 available at http://www.nel.gov/vault/2440/web/files/DietaryPatterns/DPRptFullFinal.pdf
substance/disease prevention relationship. In its guidance for industry for making a health claim, FDA set strong criteria for the evaluation of such claims, including: 1. identifying studies that evaluate the substance/disease risk, 2. identifying surrogate endpoints for disease risk, 3. evaluating the human studies to determine whether scientific conclusions can be drawn from them about the substance/disease risk, 4. assessing the methodological quality of each human study from which scientific conclusions about a substance/disease relationship can be drawn, 5. evaluating the totality of scientific evidence, 6. assessing significant scientific agreement.¹²

We ask that FDA maintain its long-standing reputation for insistence on strong scientific evidence in making changes to the NFL. It is unprecedented for FDA to assert a link or association with any individual component of the diet with a serious disease outcomes that is not supported by a thorough systematic review of the full body of science (at the highest level of evidence available). Once again we contend, in its Supplemental, FDA did not provide this quality of evidence to support its proposal for “added sugars” labeling and to set a DRV for “added sugars.”

The WHO commissioned meta-analysis as a basis for the 10% DRV

In its Supplemental, FDA cites a recent meta-analysis used by the 2015 DGAC to support its proposal for a 10% DV. To fully understand the DGAC’s recommendation of a 10% limit on “added sugars” it is important to look at the process it used. Instead of conducting their own NEL reviews, the 2015 DGAC relied heavily on a meta-analysis commissioned by the World Health Organization (WHO) on “free sugars” and body weight to support its recommendation to keep “added sugars” intake below 10 % of total energy intake. The 2015 DGAC recommendations are a vastly oversimplified and inaccurate portrayal of the scientific evidence and specifically, the findings of Te Morenga.¹³

The body of evidence actually indicates that any observed effect of “added sugars” on body weight is a function of total calories, from all sources, and not any unique obesogenic property of “added sugars.” This point is explicitly stated in the WHO-commissioned review. Further, Te Morenga’s findings do not support a 10% limit and the authors themselves acknowledge the limitations of the evidence stating, ¹⁴

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¹³ Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomized controlled trials and cohort studies. BMJ. 2013;346:e7492. PMID: 23321486

¹⁴ Ibid
• “Although comparison of groups with the highest versus lowest intakes in cohort studies was compatible with a recommendation to restrict intake to below 10% total energy, currently available data did not allow formal dose-response analysis.” [Emphasis added]

• “The data suggest that the change in body fatness that occurs with modifying intake of sugars results from an alteration in energy balance rather than a physiological or metabolic consequence of monosaccharides or disaccharides. Owing to the multifactorial causes of obesity, it is unsurprising that the effect of reducing intake is relatively small.”

• “The extent to which population based advice to reduce sugars might reduce risk of obesity cannot be extrapolated from the present findings, because few data from the studies lasted longer than ten weeks.”

• “We observed that isoenergetic replacement of dietary sugars with other macronutrients resulted in no weight change. This finding strongly suggested that energy imbalance is a major determinant of the potential for dietary sugar to influence measures of body fatness.”

The findings in the WHO commissioned review are actually consistent with the 2010 DGA advice that clearly states, “Foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits.” 15

It is critical to note that in the WHO report, WHO grades its own evidence for free sugars (added sugars) intake and body weight for both adults and children to be of moderate quality, at best.16

Further, highlighting a pattern of recommendations that are not grounded in strong science, a recent study published in the Journal of Clinical Epidemiology titled “World Health Organization recommendations are often strong based on low confidence in effect estimates” found, “Over 50% of WHO recommendations are strong and over 50% of those

16 WHO evidence grading definitions, “Based on the grades of evidence set by the GRADE Working Group - moderate quality, we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different, low quality, our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect, very low quality, we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.” Citation: Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015.
strong recommendations are based on low or very low confidence in effect estimates (study quality).” Regarding nutrition guidelines, this percentage jumps to 100%. \(^{17}\)

The WHO commissioned meta-analyses (Te Morenga, 2013) does not provide the level of scientific evidence or agreement upon which the 2015 DGAC and subsequently FDA, can suggest an evidence-based recommendation.

The U.S. has consistently maintained a high standard of evidence-based recommendations in the development of policy. We strongly contend that the 2015 DGAC alignment with the WHO's recent and controversial guideline on sugars intake and now FDA, \(^{18}\) undermines this important standard of scientific integrity.

Further, for FDA to consider a meta-analysis as sufficient scientific support to make an intake recommendation of 10% of energy, as the 2015 DGAC did, once again demonstrates that for this rulemaking process, FDA is abandoning its evidentiary standards. \(^{19}\)

**Current “added sugars” consumption should not factor into scientific decision-making**

The FDA also states in the Supplemental that it factored current U.S. consumption of “added sugars” into its determination to propose a DV. Although the 2015 DGAC looked at current “added sugars” consumption levels, without science to support a verifiable negative health impact at current consumption levels, this is not sufficient evidence for an intake recommendation. The fact remains, that there isn’t, and never has been, an intake recommendation for total sugars or “added sugars” set by an authoritative scientific body based on scientific evidence of an adverse health outcome, nor has an Upper Intake Level been established by the same criteria. We reiterate, as FDA has in the past, that USDA Food Pattern modeling is a mathematical exercise that does not have the scientific underpinning upon which to set official intakes levels.

We strongly contend that the preponderance of scientific information on “added sugars” intake does not support a 10% limit or any assertion that “added sugars” intake uniquely contributes to obesity other than as a source of calories. Further, even as a source of calories, intake data do not support “added sugars” intake as a major source of increased

\(^{17}\) Alexander PE, et al. World Health Organization strong recommendations based on low-quality evidence (study quality) are frequent and often inconsistent with GRADE guidance. J Clin Epidemiology. 2014 Dec 19


caloric intake. In the past 40 years, U.S. per capita consumption of sugar/sucrose declined by 33% as obesity and other serious diseases increased. A recent analysis of U.S. National Health and Nutrition Examination Survey (NHANES) data found that “added sugars” consumption has declined to 14.6% percent of energy, which is a decrease of 19.3% over a period of eight years (2000 to 2008) and as the 2015 DGAC noted intake continues to decrease and current intake is now 13.4% of energy. More importantly, according to USDA data, Americans are consuming 425 more calories per person per day than they did in 1970 and of these 425 calories only 38 calories are attributed to “added sugars” intake (2009).

The data also do not support that intakes of “added sugars” have a direct impact on body mass index (BMI). A 2010 analysis of the NHANES data verifies that intake of “added sugars” does not have a direct correlation with BMI. The authors of the study state, “The individuals with the highest mean BMI values were associated with the ≤ 0 ≤ 5% and > 35% added sugars categories (BMI 28.9, 28.1, respectively). With each 5% increase in added sugars category above 15% of added sugars intake, we found a lower prevalence of overweight and obese individuals, with the exception of > 35% added sugars for BMI ≥30 where the prevalence increased to 3.2%.”

Further, this same comprehensive review of NHANES data also verified that “added sugars” intake is not causing nutrient displacement at current intake levels. Although this study of NHANES data reaffirmed the conclusion of the 2002 IOM report stating, “Similar to the IOM macronutrient report Appendix Table J (IOM, 2002b) and other reports (Bowman, 1999), we found that individuals with intakes >25% appear to be at greater risk for nutrient inadequacy based on comparison with the DRIs.” The authors of this study also point to the real world population impact from these higher intake amounts stating, “*However, high levels of added sugars intake occur among only a small proportion of the population and cannot explain the existing problem of poor nutrient intake in the U.S. population as a whole.*” (Emphasis Added)

Again, we emphasize that “added sugars” consumption has decreased since 2006.

**Unintended consequences of increased focus on “added sugars”**

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21 Available at http://www.ers.usda.gov/data/foodconsumption/FoodGuideSpreadsheets.htm; last update: February 1, 2011


23 Op Cit. 19
The Association once again contends that “added sugars” labeling undermines the major premise of “Calories Count.” FDA’s Obesity Working Group (OWG) “Calories Count” report describes “an action plan to cover critical dimensions of the obesity problem from FDA’s perspective and authorities.” The OWG report provides relevant insight:

Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, “calories count.”

Recent research reiterates the fundamental importance of a focus on total calories, not individual macronutrients. Because emphasis on individual macronutrients content over caloric content is at odds with the principles expressed in the “Calories Count” recommendations, labeling should deemphasize individual macronutrients in the NFL and emphasize the caloric contribution of a product. With this labeling proposal for “added sugars” labeling, FDA is once again putting the focus on an individual macronutrient, which undermines the determination of its own working group.

Furthermore, we strongly assert that sugar is an important ingredient that contributes essential functional properties to food formulation, including safety as a natural food preservative. Additionally, historic, as well as recent analyses on “added sugars” intake confirm that sugar makes many nutrient-rich foods palatable, thus sugar is a positive factor.

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for intake levels of many essential micronutrients.\textsuperscript{28} \textsuperscript{29} \textsuperscript{30} \textsuperscript{31} \textsuperscript{32} \textsuperscript{33} \textsuperscript{34} Historic consumption data show that “added sugars” intakes have not been at these extremely low levels suggested in the USDA Food Pattern/Healthy US-Style Patterns since nutrient deficiencies were a major public health problem. The unintended consequences, including the impact on nutrient intakes, need to be strongly considered, especially for children. The American Academy of Pediatrics published a new policy statement in March 2015, which states:

“Added sugars offers no nutritional benefits. At the same time, sugars themselves are not necessarily harmful. Used along with nutrient rich foods and beverages, sugar can be a powerful tool to increase the quality of a child’s diet. Used in excess, added sugars can add substantially to daily calories. Used at extreme levels (i.e., more than 25% to 30% of total calories), sugars can displace other nutrients, resulting in nutrient deficiencies. Although added sugars are often presumed to be an independent cause of overweight, this claim has not been proven in studies.”

“Care should be taken when prohibiting sugar-containing products to avoid compromising overall nutrition among children.”

“Sugars consumed in nutrient-poor foods and beverages are the primary problem to be addressed, not simply the sugars themselves.”\textsuperscript{35}

Reducing “added sugars” or any other caloric ingredients without a coinciding reduction in total calories provides no health benefit for consumers focused on weight reduction or weight maintenance. A focus on reducing “added sugars” does not necessarily translate to reduced caloric intake. Consumers who select foods based on a reduction in grams of “added sugars” listed in the NFL are often being misled because “added sugars” are frequently replaced by carbohydrate bulking agents, such as glycerol or maltodextrins.

\textsuperscript{28} Rennie KL et al “Association between added sugar intake and micronutrient intake: a systematic review” \textit{British Journal of Nutrition} 2007; 97: 832-841
\textsuperscript{30} Frary CD et al ”Children and Adolescents’ Choices of Foods and Beverages High in Added Sugars Are Association with Intakes of Key Nutrients and Food Groups”, \textit{Journal of Adolescent Health} 2004; 34: 56-63
\textsuperscript{31} Murphy MM et al “Drinking flavored or plain milk is positively association with nutrient intake and is not associated with adverse effects on weight status in US children and adolescents” \textit{J Am Diet Assoc}, 2008 Apr; 108(4):631-9
\textsuperscript{32} RA Forshee, ML Storey, Controversy and statistical issues in the use of nutrient densities in assessing diet quality. \textit{Journal of Nutrition}, 2004 134(10): 2733-2737
\textsuperscript{34} Johnson RK et al Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. \textit{Circulation}. 2009;120:1011-1020
and/or by an increase in fat content to maintain functionality and/or taste. These sugar replacers provide no nutritional benefit or a significant caloric reduction over sugars.

Additionally, scientific studies have documented the inverse relationship between fat and sugars intake when expressed as percent of energy in both the United States and the European Union. The current focus on reducing “added sugars” in the diet exacerbates the troubling growth in fat consumption in the United States. Despite lessening health concerns about fat, it remains a major and increasing source of calories while at the same time calories from “added sugars” consumption continues to decline.

Reducing obesity is the number one public health objective and it is imperative that meaningfully reducing total caloric intake be the goal without compromising essential nutrient intakes. To do this effectively, all unintended consequences must be considered. Overly restrictive “added sugars” intake recommendations could have unintended negative consequences that are inconsistent with the public health goals of healthy diets and meaningfully impacting obesity. We once again contend, the scientific evidence does not support FDA’s proposal to require “added sugars” labeling and the setting of a DRV for “added sugars” as “necessary to assist consumers in maintaining healthy dietary practices.”

Contradictions and irregularities in FDA’s regulatory process to propose “added sugars” labeling and a DRV for “added sugars.”

In January 2007, FDA started its rulemaking process to update the NFL by publishing in the Federal Register an Advanced Notice of Proposed Rulemaking (ANPRM), Food Labeling: Revision of Reference Values and Mandatory Nutrients. In this ANPRM, the Agency asked only one question related to the “sugars” designation on the NFL, “Should “sugars” continue to be included in the Nutrition Facts label?”

This was not the first time FDA considered whether there was adequate scientific justification for the inclusion of “sugars” on the NFL. In the preamble to FDA’s 1991 proposed rule “Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision,” the Agency acknowledges the mandatory labeling of sugars may be misleading to consumers by noting,

1) There is no public health significance established by existing diet and health studies, and
2) There is no recommended level of intake.

In its 1993 Final Rule, Nutrition Labeling Education Act (NLEA) rules and regulations, FDA
chose to maintain the statutory nutrient, “sugars,” but concluded the following regarding
“added sugars:”

“The agency is not persuaded that there is a need for mandatory disclosure of added
sugars in place of, or in addition to, total sugars. There is no scientific evidence that
the body makes any physiological distinction between added sugar molecules and
those naturally occurring in a food. In addition, the agency believes that it should
not promulgate regulations that it cannot enforce. [Emphasis Added]”

It is important to note that the position articulated by FDA in 1993 is the current position
of the Codex Alimentarius,37 which the United States supports, the position of the Canadian
Food Inspection Agency 38 and was the basis of comment submitted by the European
Commission 39 during the March 3, 2014, Proposed Rule comment period, in which the
European Commission asked FDA to reconsider its “added sugars” labeling proposal.

However, on March 3, 2014, in a total reversal from its 2007 ANPRM proposal and the
Agency’s long standing science-based position on “added sugars” FDA issued a Proposed
Rule on revisions to the NFL that would require a declaration of “added sugars” as set forth
in 79 Fed. Reg.11880.40

Not only is this a significant and abrupt change in scientific position, but also in FDA’s
historical standards for rulemaking. The declaration of “added sugars” would require food
processors to keep written records on the amount of “added sugars” in every product since,
according to FDA in the March 3, 2014, Proposed Rule, there is no laboratory method to
distinguish naturally occurring from “added sugars” in a processed food product and its

37 The US delegation to Codex was one of the delegations that “proposed the deletion of added sugars from
the list of nutrients noting that there were no analytical methods to differentiate between intrinsic and added
sugars, which could create difficulties for enforcement. They also noted that the human body did not
differentiate between total sugars and added sugar and that added sugars could be addressed through other
means than nutrient declaration.” The US position on added sugars labeling was upheld in May 2010, when
the Codex Committee on Food Labeling agreed not to include added sugars in the list of nutrient. ALINORM
10/33/22, Para. 37, Report of the thirty-eight session of the Codex Committee on Food Labelling, Quebec City,
Canada, 3 – 7 May 2010 (available at http://www.codexalimentarius.org/meetings-
reports/en/?sortingDate=012011).
38 Canada Gazette, Vol. 149, No. 24, 13 June 2015
39 Available at www.regulations.gov FDA-2012-N-1210
40 Page 2098 of the Federal Register/ Vol. 58. No. 3/ Wednesday, January 6, 1993/ Rules and Regulations section
b.54:
proposed regulation cannot be enforced unless new, unprecedented recordkeeping and inspection requirements are imposed on tens-of-thousands of food producers. In the 1993 NLEA rule making process, FDA concluded, “the agency believes that it should not promulgate regulations that it cannot enforce.”

FDA typically relies on U.S. consensus reports and significant scientific consensus to inform labeling decisions. Yet, the proposal to require “added sugars” labeling is not due to a new review of the full body of scientific evidence by an authoritative scientific body. There have been no new comprehensive scientific reviews that would supersede the conclusions of major independent scientific reviews on “added sugars,” such as the 2002 National Academies of Sciences, Institute of Medicine, “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids” (IOM report) 2002.

“Based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a UL (upper level) for total or added sugars.” 41

Further, in 2010 this conclusion was reaffirmed by the European Food Safety Authority (EFSA), 42 “Available data do not allow the setting of an UL [upper level] for total or added sugars, neither an AI (Adequate Intake) nor a recommended intake range.” An “added sugars” recommendation was also not supported by the 2010 DGAC, Carbohydrate Subcommittee, which identifying carbohydrates as consisting of sugars, starches and fibers, stating their NEL review looking at the relationship between carbohydrates and health outcomes heart disease, type 2 diabetes, body weight and dental caries concluded “no detriment effects of carbohydrates as a source of calories on these or other health outcomes were reported.”43 Historically, the Agency has relied on a consensus scientific basis for promulgating labeling regulations.

It is important to look back to the scientific justification FDA used to support its statutory authority to require the addition of trans fat on the NFL. FDA relied on IOM report conclusions and guidelines from the National Cholesterol Education Program to support its determination that, “dietary trans fatty acids have adverse effects on blood cholesterol measures that are predictive of CHD risk.” (64 FR 62746 at 62754) Therefore, FDA's

inclusion of *trans* fat, a non-statutory nutrient, on the NFL was based on a health-related physiological endpoint of public health significance. Further, FDA did not set a DRV for *trans* fat because the Institute of Medicine,

“...did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that FDA believes is sufficient to support the agency’s establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV, for *trans* fat.”

However, for this rulemaking process, FDA reversed its long-standing scientific criteria for proposing “added sugars” labeling and clearly stated it was deviating from,

“...factors traditionally considered for mandatory declaration that are related to chronic disease, health-related conditions, or health-related physiological endpoints linked to the particular nutrient.”

In FDA’s March 3, 2014, proposal to require “added sugars” labeling on the NFL, the Agency relied on general dietary guidance from the 2010 Dietary Guidelines for Americans (2010 DGA) that recommended Americans “reduce calories from solid fats and 'added sugars’” as its primary scientific justification for its proposal to require “added sugars” labeling. In its March 3, 2014, Proposed Rule, FDA classified the Dietary Guidelines for Americans as a consensus report.

Further, in its March 3, 2014, Proposed Rule, the Agency did not set a DRV for “added sugars” stating,

“...we have no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived,” 79 Fed. Reg. at 11906.

However, on July 27, 2015, FDA once again reversed a previous position, this time issuing Supplemental to now set a DRV for “added sugars.” The FDA did not reverse its decision regarding a DRV for “added sugars” based on new recommendations from the Institute of Medicine or other authoritative scientific bodies as required for meeting its 1993

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44 Federal Register, Vol. 68, No. 133, Friday, July 11, 2003  Rules and Regulations 41436
45 “We specifically consider recommendations from the 2010 DGA related to the intake of added sugars in the diet and the role of such information in assisting consumers to maintain healthy dietary practices.” Federal Register /Vol. 79, No. 41 /Monday, March 3, 2014 / Proposed Rules 11891
rulemaking standard of “sufficient scientific consensus.” Rather, the Agency provides the following in the Supplemental as its scientific basis for setting a DRV for “added sugars”:

“As results of our review of the science underlying the 2015 report, we are proposing to establish a DRV for added sugars and to require the percent DV declaration of added sugars on the Nutrition Facts and Supplement Facts labels.”46
(Emphasis added)

In doing so in this manner, FDA is bypassing its traditional reliance on the IOM to set Dietary Reference Intakes, which provide the scientific basis for the development of food guidelines in both the United States and Canada. IOM recommendations are based on thorough and systematic reviews of the scientific literature; a process that usually takes 2 to 3 years to complete by experts in the field of investigation.

Instead, FDA is relying on the 2015 DGAC report, a report that’s scientific evidence and process used to evaluate it is marred with controversy. This raises serious concerns about FDA’s decision to use such selective science as used by the 2015 DGAC to set a DRV. The DGAC’s efforts behind its evidence review to determine its 10% energy limit for “added sugars” were far from thorough. In addition to relying on few pre-existing reviews, it is concerning given this was an 18 month process, spanning June 2013 – December 2014, that the DGAC waited until September 2014 to form its Added Sugars Working Group. This gave the Committee a mere 90 days to collect, review, synthesize and formulate conclusions on the extensive body of literature on sugars, with no experts in carbohydrate metabolism on the 2015 DGAC.

We strongly contend that FDA’s reliance on the selective science of the 2015 DGAC, prior to its review, sign off by the Secretaries, and release of the official Dietary Guidelines, raises serious concerns that FDA’s actions in the rulemaking process for “added sugars” labeling are arbitrary and capricious. (Emphasis added)

It is critical to note that the DGAC report has not yet been sanctioned by the Secretaries of Health and Human Service and the U.S. Department of Agriculture, which are under Congressional mandate to ensure that the general dietary guidance for the American public in the Dietary Guidelines for Americans is based on the preponderance of scientific and medical knowledge at the time of the report. The Secretaries not only consider the recommendations in this advisory report to ensure the Dietary Guidelines are based on the preponderance of science and medical knowledge but also take into consideration public comment, a process that has not yet been completed.

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46 Federal Register, Vol 80 No. 143 July 27, 2015/Proposed Rule, 44304
The extraordinary contradictions and irregularities in this rulemaking process and the use of scientific evidence of such low evidentiary value to propose “added sugars” labeling and a DRV is unprecedented for the Food and Drug Administration. See Appendix 2

**Consumer Studies to Support FDA’s “Added Sugars” Labeling Proposal and Setting a DRV for “Added Sugars.”**

First and foremost, FDA did not conduct any consumer research to ensure that the addition of a percent DV for “added sugars” on the NFL will not confuse and mislead consumers.

Regarding FDA’s “Experimental Study on Consumers Response to Nutrition Facts Label with Declaration of Amount of Added Sugars,” the data provided by FDA from this study clearly shows consumer confusion regarding the Agency’s “added sugars” labeling proposal. Specifically, the study shows statistically significant findings for 1) consumers’ inability to accurately determine the amount of “Total Sugars” when “Added Sugars” are declared, and 2) consumers’ inability to identify more nutritious foods with higher amounts of “added sugars” when compared to less nutritious foods with lower amounts. Both of these findings indicate consumer confusion and the potential to undermine consumers’ efforts to maintain healthy dietary practices. See Appendix 3

Regarding the “Experimental study of proposed changes to the Nutrition Facts label formats (OMB No. 0910-0774),” in FDA’s memorandum, it clearly states in section E. Results:

> “Respondents were more accurate in identifying the grams of sugars per serving using the Current label compared to the Proposed or Alternative label and they were more accurate in identifying the grams of sugars per container using the Current label compared to the Proposed label.”

Table 3. in this memorandum shows that the “Sugars” designation on the NFL was the only nutrient, of all the nutrients tested on the NFL, i.e., calories, saturated fats, where the Proposed label format did not result in increased accuracy compared to the Current label format in assisting consumer in identify individual nutrient amounts per serving and per container- 81% accuracy for the Current label format and 65% accuracy for the Proposed label format.

The Food Drug and Cosmetic Act gives FDA the responsibility to ensure "labeling
is not false or misleading in any particular” however, FDA’s own consumer research shows that should FDA move forward with its “added sugars” labeling proposal it will mislead consumers.

**In conclusion:**

- FDA has provided no scientific evidence to dispute the fact that “added sugars” are physiologically equivalent to naturally occurring sugars or intrinsic sugars and that the body can tell the difference.

- FDA has provided no evidence of a specific health risks associated with consumption of “added sugars” over naturally occurring sugars or that consumption of “added sugars” results in unique health consequences for consumers health.

- FDA has provided no evidence to support mandatory “added sugars” labeling is necessary to ensure that consumers are not adequately informed about the product’s attributes under the current labeling category of “Sugars.”

- FDA has arbitrarily selected from general dietary guidance, science of low evidentiary value and selective reports to support its proposal for “added sugars” labeling and to set a DRV.

- FDA’s own consumer studies clearly show that consumers understand the current NFL category of “Sugars” and the inclusion of “added sugars” misleads consumers related to the amount of “Total Sugars” in a product and in choosing the more nutritious version of a product.

Therefore, FDA has not provided evidence that under section 403(q)(2)(A) of the act, sufficient scientific evidence of a compelling public health reason to modify the current “Sugars” category to include “added sugars” labeling and a set DRV for “added sugars.” The Agency has provided evidence that “added sugars” labeling is necessary “to assist consumers in maintaining healthy dietary practices.”

For the reasons outlined above, we ask FDA to withdraw its proposals to include “added sugars” on the NFL and to set a DRV for “added sugars.” Should FDA believe that “added sugars” labeling is important then the Agency should follow its standard of sufficient scientific agreement and ask the Institute of Medicine to do a thorough review of the full body of scientific evidence (at the highest level of evidence available) on “added sugars” intake.

We thank you for your consideration of this comment.
Sincerely,

Andrew C. Briscoe III

President

P. Courtney Gaine, PhD, RD

Vice President of Scientific Affairs
Appendix 1 Figure 1

Red and Processed meat intake (g/1000 kcal) for Healthy Dietary Patterns

- SUN
- SUN M
- SUN F
- EPIC SPAIN
- NHS, EPIC PAN F
- EVOO NUTS
- EPIC PAN M
- NHS, NIH, FOS
- HPFS WHITEHALL
- OMNI PRO, OMNI UNSAT
- OMNI CHO, DASH
- DASH/OMNI
- Predimed
- Med Diet Score
- Other score
- WHI
- SHANGHAI

Range of usual adult consumption in USDA Food Patterns
Dairy intake (g/1000 kcal) for Healthy Dietary Patterns

2015 DGAC: MEETING 6

Appendix 1 Figure 2
Appendix 1 Figure 3

Fruit intake (g/1000 kcal) for Healthy Dietary Patterns

2015 DGAC: MEETING

Range in USDA Food Patterns

Range of usual adult consumption
Seafood intake (g/1000 kcal) for Healthy Dietary Patterns

- DASH/OMNI
- Predimed
- Med Diet Score
- Other score
- Factor/cluster

Range of usual adult consumption

Range in USDA Food Patterns
Vegetable intake (g/1000 kcal) for Healthy Dietary Patterns

- **Cups/1000 kcal**
  - 300: OMNI UNSAT, NHS, HFFS
  - 275: OMNI PRO
  - 250: OMNI CHO
  - 225: SUN F, NHS
  - 200: DASH, EVOO NUTS
  - 175: SUN M, SUN EPIC PAN F, EPIC SPAIN
  - 150: WHI, SHANGHAI, POS, HPPS
  - 125: WHITEHALL
  - 100: EPIC POT F, EPIC POT M
  - 75: EPIC POT M
  - 50: EPIC POT F
  - 25: EPIC POT M
  - 0: EPIC POT M

- **Grains**
  - 1 cup: DASH/OMNI, Predimed, Med Diet Score
  - 1/2 cup: Other score, Factor/cluster

- **Range in USDA Food Patterns**
  - Range of usual adult consumption
Table D6.1. Added sugars available in the USDA Food Patterns (Healthy U.S.-Style, Healthy Mediterranean-Style, and Healthy Vegetarian Patterns) in calories, teaspoons, and percent of total calories per day*

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<td>(assuming 45% empty calories from added sugars and 55% from solid fat)</td>
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### Appendix 1 Table 2

Table 4-B-I-1 Comparison of Dietary Components across Diet Pattern Scores

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**Notes:**
- The table compares various dietary components across different diet patterns.
- Each component is scored on a scale of 0-9, with 9 being the highest score.
- The table includes categories such as Vegetables, Legumes, Fruits & Nuts, Cereals & Grains, Fish & Frozen Fish, and Total.
- Specific stars and arrows indicate the direction and magnitude of the association with outcomes of interest.
APPENDIX 2

October 13, 2015

Docket No. FDA 2012-N-1210
Revision of the Nutrition and Supplement Facts Labels;
Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions

The FDA’s Proposal to Create a Daily Reference Value for Added Sugars and Continued Efforts to Require the Disclosure of Added Sugars Content on the Nutrition Facts Label Violates the Food, Drug, and Cosmetic Act and the Administrative Procedure Act.

I. FDA’s proposal to create a Daily Reference Value for Added Sugars1 violates the FDCA.

A. The proposed rule is not supported by “sufficient scientific consensus.”

Section 2(b)(1)(A) of the Nutrition Labeling and Education Act (NLEA) instructed FDA to issue regulations ensuring that the nutrients required to be listed on the label by 21 U.S.C. §403(q)(1)(D) of the Food, Drug, and Cosmetic Act (FDCA) “be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.”2

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Congress stated that “in order to present nutrition information in a manner that facilitates the public’s understanding, the Secretary may choose among a variety of options. For example, one way this could be accomplished would be to include information about the recommended daily intake on the label.”

FDA chose, in 1993, to implement this requirement by establishing Daily Reference Values (DRV). Congress did not specify the level of scientific evidence needed by FDA to create DRVs, but the Agency itself did. FDA stated:

Several comments expressed concern that the DRV’s were based on insufficient or conflicting data, or that they lack sufficient scientific justification. FDA acknowledges that the role of nutrients and food components in reducing the risk of disease is in an evolving state. **However, numerous dietary reports and reviews relating to diet and health – particularly on the effect of diet on the risk of developing certain chronic diseases – have been published in the last decade.** These reports, including *Diet and Health* [published by the National Research Council of the National Academy of Sciences], *The Surgeon General’s Report on Nutrition and Health*, and *Dietary Guidelines for Americans*, represent a sufficient scientific consensus that justifies proceeding with the establishment of DRV’s. *This conclusion is supported by the [National Academy of Sciences] Institute of Medicine report entitled “Nutrition Labeling: Issues and Directions for the 1990s” . . . .*

When FDA set DRVs in 1993, it followed the “sufficient scientific consensus” standard. The Agency only minimally relied on the final U.S. Dietary Guidelines. Instead, FDA relied on a number of consensus reports that, taken together, constituted “sufficient scientific consensus,” the standard the Agency set for establishing DRVs. For example:

- In setting the DRV for potassium, FDA used major consensus reports, relying primarily on the National Academy of Science’s *Diet and Health* report. FDA specifically rejected the Dietary Guidelines for Americans as a credible source of information. FDA stated:

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5 *Id.* at 2224.
The Dietary Guidelines are intended to provide general food guidance and do not necessarily specify recommended intakes for individual nutrients.6

- In setting the DRV for Total Fat, FDA stated:

  the major available consensus documents, which were used by FDA in developing the DRV, consistently recommend 30 percent of calories or less from fat as an appropriate intake . . . .7

- In setting the DRV for fiber and citing the Office of the Surgeon General, the National Research Council of the National Academy of Sciences (NAS), and the National Cancer Institute, FDA stated:

  several scientific bodies have recommended increased intake of fiber . . . .8

The legislative history of the NLEA demonstrates that Congress emphasized the important role that the NAS should play in determining which nutrients should be declared on the Nutrition Facts label.9 In establishing DRVs, Congress intended FDA to rely on consensus reports published by the NAS’s National Research Council and Institute of Medicine. As FDA stated, taken together, such reports would constitute “sufficient scientific consensus” supporting the establishment of a DRV.10 Yet, here, with respect to added sugars, FDA abandons its own standard of “sufficient scientific consensus” without any explanation.

B. The proposed rule is not based on information recognized as “authoritative.”

Furthermore, the FDCA does not consider the Dietary Guidelines Advisory Committee (DGAC) Report to be “authoritative.”11 Under the Food and Drug Administration Modernization

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6 Id.

7 Id. at 2218.

8 Id. at 2222.


10 58 Fed. Reg. at 2217.

11 The 2010 version of the Dietary Guidelines for Americans states that it "has the potential to offer authoritative statements as a basis for health and nutrient content claims, as provided for in the Food and Drug Modernization Administration Act (FDAMA)” but makes no mention of the DGAC Report as a source of authoritative statements. U.S. Department of Health and Human Services, USDA, Dietary Guidelines for Americans, at 7 (2010).
Act (FDAMA).\textsuperscript{12} FDA can authorize health claims for foods based on “authoritative” statements from “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition . . . or the National Academy of Sciences or any of its subdivisions . . . .”\textsuperscript{13}

The law specifically recognizes the National Institutes of Health and the Centers for Disease Control and Prevention as federal government agencies identified as a “scientific body of the United States.”\textsuperscript{14} FDA has stated that other federal agencies, including the Office of Surgeon General, and the U.S. Department of Agriculture’s (USDA) Food and Nutrition Service, Food Safety Inspection Service, and Agricultural Research Service, may also qualify as appropriate sources for such authoritative statements.\textsuperscript{15} The DGAC Report is a report to the Secretaries of Agriculture and Health and Human Services that has no official status.

C. Added Sugars is not an additional nutrient that FDA can add to the Nutrition Facts Label.

Under the FDCA, FDA can add additional nutrients to the Nutrition Facts label to “assist consumers in maintaining healthy dietary practices . . . .”\textsuperscript{16} The FDCA specifies a list of substances considered nutrients. Each of the substances is chemically distinct and has different physiological effects on the body. In contrast, “added sugars” are chemically identical to natural sugars already listed on the label. Thus, the term “additional nutrients” as used by Congress in the statute was meant to refer to substances that are chemically different from one another. FDA concedes that “added sugars” are not chemically distinct from naturally occurring sugars.\textsuperscript{17} In brief, “added sugars” is not a nutrient that FDA can add to the Nutrition Facts label under the authority granted to it by Congress. A regulation may be overturned if it does not bear a reasonable relationship to the statute.”\textsuperscript{18}

\textsuperscript{12} Sections 303 and 304 of the Food and Drug Modernization Act amended sections 403(r)(2)-(3) of the FDCA, 21 U.S.C. §§ 343(r)(2)-(3)), permitting food companies to use health claims on food labels if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the NAS.


\textsuperscript{14} Id.


\textsuperscript{17} 79 Fed. Reg. 11,880, 11,906 (Mar. 3, 2014).

D. The proposed rule, if finalized, would violate both the FDCA and the APA.

The legislative history of the NLEA shows that Congress emphasized the important role that the NAS should play in determining which nutrients should be declared on the Nutrition Facts label. The House Committee Report urged FDA to rely particularly on an NAS report on nutrition labeling, underway at the time of the passage of the NLEA, when proposing what nutrients should be listed on the label. Here, instead of relying on the NAS, FDA chose to rely only on DGAC’s non-authoritative report to justify establishing a DRV for added sugars.

The courts have held that such inconsistencies in Agency reasoning are impermissible and render Agency actions arbitrary and capricious. As the Supreme Court stated, “applying a rule of primary conduct . . . which is in fact different than the rule or standard formally announced,” is the epitome of failing to engage in reasoned decision making.

Further, it is well settled under the APA that a court may invalidate a regulation if the Agency has failed to explain adequately the basis for a change in policy. Unexplained decisions receive no deference from the courts and a change in policy made with no explanation in the administrative record is arbitrary and will be reversed.

Here, FDA has provided no explanation whatsoever as to why the Agency chose to depart from basing a new DRV on “sufficient scientific consensus” and instead chose to rely on a single non-authoritative DGAC Report. Thus, the Agency’s proposal to establish a DRV for added sugars, if finalized, would be reversed as a violation of the APA.

II. FDA relied on portions of the DGAC Report not directly related to added sugars consumption and cardiovascular disease (CVD) while ignoring portions of the DGAC Report specifically pertaining to the relationship between added sugars and the most common form of CVD, in violation of the APA.

Even assuming the DGAC Report meets FDA’s standard of “sufficient scientific consensus” – which it does not – the Agency relied on selective portions of the DGAC Report only tangentially related to added sugars consumption and CVD while ignoring portions of the DGAC specifically pertaining to the consumption of added sugars and the most common form of CVD.

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20 Allentown Mack Sales & Serv., Inc. v. N.L.R.B., 522 U.S. 359, 374-75 (1998) (agency may change its interpretation of a statute only if it provides a reasoned basis for doing so and applies its new interpretation consistently).


22 Yakima Valley Cablevision, Inc. v. F.C.C., 794 F.2d 737, 745-47 (D.C. Cir. 1986); Humane Soc. of U.S. v. Locke, 626 F.3d 1040, 1047 (9th Cir. 2010).
Such action is arbitrary and capricious, and constitutes an abuse of discretion in violation of the APA.\textsuperscript{23}

In an effort to justify the proposed DRV for added sugars, FDA relies on Part D. Chapter 2 of the DGAC Report entitled “Dietary Patterns, Foods and Nutrients and Health Outcomes.” The Agency claims that Chapter 2 of the DGAC report supports FDA’s proposal to establish a DRV for added sugars because it states, in the Agency’s own words, that “there is evidence of a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD.”\textsuperscript{24} However, what Part D. Chapter 2 of the DGAC report actually says is:

\begin{quote}
strong and consistent evidence demonstrates that dietary patterns associated with decreased risk of CVD are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages . . . .\textsuperscript{25}
\end{quote}

The portion of the DGAC report that FDA cites to justify the establishment of a DRV for added sugars thus did not focus specifically on scientific evidence related to the relationship between added sugars and CVD, but rather on a combination of nine dietary factors and eating patterns, which taken as a whole constitute “strong” evidence. Added sugars is but one of many dietary factors cited as contributing to CVD risk.

In a blatant abuse of discretion, FDA’s Federal Register notice ignores the portion of the DGAC report that specifically focuses on scientific studies pertaining to the relationship between added sugars consumption and CVD. That information, found in Part D. Chapter 6 of the DGAC Report, states:

\begin{quote}
Moderate evidence from prospective cohort studies indicates that higher intake of added sugars, especially in the form of sugar-sweetened beverages, is consistently associated with increased risk of hypertension, stroke, and CHD\textsuperscript{26} in adults. Observational and intervention studies indicate a consistent relationship between
\end{quote}

\textsuperscript{23} 5 U.S.C. § 706(2).

\textsuperscript{24} 80 Fed. Reg. at 44,308.


\textsuperscript{26} CHD is the most common form of CVD.
higher added sugars intake and higher blood pressure and serum triglycerides. *DGAC Grade: Moderate.*\(^{27}\)

USDA’s Nutrition Evidence Library has developed official definitions of “Strong,” “Moderate,” and “Limited” ratings used by the DGAC to characterize the relationship of specific nutrients to diet-related disease.\(^{28}\) The “Moderate” rating that DGAC gave to characterize the evidence pertaining to the consumption of added sugars and CVD is described by USDA as including:

- “studies of weaker study design for question,”
- studies containing “doubts about adequacy of sample size,”
- studies demonstrating “inconsistency in results in direction and size of effect, degree of association, or statistical significance,” and
- studies with “[s]ome doubt about the clinical significance of the effect.”\(^{29}\)

Such evidence is far afield from the type of consensus findings Congress intended FDA to use to establish DRVs.

Further, contrary to FDA’s purported justification for its proposed DRV,\(^{30}\) the evidence specifically pertaining to added sugars and CHD (the most common form of CVD) reviewed by DGAC is not “Strong.” Rather, the DGAC Report characterizes the evidence as only “Moderate.” The preamble to FDA’s supplemental proposed rule disingenuously implies otherwise and FDA’s effort to mischaracterize a “Moderate” finding in the DGAC Report as a “Strong” finding is arbitrary and capricious, and an abuse of discretion in violation of the APA.

III. FDA has repeatedly changed its position on the nutritional significance of added sugars over the past few years, undermining any claim of judicial deference to the Agency’s scientific judgment.

FDA has had a difficult time attempting to justify why added sugars should be disclosed on the Nutrition Facts Label (with or without a % DV). In 2011, the Agency stated in the *Federal Register:*

\(^{27}\) DGAC Report, Part D. Ch. 6, at 20.


\(^{29}\) Id.

\(^{30}\) 80 Fed. Reg. at 44,308.
This new requirement [added sugars content disclosure on the Nutrition Facts label] would be the first time that the mandatory declaration of a nutrient is shown in this format on the Nutrition Facts label. Because added sugars have been linked to obesity, a significant public health problem in the country [references omitted], it is important that this new requirement is supported by evidence so that consumers can correctly use the information.31

In 2014, when the Agency proposed a regulation to disclose added sugars on the Nutrition Facts label, the Agency flip-flopped and concluded:

U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.32

FDA claimed instead that the disclosure was important to inform consumers about the nutrient density of various foods.33

In 2015, the Agency changed direction yet again, and based on the DGAC Report, found “Strong” evidence that added sugars consumption and CVD are linked, relying on portions of the Report dealing with general dietary patterns.”34 However, as noted above, FDA ignored the specific portion of the DGAC Report pertaining to the relationship between consumption of added sugars and CHD. That portion of the DGAC Report characterized such evidence as only “Moderate.”35

The Supreme Court has made clear that a court may overturn a regulation if the asserted factual basis does not withstand scrutiny.36 In this case, FDA first claimed in 2011 that its Nutrition Facts label regulation should be changed because added sugars were related to obesity. Then in 2014, the Agency reversed itself and said that its Nutrition Facts regulations should be changed because the disclosure of added sugars should be required to help consumers choose more nutrient dense foods. The Agency discounted any relationship between added sugars consumption

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32 79 Fed. Reg. at 11,904 (emphasis added).

33 Id.


35 DGAC Report, Part D., Ch. 6, at 20.

and CVD. Then, in a third reversal in 2015, the Agency changed its mind again and said label disclosure was necessary because added sugar consumption and CVD were associated. However, FDA ignored the most relevant chapter of the DGAC Report that directly pertained to the relationship between added sugars consumption and CHD, the most common form of CVD, which found only a “Moderate,” not “Strong,” association as the Agency implies in its Federal Register notice.

An Agency change in policy will be overthrown if based on supporting data that is mixed and inconclusive. The Agency must rely on something more than inconclusive data if the Agency changes direction. The Agency’s latest flip-flop was based on evidence characterized by the DGAC as “moderate.” Such evidence, in a single, non-authoritative report that does not meet the Agency’s only standard of “significant scientific consensus,” plainly fails to provide the requisite “factual basis” required for a policy change by the Supreme Court in State Farm.

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The Results of FDA’s Experimental Study on Consumer Response to Nutrition Facts Labels with Declaration of Amount of Added Sugars Demonstrates That Such Disclosures Would be Misleading to Consumers in Violation of the FDCA and the APA.

I. FDA’s own consumer survey study shows that Added Sugars labeling would mislead substantial numbers of consumers.

FDA initiated efforts with OMB to conduct research on how consumers would interpret an added sugars disclosure on the NFP in 2011, but OMB did not give the Agency permission to proceed with the study, until after\(^1\) FDA already proposed a regulation mandating the requirement.\(^2\)

After the study was finally completed, FDA initially denied the public an opportunity to review or comment on the results. Apparently, FDA was disappointed with the results of its study that


demonstrated that substantial numbers of consumers would be confused and misled by an added sugars disclosure in at least two major ways. Under public pressure, the Agency just recently opened the study results to public comment and released the raw data. However, the comment period has been running for some time, leaving stakeholders with inadequate time to fully analyze the data and complete their own research.

A. The FDA study showed that an added sugars disclosure would lead substantial numbers of consumers to miscalculate the total sugar content of a food.

An FDA Memorandum summarizing its study states:

The study showed that while added sugars declarations increased the ability of some participants to identify those products with less added sugars, and to determine the quantity of added sugars in a food, the declarations decreased the ability of some participants to correctly identify the quantity of total sugars in a food.4

Table 3 in the FDA Memorandum referred to by the Agency as Reference 1 in its Federal Register notice above reveals that substantial numbers of consumers are indeed misled by the proposed disclosure.

- According to Table 3, 24% of consumers gave an incorrect or “Don’t know” answer to the question “What is the total amount of sugars in one serving of this product?” when the terms “Added sugars” and “Total sugars” were disclosed on the label.

- Further, 35% of consumers gave an incorrect or “Don’t know” answer to the question “What is the total amount of sugars in one serving of this product?” when simply the term “Added sugars” was disclosed on the label along with the term “Sugars.”

- When added sugars declarations appeared on the test labels, the incorrect answer that was most frequently observed was an amount equal to the sum of the product’s total sugars and added sugars. This means that consumers would grossly overestimate their consumption of total sugars, which is not only misleading for the public but could have detrimental consequences for diabetics.5

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4 See FDA Memorandum to the File, at 1, 11 T. 3a – Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB Control No. 0910-0764) (emphasis added) (cited in 80 Fed. Reg. at 44,311, ref. 1).

5 Id.
B. FDA’s study found that consumers shown nutritious foods with added sugars labeling misidentify them as less healthy than foods lower in nutritional value but containing less added sugars.

The FDA Memorandum summarizing the consumer study states:

Results showed the when the more nutritious (i.e. lower-calorie, lower-fat, higher-fiber, and higher-vitamin) product had less added sugars, label format had no statistically significant effect on the likelihood of respondents identifying that product as healthier [parenthetical omitted]. In contrast, when the more nutritious product had more added sugars, the percentage of respondents identifying that product as healthier decreased.6

This perverse result hardly helps the Agency achieve its statutory mandate to “assist consumers in maintaining healthy dietary practices . . . .”7

Thus, Reference 1 to the Agency’s Federal Register notice – FDA’s own Memorandum summarizing the results of the Agency’s consumer study – demonstrates that an added sugars disclosure leads to a significant number of consumers unable to identify the total sugars content of a food. Even more importantly, consumers chose less nutritious foods over more nutritious foods merely because the more nutritious foods contained added sugars.

C. The high proportion of consumers misled by FDA’s Proposed Regulation would violate the FDCA.

The proposed rule would, in effect, mandate label statements that are misleading under federal law, thus constituting a violation of section 403(a)(1) of the FDCA.8 The high percentage of consumers misled by the Agency’s proposed rule to disclose “added sugars” content, with or without “total” sugars content, is sufficient to consider such labeling misleading under both section 5 of the Federal Trade Commission (FTC) Act9, and section 43(a) of the Lanham Act.10

The Eighth Circuit Court of Appeals upheld an FTC holding that a claim is misleading if as little as 14% of consumers surveyed are misled.11 Here, the percentages of consumers misled

6 Id. at 17 (emphasis added).


would be, according to FDA’s own study, 24% to 35% depending on how the disclosure would be formatted.

The Third Circuit came to a similar conclusion in an advertising case brought under the Lanham Act. In Johnson & Johnson-Merck Consumer Pharmaceuticals Company, V. Rhone-Poulenc Rorer Pharmaceuticals, Inc., with regard to what constitutes a substantial or significant number of consumers who are misled, the court recognized significant federal precedent suggesting that 20% would be sufficient. 19 F.3d 125 (3rd Cir. 1994) (citing R.J. Reynolds Tobacco Co. v. Loew’s Theatres, Inc., 511 F. Supp. 867, 876 (S.D.N.Y. 1980) (“deception rate” of between 20% and 33% sufficient to warrant preliminary injunctive relief); McNeilab Inc. v. American Home Products Corp., 501 F. Supp. 517, 527 (S.D.N.Y. 1980) (23% not insubstantial number of consumers); Stiffel Co. v. Westwood Lighting Group, 658 F. Supp. 1103, 1114 (D.N.J. 1987) (potential that between 22% and 57% of consumers will be misled is not insubstantial)).

FDA’s own study shows that between 24% and 35% of consumers would be misled by the proposed disclosure requirement. Such label statements, if made by a commercial entity, would be actionable under the FTC Act and the Lanham Act.

Accordingly, the proposed disclosure requirement would violate the FDCA because based on the results of FDA’s own study, the disclosure of added sugars content information would be “misleading” to substantial numbers of consumers and prohibited by Section 403(a)(1) of FDCA.

Although agencies are entitled to rely on their own expertise, in this case, FDA recognized that a consumer research study was essential because there was a complete dearth of research on the issue:

[t]he Agency is not aware of any existing consumer research that has examined this topic and is therefore interested in pursuing this study to enhance its understanding of how consumers might currently perceive and use the new information if it is presented on the Nutrition Facts label.12

FDA thus proposed to conduct a consumer study on how consumers would interpret a Nutrition Facts label that included added sugars content. The results did not turn out as the Agency had planned. Now, the Agency is claiming only limited reliance on its consumer research study.13 However, whether FDA claims to be relying on it or not, the Agency’s study demonstrates that the

D. FDA’s promise to conduct a consumer education program does not render the proposed misleading label disclosure valid.

The only explanation FDA offers in defense of its proposed confusing label disclosure is that it recognizes that the Agency must conduct a consumer education program to help the substantial number of consumers that would be misled by the disclosure. That explanation, however, is insufficient because the Agency admits elsewhere in its Federal Register notices that consumer education in this area has been ineffective.

In its Federal Register notice proposing to require added sugars labeling on the Nutrition Facts label, FDA states, “[c]onsumer research data suggest that, despite the widespread use of food labels, certain elements of the Nutrition Facts label may need improvement. For example, some consumers have difficulty understanding the concept of percent DV . . . .”

Reference 43 cited by the Agency is: Levy Patterson Kristal Li, “How well do consumers understand percentage DV on labels,” AJPH (2000), and involved a study conducted after 10 years of consumer education by the Agency. The study states:

“Abstract: One hundred four adults completed a multiple choice food label comprehension questionnaire and a food frequency questionnaire . . . only 29% correctly selected the definition of % daily value for fat (%DV), as “percent of the maximum daily recommended amount of fat.”

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16 Almay, Inc. v. Califano, 569 F.2d 674 (D.C. Cir. 1977). (Involving used of discredited study by second agency).
17 St. James Hosp. v. Heckler, 760 F.2d 1460, 1468 (7th Cir. 1985).
19 Id. (citing ref. 43 to the Notice of Proposed Rulemaking).
The primary Reference that FDA relies on in its Federal Register notice thus demonstrates that consumer education programs are ineffective and would not prevent substantial numbers of consumers from being misled by a %DV for added sugars.

Similarly, when FDA made a 2011 request to OMB to conduct consumer research on declaration of added sugars, the Agency stated, “consumers’ understanding and use of Percent Daily Value may be somewhat inconsistent [Ref. 7].” The Journal of the Academy of Marketing Science reference cited by FDA states:

As a means of enhancing consumer understanding of nutritional information, the Nutrition Labeling and Education Act of 1990 requires the provision of percentage daily values (%DVs) on food labels. Findings from existing research, however, vary in their support for the assumption that including %DVs will assist consumers in their efforts to comprehend nutritional information.

To summarize, whereas FDA-sponsored research has supported the desirability of including %DVs for certain nutritional tasks, neither it nor other research (the single exception being Suter and Burton's [1996] investigation that is discussed subsequently) has indicated that %DVs can help consumers to better evaluate a product's healthiness. In the best case, a label containing %DVs enabled consumers to make discriminating nutritional judgments, although no more so than when using the old label (i.e., the new label did not produce a significant improvement). In the worst case, the %DVs label actually impaired judgmental accuracy. At this point, then, questions remain about the effectiveness of such reference information.

[T]he limited literature that speaks to whether greater knowledge facilitates the effectiveness of including reference information on a nutritional label sends conflicting messages. Evidence reported by two of the three investigations is unsupportive. Moreover, in the

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21 76 Fed. Reg. at 81,948.


23 Id. at 426.
research observing supportive effects, it is unclear whether its results are due to ability or motivational influences.24

This Reference, relied on by FDA itself in its Federal Register notice, shows that substantial numbers of consumers do not understand %DV. In order to put this finding into context – the Agency had been conducting significant consumer education efforts for more than a decade at the time the study was published. Moreover, the study finds that motivation, not knowledge, persuades consumers to try to understand the %DV.

Although the study concludes that certain intensive forms of consumer education may work under certain circumstances, it concedes that:

the rather extensive set of materials and training provided to our participants might not parallel the educational programs that public policy makers may implement in the marketplace. . . Further research will be necessary for determining the type of education programs that would be feasible and effective in the real world.25

The studies cited by FDA itself in its Federal Register notice show that despite years of consumer education efforts by the Agency, substantial numbers of consumers do not understand %DV. Further, the studies cited by FDA in the Federal Register demonstrate that any realistic consumer education program the Agency might conduct would be as ineffective as its previous efforts.

Failure of an Agency to respond regarding flaws or reasonably obvious alternatives justifies reversal by the courts. In Lloyd Noland Hosp. and Clinic v. Hecker26, the Agency said that since the pre-rule stage, there had been no study at all, that a flawed study was still somewhat of a basis for a new rule. The court found that while nothing had required the Agency to rely on a study, when it changed a rule, as is being proposed here, it must have a reasoned analysis for the change to avoid being found in violation of the APA.

In sum, the results of FDA’s own consumer study demonstrate that substantial numbers of consumers would be misled by an added sugars disclosure. The Agency did not even bother to study consumer comprehension of a %DV for added sugars, but studies cited by the Agency show that it too would be misleading.

The proposed rules thus violate the FDCA. Further, the Agency’s attempt to explain away the results of its own research by promising a consumer education program when the Agency itself

24 Id. at 427.
25 Id. at 435.
26 762 F.2d 1561 (11th Cir. 1985).
cites references in its *Federal Register* notice demonstrating that consumer education programs don’t work, hardly constitutes reasoned decision-making as required by the APA. A court would therefore void the rule, if finalized as proposed.