1300 L Street NW, Suite 1001
Washington, DC 20005
(202) 785-1122

May 7, 2015

The Honorable Sylvia M. Burwell
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

The Honorable Thomas J. Vilsack
Secretary of Agriculture
1400 Independence Avenue, SW
Whitten Building, Room 200A
Washington DC, 20250

Dear Secretaries Burwell and Vilsack:

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 [1] [2] [3] [4] 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.

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[1] National Nutrition Monitoring and Related Research Act of 1990, Public Law 445, 101st Congress, 2nd session (October 22, 1990). Public Law 101-445, section 301.
[2] Office of Management and Budget. Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies; republication. Federal Register 67(36): 8452 – 8460. Friday, February 22, 2002. Available at http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf.
[3] U.S. Department of Health and Human Services. HHS Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies. Last HHS revision: Available at http://aspe.hhs.gov/infoQuality/index.shtml
[4] Improving Regulation and Regulatory Review, Executive Order 13563 of January 18, 2011, Federal Register 76(14) Friday, January 21, 2011.

This comment reflects our position on sugar/sucrose. Of note, the Association has long been on the record objecting to the use of the term "added sugars" as misleading and without scientific justification.

The Association has participated in the Dietary Guidelines process since its inception and appreciates the hard work of Dietary Guidelines Advisory Committees and Federal staff to provide an advisory report to the Secretaries of Health and Human Services and the U.S. Department of Agriculture (Secretaries) every five years. We support past Dietary Guidelines' recommendations to reduce certain foods and beverages containing "added sugars" to within caloric needs. However, for the 2015 process, the Dietary Guidelines Advisory Committee (2015 DGAC) has taken "added sugars" recommendations to unchartered territory, thus raising serious concerns about the manner by which these recommendations were derived.

We emphasize that Congress in its wisdom understood that the American public is best served by dietary guidance that is based on a robust evaluation of the totality of scientific evidence. Section 301 of Public Law 101-445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) clearly mandates that the nutrition and dietary guidance in the Dietary Guidelines for Americans (DGAs) is based solely on the preponderance of science and medical knowledge current at the time of publication. The Association strongly contends that the recommendations on "added sugars" put forth in the 2015 DGAC report do not meet these important scientific standards.

The mandate of the Dietary Guidelines is to provide general dietary guidance for the American public. We contend that the 2015 DGAC has not undertaken the rigorous scientific investigation necessary to conclude links or associations between "added sugars" and serious disease outcomes. Recommendations that lead the American public to believe any dietary component is a causal factor in a serious disease outcome should only be made based on significant scientific agreement due to a robust review of the entire body of scientific literature by experts in the field of investigation. Such scientific agreement does not exist for the 2015 DGAC "added sugars" recommendations.

Therefore, we ask that the Secretaries maintain the 2010 Dietary Guidelines advice on "added sugars" and offer this comment to support this request.

We address the following issues in this comment:

- **The integrity of the 2015 DGAC scientific process is in question, for the following reasons:**

- ***There was a lack of fair dealing with interested parties in the 2015 DGAC process***
- ***The 2015 DGAC bypassed the established Nutrition Evidence Library (NEL) review process and, instead, subjectively selected previously published systematic reviews, raising red flags of selection bias***
- ***The 2015 DGAC conclusions contradict major, authoritative, evidence-based reviews on "added sugars" intake and health outcomes***
- ***The 2015 DGAC's reliance on pre-existing systematic reviews undermines what should be a scientifically rigorous DGA process***
- ***There was a lack of transparency in how pre-existing systematic reviews were selected***

- **The 2015 DGAC used an abundance of poor-quality evidence to form conclusions, for example:**
  - ***A systematic review is only as strong as the studies it contains***
  - ***There was a heavy reliance on observational data to inform conclusions***
  - ***The use of observational data of "sugar-sweetened beverage" (SSB) consumption is an inappropriate surrogate/proxy for making conclusions about "added sugars" intake and health outcomes***
  - ***The 2015 DGAC's "strong" conclusions linking "added sugars" to health outcomes is overstated, given the lack of rigorous and consistent data***
- **Specific points are made below regarding the lack of objectivity by the 2015 DGAC in its overlooking of the flaws and limitations of the science used to support recommendations on "added sugars"**
  - ***"Added sugars" and obesity***
  - ***"Added sugars" and type 2 diabetes***
  - ***"Added sugars" and cardiovascular disease***
  - ***"Added sugars" and dental caries***
- **The 2015 DGAC provided no credible science-based evidence to support its recommendation to reduce "added sugars" intake to below 10 percent of total energy intake**
  - ***Calories are the real issue***
  - ***Calories from "added sugars" are not a major contributing factor in increased caloric intakes or obesity***
  - ***Food pattern modeling does not have the scientific underpinning to support "added sugars" intake recommendations***

- **The 2015 DGAC aligning with the controversial World Health Organization's (WHO) Guideline on Sugars is a step back for U.S. standards of evidence**
- **The use of hypothesis-based dietary pattern studies to link or associate dietary components with serious disease outcomes or set intake recommendations is not a validated scientific methodology**
- **There are unintended consequences of the 2015 DGAC recommendations to reduce "added sugars" intake to historically low levels**
- **The 2015 DGAC "Added Sugars" policy recommendations went far beyond the Congressional mandate and DGAC Charter with no evidence-based support**
- **USDA has undue influence on the DGAC processes relating to its role in food patterns modeling.**

The integrity of the 2015 DGAC scientific process is in question

There was a lack of fair dealing with interested parties in the 2015 DGAC process

Sugars guidance has appeared in every version of the Dietary Guidelines and the potential relationship between "added sugars" intake and health outcomes has been a source of conflicting opinions among nutrition academics for years. So, we must ask, how is it that "added sugars" were not addressed earlier in the process? Nutrition Evidence Library (NEL) questions should have been formulated early in this process with reviews conducted on the full body of scientific literature on "added sugars" to ensure recommendations on this increasingly important topic are grounded in an extensive review of the totality of high-quality scientific evidence. Instead, the DGAC waited until the very end of the process, September 2014, to announce the creation of an Added Sugars Working Group. The 2015 DGAC process ended on December 15, 2014; **this three-month timeframe was certainly not long enough to adequately evaluate this important and large body of research**, or to allow sufficient time for interested parties to respond to the Committee's conclusions.

The fact that this important topic was not given sufficient deference in this process raises serious concerns not only about fair dealing, but also the motivation of this Committee to fast-track this issue.

The 2015 DGAC bypassed the established NEL review process and, instead, subjectively selected previously published systematic reviews, raising red flags of selection bias

The 2015 Dietary Guidelines Advisory Committee Charter states:

> "The USDA Nutrition Evidence Library will assist the Committee in conducting and creating a *transparent* database of systematic reviews reflecting the *most current research* available on a wide range of food and nutrition-related topics to inform its recommendations." [Emphasis added]

Yet, for three out of four of the "added sugars" research questions, the DGAC ***bypassed*** the NEL process entirely.

Establishment of the NEL was a critical step in assuring that the DGAs are based *solely* on the preponderance of scientific evidence, through the process' ability to reduce bias, increase transparency and help ensure that all literature is considered. When properly employed, the NEL process yields evidence-based conclusions through a series of well-defined and pre-determined steps. The consistent use of NEL reviews across *all* research topics would have provided interested parties reasonable assurance that all subject areas were given the same consistent and unbiased consideration.

Instead, the Working Group bypassed the established NEL review process to inform its "added sugars" recommendations and almost solely used pre-existing and hand-picked systematic reviews. This raises serious concerns that *the Committee bypassed a review of the full body of science and instead* ***selected science to support its pre-determined conclusions****.*

We question the DGAC's citing of a "short duration of time" and "limited resources" as an adequate explanation for why the Added Sugars Working Group conducted only *one* NEL review to inform its four conclusions on "added sugars," despite the known importance of the NEL process to the integrity of the DGAs.

The 2015 DGAC conclusions contradict major, authoritative, evidence-based reviews on "added sugars" intake and health outcomes

Bypassing the NEL process is of concern, particularly when doing so ultimately leads to conclusions for "added sugars" that ***contradict*** major evidence-based reviews by authoritative scientific bodies, including the Institute of Medicine (2002)(IOM)[5], the European Food Safety Authority (2010) (EFSA)[6], the U.K.'s Scientific Advisory Committee draft Carbohydrate and Health report (2014)(SACN)[7] and also contradict the advice in position statements of the American Diabetes Association (2014), [8] American Dental

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[5] Food & Nutrition Bd., Nat'l Acad. of Sciences, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (2002)

[6] EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA). Scientific opinion dietary reference values for carbohydrates and dietary fibre (2010). *EFSA Journal* **8(3):** 1462 [77 pp]. Available at http://www.efsa.europa.eu/en/scdocs/scdoc/1462.htm.

[7] Scientific Advisory Committee on Nutrition (SACN), Draft Carbohydrates and Health Report. June 2014. (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/339771/Draft_SACN_Carbohydrates_and_Health_report_consultation.pdf)

[8] Evert AB, et al. Nutrition therapy recommendations for the management of adults with diabetes. Diabetes Care. 2014 Jan;37 Suppl 1:S120-43

Association (2001),[9] and the American Heart Association/American Stroke Association (2014).[10]

The 2015 DGAC recommendations also differ dramatically from the conclusions of the 2010 DGAC NEL reviews [11] and contradict the advice in the 2010 Dietary Guidelines relating to "added sugars" calories not being a direct contributor to obesity, heart disease as well as its science-based advice on dental caries.

- The 2010 DGAC Carbohydrate Subcommittee identified carbohydrates as consisting of sugars, starches and fibers. The Carbohydrate Subcommittee, following the NEL review of the impact of carbohydrates on heart disease, type 2 diabetes, body weight and dental caries, stated this finding "no detrimental effects of carbohydrates as a source of calories on these or other health outcomes were reported."[12] (2010 DGAC advisory report)
- 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. [13] (2010 DGAs)

The conclusions of the 2015 DGAC contradict major evidence-based reviews on "added sugars" intake; therefore, they are already proven to *lack reproducibility.* The fact that the conclusions from the 2015 DGAC contradict all of these other major reviews is foregone proof that external, previously published systematic reviews are too subjective to be used as the sole basis for dietary guidance and recommendations.

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[9] Burt BA, Pai S. Sugar consumption and caries risk: a systematic review. J Dent Edu. 2001;65(10):1017-23

[10] Meschia JF, et al. Guidelines for the primary prevention of stroke: a statement for healthcare professionals from the american heart association/american stroke association. Stroke. 2014 Dec;45(12):3754-832.

[11] "The role of carbohydrates in the diet has been the source of much public and scientific interest. These include the relationship of carbohydrates with health outcomes, including coronary heart disease (CHD), type 2 diabetes (T2D), body weight, and dental caries. The 2010 DGAC conducted Nutrition Evidence Library (NEL) evidence reviews on these and other carbohydrate-related topics. The Committee also relied on evidence contained in the 2002 Dietary Reference Intakes (DRIs) report and conducted a non-NEL review of recent literature to specifically examine the relationship of carbohydrates with CHD, T2D, behavior, and cognitive performance (Colditz, 1992; Dolan, 2010; IOM, 2002; Laville, 2009; Meyer, 2000; Stanhope, 2009; Wolraich, 1995). No detrimental effects of carbohydrates as a source of calories on these or other health outcomes were reported." Dietary Guidelines Advisory Committee. 2010. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

[12] *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010 To the Secretary of Agriculture and the Secretary of Health and Human Services* May 2010 pg. 286

[13] U.S Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans 2010, 7th Edition, Washington DC: U.S. Government Printing Office, December 2010 pg. 28

The 2015 DGAC's reliance on pre-existing systematic reviews undermines what should be a scientifically rigorous DGA process

There is considerable difference between the Committee subjectively selecting pre-existing systematic reviews versus relying on existing reports that are the result of a thorough evidence-based review of the full body of literature by authoritative scientific bodies, and conducted by panels that are experts in the field of investigation (i.e. the *2008 Physical Activity Guidelines for Americans).*

While systematic reviews are valuable tools in synthesizing a body of research, they are subject to multiple biases and methodological decisions of the authors; thus, systematic reviews often contradict each other even when examining the same research question.[14] So, when the NEL process is bypassed, and pre-existing reviews are selected, this means that the Committee is basing conclusions that utilize questions, search criteria, study quality, and evaluations that were determined not by the DGAC and the standardized NEL review process, but by those reports' authors. This eliminates the possibility of a review of the total body of evidence from the start, as the authors of these reviews have made study inclusion decisions for the DGAC. As it follows, this means lesser quality studies may be included and studies of high-quality containing important evidence can be left out. As such, it is widely known in the scientific community that the findings of meta-analyses differ based on the approach used by the researchers. However, when the NEL systematic review process is employed, *it is the DGAC who debates and develops the research question* and then determines these important criteria that go into the evidence-based conclusion.

Of additional concern is that in many cases the processes employed in these pre-existing reviews don't share the same rigorous scientific principles and protocols outlined in the NEL review process. As mentioned above, when using pre-existing reviews, important study inclusion determinations, such as grading of study quality and the dates of the studies to be included, are out of the DGAC's control to determine. For example, in examining the reviews used by the Added Sugars Working Group, there is significant variation with regard to study selection criteria. Using study date as an example, there are inconsistencies across the health outcomes examined with regard to the timeframe of studies included in these reviews, with studies from 1969 to present (body weight), 1950 to present (dental caries) and 1990 to present (diabetes) used to form the respective conclusions. Over time, diets change, populations change and methodologies improve; this *lack of consistency* in evidence selected by the DGAC *is* an issue.

Supporting our concerns about the 2015 DGAC's heavy reliance on prior reviews are many recently published papers that raise issues about use of systematic reviews in evidence-

[14] Berlin JS. "Meta-analysis as Evidence Building A Better Pyramid." JAMA. August 2014. Vol. 312 (6)

based dietary recommendations given the biases and errors inherent to conducting this type of analyses.[15] [16] [17] [18]

There was a lack of transparency in how pre-existing systematic reviews were selected

We question the transparency of some of the Added Sugars Working Group's decision-making. Given that the NEL was bypassed, leaving a non-existent protocol for evidence selection, it remains unclear *how* the existing reviews were selected and how and why other studies and reviews were excluded. This is of particular concern since the Working Group identified systematic reviews that were later seemingly dismissed if their conclusions contradicted the ultimate recommendations. Throughout the process, the Working Group considered a total of four systematic reviews to address body weight, at least that the public was made aware of. The two reviews that findings differed from the Working Group's conclusion on body weight were thrown out with minimal or no explanation as to why. Below are the conclusions from the two reports that were dismissed:

> "No intervention studies were identified from which scientific conclusions could be drawn about the relationship between SSB intake and BMI or risk of obesity. The evidence for an association between SSB intake and obesity risk, when adjustment for energy and physical activity was performed, was ***inconsistent*** for children, adolescents, and adults." [19]
>
> "Our updated meta-analysis shows that the currently available randomized evidence for the effects of reducing SSB intake on obesity is equivocal." [20]

This is an example of the subjectivity used by the 2015 DGAC in choosing science to support its conclusions, and demonstrates the lack of transparency in evidence selection.

The 2015 DGAC used an abundance of poor-quality evidence to form conclusions

A systematic review is only as strong as the studies it contains

Not all systematic reviews, even if peer-reviewed and published, are of high quality. It is well established in the scientific literature that a high quality meta-analysis requires a

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[15] Kicinski, M. "Publication Bias in Recent Meta-Analysis." PLOS ONE. November 201: Vol. 8 (11)

[16] *Op. Cit.* 14

[17] Maki KC et al. "Limitations of Observational Evidence: Implications for Evidence-Based Recommendations." ASN Adv. Nutr. 5:7-15, 2014, doi:10.3945/an.113.004929

[18] Rothstein HR. "Publication Bias in Meta-Analysis." *Prevention, Assessments and Adjustments.* 2005, John Wiley & Sons, Ltd.

[19] Trumbo PR, Rivers CR. Systematic review of the evidence for an association between sugar-sweetened beverage consumption and risk of obesity. *Nutr Rev.* 2014.

[20] Kaiser KA, Shikany JM, Keating KD, Allison DB. Will reducing sugar-sweetened beverage consumption reduce obesity? Evidence supporting conjecture is strong, but evidence when testing effect is weak. Obes Rev. 2013 Aug;14(8):620-33.

homogeneous body of literature, with consistent definitions, study designs and measured outcomes.[21] [22] To the contrary, the body of scientific evidence relating to "added sugars" intakes and health outcomes is known to be highly heterogeneous and often conflicting. These points are frequently cited in the literature and major factors as to why syntheses and conclusions regarding "added sugars" studies are extremely difficult.

The subjective input generally required in conducting systematic reviews was mentioned previously, but given that the studies addressing "added sugars" are so diverse, authors of these systematic reviews must make decisions on inclusion criteria that are irrefutably *subjective* in nature. For example, the Working Group ended up selecting three existing systematic reviews to form their conclusion on the relationship between "added sugars" intake and body weight. In total, there were 92 unique studies included in these three reviews. Only 21 of these studies were included in two or more of the reviews. This means that the study selection criteria defined by these authors for these three reports were so varied that 71 of the studies did not meet the criteria to be included in all three reviews *answering the same question*. This example highlights the inherent subjectivity of study selection for a systematic review, and warrants extreme caution when using these pre-existing reports as the sole basis for drawing evidence-based conclusions.

As with all studies, there are limitations that must be considered when interpreting and extrapolating findings. As such, the authors of the pre-existing reviews on "added sugars" used by the DGAC cite numerous limitations of their reviews which are found in the papers themselves. Below are some of these limitations, overlooked by the DGAC, which highlights some of the weaknesses of the science used to make the DGAC's recommendations.

- "The relatively high degree of unexplained heterogeneity observed in our analyses may limit the validity of our summary estimates." [23]
- "The studies included in our meta-analyses varied substantially with respect to study design, exposure assessment, adjustment for covariates, and specific outcomes evaluated." (Malik, 2014)
- "Assessment of dietary intake of sugars, whether by some method of recall as used in the trials, or by food frequency questionnaire as in cohort studies, was associated

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[21] *Op. Cit. 14*

[22] Walker E, et al. Meta-analysis: Its strength and limitations. *Clev Clin J of Med.* 2008; 75(6):431439.

[23] Malik VS, Pan A, Willett WC, Hu FB. Sugar-sweetened beverages and weight gain in children and adults: a systematic review and meta-analysis. *Am J Clin Nutr.* 2013 Oct;98(4):1084-102

> with a considerable degree of measurement error even when using validated methods." [24]

- "The heterogeneity of the studies, especially in terms of the consequences of altering intake of sugars in ad libitum diets, resulted in difficulties in fully explaining the effects of different dietary changes." (Te Morenga, 2013)
- "Overall, between-study heterogeneity was high. The included studies were observational, so their results should be interpreted cautiously …." [25]

Not all systematic reviews are good; a systematic review is only as strong as the studies (primary research) it contains. Essentially, garbage in equates to garbage out. The Working Group did acknowledge limitations of the systematic reviews they used to support "**strong"** recommendations for body weight (ultimately, just two); yet, they chose to ignore them, as stated in the DGAC report:

> "Despite these limitations the DGAC gave this evidence a grade of "**strong,"** as the limitations are those inherent to the primary research on which they are based, notably inadequacy of dietary intake data and variations in the nature and quality of the dietary interventions."

At the bare minimum, given the weight that each of these pre-existing reviews had in the DGAC conclusions, these important limitations cited by each report's authors and acknowledged by the DGAC must be taken seriously by the Secretaries, as they are ultimately the limitations of the scientific evidence used by the 2015 DGAC to make its recommendations.

There was a heavy reliance on observational data to inform conclusions

The evidence-basis for the Added Sugars Working Group's conclusions linking "added sugars" intake with *serious* disease outcomes consists heavily of epidemiological (or observational) data and, as mentioned above, pre-selected systematic reviews. Epidemiological studies, and even meta-analyses of RCTs, are considered observational data and their findings should be interpreted as *associations* because they ***do not provide proof of cause and effect***. It is widely accepted in the scientific community that caution should be applied when making and communicating recommendations that are based primarily on observational data and not confirmed through well-designed trials. [26]

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[24] Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. Bmj. 2013;346:e7492. PMID: 23321486

[25] Greenwood DC, et al. Association between sugar-sweetened and artificially sweetened soft drinks and type 2 diabetes: systematic review and dose-response meta-analysis of prospective studies. *Brit J of Nutr.* 2014, 112, 725-734.

[26] *Op. Cit. 17*

One of the major issues with observational studies, such as population cohort studies, is that the dietary intake assessment tools commonly used are subject to substantial measurement error, resulting in imprecise measures of exposure, or intakes, of foods/beverages or ingredients. [27] There were numerous cohort studies used in forming the conclusions of the Added Sugars Working Group. These cohort studies predominantly examined (what are often called) sugar-sweetened beverage (SSB) intake in relation to health outcomes. The accuracy of food frequency questionnaires (FFQ) for determining SSB consumption ranges between only 30-80%, highlighting an imprecision that is well known across the nutrition field. When the intake measurement itself is this imprecise in capturing intakes, extreme caution should be employed when concluding a link between the intake of a food/beverage or ingredient with an observed health outcome.

In fact, 10 out of the 12 cohort studies used to evaluate the effects of "added sugars" on cardiovascular disease (CVD) used a FFQ tool that does not accurately capture exposure. This methodological concern was recognized and noted in the 2010 DGAC report by the Carbohydrate Working Group, stating, "Drinks can include a wide range of macronutrients and artificial sweeteners, and are difficult to assess with food frequency instruments." Adding to this established inaccurate assessment of SSB intake is the fact that in these cohort studies, dietary assessments are often performed several years (even decades) prior to the outcome measurement (i.e. blood pressure, diabetes, cholesterol, mortality), with the *assumption* that the subjects' diets did not change at all over the course of 5, 10, 20 years. This is a major assumption made worse by the fact that the initial intake assessment is only 30-80% accurate to begin with.

Given that the determination of causality between a food or nutrient and a health outcome has serious implications that are far-reaching, the Hill criteria for judging causality must be employed. These steps include an assessment of: strength and consistency of the association, evidence of dose-response, biological plausibility, and concordance with other data, particularly clinical trials. [28] This rigor was not employed by the Added Sugars Working Group in its recommendations for "added sugars."

The limitations of observational data are real and must be recognized given the magnitude of impact of the Dietary Guidelines for Americans.

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[27] *Ibid.*

[28] Hill, Austin Bradford (1965). "The Environment and Disease: Association or Causation?". *Proceedings of the Royal Society of Medicine* **58** (5): 295–300.

The use of observational data of "sugar-sweetened beverage" (SSB) consumption is an inappropriate surrogate/proxy for making conclusions about "added sugars" intake and health outcomes

Although we contend that the science the Committee has used to support its links and association between "added sugars" and serious disease outcomes is weak, we strongly contend that without the substantial inclusion of SSB studies, there would be little or no scientific evidence to support or even imply any association between "added sugars" and disease outcomes.

"Sugar-sweetened beverages" are a class of beverages that indeed contain "added sugars," but SSBs do not represent the wide applications for sugars, reflect the intakes of "added sugars," and further, evidence exists for differential metabolic and health effects of SSBs versus "added sugars" consumed in other varieties and modes. In observational studies, SSB intake in the highest quartile or quintile can simply serve as markers of a less healthy lifestyle compared to those who never consume SSBs; these confounding factors are difficult if not impossible to tease out when analyzing data. We strongly question the scientific validity of the Added Sugars Working Group's use of SSBs as a "proxy" for all "added sugars" intake. The evidence used to evaluate health impacts from all "added sugars" intake relied heavily on studies solely assessing SSB consumption.

This reliance on SSB studies is evidenced by 10 of the 12 cohort studies and 3 of 11 trials used to evaluate CVD, 2 of the 3 systematic reviews to evaluate body weight and obesity, and 4 of 5 studies used to evaluate diabetes examining SSB intake, exclusively.

Given that SSBs are a unique source of "added sugars" intake, studies that examine potential health impacts from SSBs should not be generalized to infer similar metabolic impacts for intakes of all "added sugars." SSBs are strictly a liquid source of intake and are primarily sweetened with high fructose corn syrup (HFCS). Further, unlike the majority of foods and beverages that contain sugar (sucrose), with only a few exceptions, they do not contribute to intakes of fiber, protein and other essential micronutrients, as do cereals, other grain products and dairy products. With **less than 50% of the US population consuming SSBs on any given day**, [29] scientific conclusions based on SSBs and not "added sugars" (as consumed by the whole population) adds to the argument that relying on SSBs as a "proxy" is not valid.

[29] Ogden, et al. Consumption of Sugar Drinks in the United States, 2005-2008. NCHS Data Brief. No.71, August 2011.

The inappropriate use of SSBs as a "proxy" for "added sugars" in the DGAC's report is probably best highlighted by the findings of Sonestadt et al.,[30] one of five papers used to inform the diabetes conclusions and the only paper to measure and analyze "added sugars" and "total sugars" in addition to SSBs. The other four papers looked at SSB intake exclusively. The researchers report that none of the three studies reporting sucrose (sugar) intakes and none of the three studies reporting total sugars intake found a positive association with incident diabetes. Three of the studies even found an inverse association. These were the only data on "added sugars," and not just SSB intake, which were considered for diabetes. Yet, the DGAC report reads:

> "Strong evidence shows that higher consumption of added sugars, especially sugar-sweetened beverages, increases the risk of type 2 diabetes among adults and this relationship is not fully explained by body weight."

Quite simply, this statement is not a reflection of what the data indicate; a theme found throughout this report.

Similar to the methodology of Sonestadt et al.,[31] other attempts to answer questions around "added sugars" intake and health outcomes that the Added Sugars Working Group answered have recognized these differences and separated analyses by 'SSB' and 'added sugars' in relation to various outcomes. In fact, the 2010 DGAC performed their analyses this way, as did the recent SACN [32] review in the U.K.

The 2015 DGAC's "strong" conclusions linking "added sugars" to health outcomes is overstated, given the lack of rigorous and consistent data

The body of literature on the topic of "added sugars" is not only highly heterogeneous, as stated previously, but also lacks rigorous data, consistent definitions across studies and accurate measurement tools. These factors were concerns of the Carbohydrate Working Group of the 2010 DGAC and stated in its report[33] in the "Needs for Future Research":

> "Studies of carbohydrates and health outcomes on a macronutrient level are often inconsistent or ambiguous due to inaccurate measures and varying food categorizations and definitions. The science cannot progress without further advances in both methodology and theory."

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[30] Sonestedt E, et al. Does high sugar consumption exacerbate cardiometabolic risk factors and increase the risk of type 2 diabetes and cardiovascular disease? *Food & Nut Res.* 2012. 56:19104.
[31] *Ibid.*
[32] *Op. Cit.* 7
[33] Dietary Guidelines Advisory Committee. 2010. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Pages 311 - 312

The 2010 DGAC report goes on to state that there is a need to, "Develop standardized assessment tools to determine the accurate intake of added sugars."

The methodologies for making these determinations have not changed since 2010; therefore, our ability to attribute a health effect to a type of carbohydrate remains no different or more reliable than it was in 2010. Yet, the 2015 DGAC made **"strong"** recommendations based off of these data anyway.

The lack of rigorous and consistent methodology, including poor measurement tools and inconsistencies in definitions and designs, are also critical reasons why systematic reviews for this body of literature on "added sugars" are so difficult to perform and often vary in their conclusions.

Specific points are made below regarding the lack of objectivity by the 2015 DGAC in its overlooking of the flaws and limitations of the science used to support recommendations on "added sugars"

"Added sugars" and obesity

The recommendation states that: "Strong and consistent evidence indicates that intake of added sugars from food and/or SSBs are associated with unfavorable body weight in children and adults. The reduction of added sugars and SSBs in the diet reduces BMI in both children and adults. Comparison groups with the highest versus the lowest intakes of added sugars in cohort studies were compatible with a recommendation to keep added sugars intake below 10% of total energy intake."

- These recommendations are based solely on two pre-existing systematic reviews. Four reviews were considered during the process but two, which happen to refute the ultimate conclusions, were ultimately discarded from consideration.
- It is incongruent with the evidence to conclude a relationship that is "strong and consistent" when the authors of the two reviews state such limitations as:
    - "The studies included in our meta-analyses varied substantially with respect to study design, exposure assessment, adjustment for covariates, and specific outcomes evaluated." (Malik, 2014)
    - "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." (Te Morenga, 2013)

- "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." (Te Morenga, 2013)

It has consistently been reported in the scientific literature that the observed association between "added sugars" intake, particularly SSB intake, and body weight is true only in situations of overall positive energy balance, meaning when individuals are consuming too many calories – from all sources – and *not* a unique function of sugars. This was stated by the 2010 DGAC in its report and reiterated by the author of one of the two systematic reviews used by this Committee: "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." (Te Morenga, 2013).

We contend that the 2015 DGAC recommendations oversimplify and inaccurately portray the scientific evidence that currently exists on "added sugars" and body weight.

"Added sugars" and type two diabetes (T2D):

The recommendation states that there is "**strong**" evidence for: "Higher consumption of added sugars, especially 'sugar-sweetened beverages,' increase the risk for T2D among adults and this relationship is not fully explained by body weight."

- The evidence evaluated for T2D included four systematic reviews and one cohort study. It is unclear how these five papers were selected for consideration. It is worthwhile to note that this question has not been previously evaluated by any DGAC, meaning that a formal NEL search and review of the literature on added sugars and diabetes has never occurred.
- Four of the five papers examined SSBs exclusively and the fifth was a meta-analysis that looked at both SSBs and sugars intake. ***This meta-analysis concluded that "The results were limited or inconsistent on the adverse effect of intake of total sugars, glucose or fructose on the incidence of type 2 diabetes."*** [Emphasis added][34] This was the only paper of the five to examine sugars other than SSBs, therefore the conclusion statement for diabetes, as written, is substantially overstating the findings.
- Two of the studies assessed the risk of T2D for *both* artificially and "sugar sweetened beverages" and found increased risk of T2D for *both*. These findings negate the conclusion that "added sugars" intake explains the observed associations between SSBs and T2D and provide support for questioning the utility of cohort data (and FFQs to assess soda intake) and also support the case that soda drinking

[34] *Op. Cit. 30*

has collinear diet and lifestyle behaviors that can't be well controlled for, and thus impact findings.

- Importantly, this conclusion by the Added Sugars Working Group differs from those from the 2014 U.K. SACN draft report, [35] an evaluation with access to the same body of literature as the DGAC given the similar timeline of their respective evaluations. In this SACN report, no association was found between sucrose, glucose, fructose and T2D (in fact, a borderline inverse association between sucrose and T2D was found). With regard to SSBs, which were studied separately, SACN found moderate, not "**strong**," evidence for an association with T2D. The SACN conclusion, however, was not extrapolated to include all "added sugars" as stated in the DGAC recommendation.
- By declaring "**strong**" evidence, the Working Group ignores the limitations cited in the most recent of the five papers they examined, a meta-analysis by Greenwood et al. in June 2014,[36] which states: "Overall, between-study heterogeneity was high. The included studies were observational, so their results should be interpreted cautiously…."

In summary, the draft conclusion statement on "added sugars" intake and diabetes does not reflect the preponderance of science, let alone reflect the select body of science that was examined. To make such a "**strong**" recommendation linking added sugars intake to T2D based on weak scientific evidence is misleading, not evidence-based, and contradicts conclusions by other authoritative bodies and position statements of the American Diabetes Association (ADA). The ADA states that sugar is not different than starch with respect to blood glucose and lipid levels, when consumed up to 35% of calories. [37] Of note is that current intakes of "added sugars" are only ~13% of calories and the DGAC is proposing a limit of less than 10%. Again, the scientific evidence presented by the Working Group does not validate its conclusion statement and does not provide a scientific basis for any intake recommendation.

"Added sugars" and cardiovascular disease:

The recommendation states that there is **"moderate"** evidence that: "Evidence from prospective cohort studies indicates that higher intake of added sugars, especially in the form of SSBs, is consistently associated with increased risk of hypertension, stroke, and coronary heart disease in adults. Observational and intervention studies indicate a consistent relationship between higher added sugar intake and higher blood pressure and serum triglycerides."

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[35] *Op. Cit.* 7
[36] *Op. Cit.* 25
[37] *Op. Cit.* 8

- The majority of studies included in this evaluation examined intakes of either "added sugars" or SSB intakes that, if even reported, were at least twice as high as current mean intakes in the U.S. (~13%). Many of the studies did not even report total "added sugars" intakes, leaving actual exposure or intakes unknown.
- Over half of the studies included in this analysis were observational studies and over half of them examined SSBs exclusively, often not reporting intakes of total "added sugars," total sugars, total carbohydrates, energy intakes, or other important dietary factors associated with CVD (i.e. fats, sodium).
- Additionally, very few of the 11 trials included employed isocaloric treatments, making evaluation of the role that sugars plays, independent of total energy or carbohydrate intake, impossible.

Ultimately, the conclusion on "added sugars" and CVD overstates what the evidence says. The study quality is generally weak, with poor control and with a heavy reliance on observational data. The CVD variables the Working Group chose to look at are numerous and a review of this nature, with studies of this quality and so few in number, is not a true evidence-based approach to making links between diet and disease. That said, even with the approach and evidence the DGAC considered, consistent associations between "added sugars" intake and any of the CVD variables studied do not exist. For example, of 11 trials, only two measured blood pressure and only one saw an effect of "added sugars" intake – at an intake of 27% energy (twice the current average in the US). As is the case with each of the DGAC recommendations, the scientific evidence does not support them.

"Added sugars" and dental caries:

The recommendation states that: "The DGAC concurs with the World Health Organization's commissioned systematic review that there is moderate consistent evidence supporting a relationship between the amount of sugars intake and the development of dental caries among children and adults. There is also evidence of moderate quality showing that caries are lower when free-sugars intake is less than 10% of energy intake."

- This conclusion was based on *one* systematic review. This review was not a meta-analysis because, according to the authors, variability in the data was too large to analyze as such.
- This one review studied only the amount of "added sugars" intake associated with dental caries and did not evaluate the role of frequency, total sugars or fermentable carbohydrates, all of which are considered to be cariogenic. This is an important point recognized in the 2010 Dietary Guidelines for Americans, where it states that, "Both naturally occurring sugars and added sugar increase the risk of dental caries." The DGAs also recognize additional factors involved in cariogenesis:

> "During the time that sugars and starches are in contact with teeth, they also contribute to dental caries. A combined approach of reducing the amount of time sugars and starches are in the mouth, drinking fluoridated water, and brushing and flossing teeth, is the most effective way to reduce dental caries."

- Of note, this sole review used as the basis for this conclusion does not contain any publication more recent than 2010. This is also an important point because in 2010 EFSA concluded their review, which evaluated the role of sugars in dental caries, and made the following conclusion:

> "Frequent consumption of sugar-containing foods can increase risk of dental caries, especially when oral hygiene and fluoride prophylaxis are insufficient. However, available data ***does not allow setting an upper limit for intake of (added) sugars on the basis of a risk reduction for dental caries***, [Emphasis added] as caries development related to consumption of sucrose and other cariogenic carbohydrates does not depend only on the amount of sugar consumed, but is also influenced by frequency of consumption, oral hygiene, exposure to fluoride, and various other factors."[38]

In conclusion, by selecting one pre-existing review, the DGAC's shortcut to a conclusion on the role of "added sugars" and dental caries has bypassed an evidence-based approach to determine a diet and health relationship, and ignores the multifactorial nature of the role of all fermentable carbohydrates in the development of dental caries.

The 2015 DGAC provided no credible science-based evidence to support its recommendation to reduce "added sugars" intake to below 10 percent of total energy intake

The 2015 DGAC made its recommendation of **"strong"** evidence for its 10 percent of total energy from "added sugars" based on weak scientific evidence and mathematical food modeling that has not been tested for effectiveness in influencing body weight or other health outcomes. This value, 10 percent, is arbitrary and has not been scientifically tested, let alone proven.

Calories are the real issue

In fact, 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 even made in the WHO-commissioned review (Te Morenga, 2013), the nexus that has empowered the DGAC to set an "added sugars" intake level. The authors acknowledge the limitations of the evidence stating,

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[38] *Op. Cit.* 6

- "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***." (Te Morenga, 2013) [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." (Te Morenga, 2013)
- "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." (Te Morenga, 2013)
- "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." (Te Morenga, 2013).

The findings in the WHO commissioned review are actually consistent with the 2010 DGAs 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." [39]

Calories from "added sugars" are not major contributing factor in increased caloric intakes or obesity

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 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)[40] and as the 2015 DGAC noted current intake is now 13.4% of energy. More importantly, according to USDA data, Americans are consuming 425

[39] U.S Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans 2010, 7th Edition, Washington DC: U.S. Government Printing Office, December 2010 pg. 28

[40] JA Welsh, AJ Sharma, L Grellinger, MB Vos. Consumption of added sugars is decreasing in the United States. *American Journal Clinical Nutrition* (2011) **94(3):** 726 – 734.

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).[41]

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%." [42]

Food pattern modeling does not have the scientific underpinning to support "added sugar" intake recommendations

The fact remains that no authoritative scientific body after a thorough review of the scientific literature has found a public health need to set an intake level or upper level for "added sugars" intake, including the IOM[43] and in 2010 the EFSA.[44] This was also the conclusion of the Food and Drug Administration (FDA) in its recent Nutrition Facts Panel (NFP) Proposed Rule stating,

> "…we have no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived. Therefore, we are not proposing a DRV for added sugars."

Regarding the use of USDA food modeling for setting a DRV for "added sugars" intake the FDA states,

> "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."

Further, the 2010 DGA policy document clearly states that the USDA Eating Patterns is but one example of suggested eating patterns and that the USDA Eating Patterns "***have not been specifically tested for health benefits***."

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

[42] B P Marriott et al (2010) 'Intake of Added Sugars and Selected Nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003-2006', Critical Reviews in Food Science and Nutrition, 50: 3, 228-258.

[43] *Op. Cit.*5

[44] *Op. Cit.* 6

Serious concerns must be raised regarding the scientific integrity of the 2015 DGAC's efforts to validate food pattern modeling as an evidence-based guide for food consumption or intake recommendations. At the DGAC's sixth meeting it was asserted, "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 serious questions.

The table below quantifies the information provided in these graphs that depicted the correlation between intakes in *cited dietary pattern studies* and USDA Food Pattern recommendations.

Dietary Component	Studies	Within USDA Food Pattern Range	Intakes Outside USDA Food Pattern Range	Lower	Higher
Vegetables	23	9	14	6	8
Fruit	23	5	18	3	15
Dairy	19	6	13	13	
Red & Processed Meat	20	1	19	6	13
Seafood	20	5	15		15

We question how their graphical depiction can be considered evidence-based and therefore grounds for empirical support that USDA Food Patterns are an evidence-based guide for food consumption. Furthermore, this quantified table shows that in fact the majority of food group intakes from these published dietary pattern studies do not actually fall within the recommendations of the USDA Food Pattern ranges as asserted by the 2015 DGAC. Additionally, because the dietary pattern studies cited did not include "added sugars" criteria, there is no graph/empirical evidence to support the extremely low "added sugars" intake in the proposed "Healthy US-Style Patterns" or in any of the patterns in the table provided in the 2015 DGAC advisory report to support a 10 percent intake recommendation.

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 the Dietary Guidelines process. [Emphasis added]

Therefore, we assert the use of the scientifically questionable WHO intake recommendation and hypothesis-based food modeling for recommending "added sugars" intakes undermines U.S.'s high standards in evidence-based nutrition guidance and policy.

The 2015 DGAC aligning with the controversial World Health Organization's (WHO) Guideline on Sugars is a step back for U.S. standards of evidence

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 recent and controversial guideline on sugars intake[45] undermines this important standard of scientific integrity.

The WHO commissioned two systematic reviews to inform their March 2015 report, "WHO Guidelines: Sugars intake for adults and children;" one of these addressed body weight (Te Morenga, 2013) and the other dental caries.[46] Instead of conducting their own NEL reviews of these important questions, the 2015 DGAC relied heavily on the body weight review (Te Morenga, 2013) for its **"strong"** recommendation on "added sugars" and body weight and to supports its recommendation to keep "added sugars" intake below 10 percent of total energy intake. The Committee made its recommendation for dental caries solely on this WHO commissioned systematic review. 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***. Its evidence for reducing dental caries by reducing free sugars as moderate and evidence relating to population studies as ***very low quality***.[47]

The WHO has a history of controversial reports due to their recommendations being political and based on of low quality evidence. For example, regarding WHO's 2009 Report 916 free sugars recommendations in 2004, the American Dietetic Association (now the Academy of Nutrition and Dietetics) stated in its "Position of the American Dietetic Association: Use of Nutritive and Nonnutritive Sweeteners:"

> "The WHO is currently in the process of designing a global strategy for making recommendations regarding diet, physical activity and health. On the basis of the opinions of a joint consultation report the WHO recommended 10% of energy from

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[45] Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015.
[46] Moynihan PJ, Kelly SA. Effect on caries of restricting sugars intake: systematic review to inform WHO guidelines. *J Dent Res.* 2014 Jan;93(1):8-18.
[47] 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.

> added sugars (defined as "free sugars"). The strategies used in the panel's deliberations encompass *their interpretation* of a range of epidemiologic, economic, social, and political impacts on the prevention and control of non-communicable diseases. Thus, the 10% intake recommendation may *not be based solely on scientific evidence."*[48]

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 strong recommendations are based on low or very low confidence in effect estimates (study quality)." Regarding nutrition guidelines, this percentage jumps to 100%. [49]

In an evidence-based process, such as mandated for use in the U.S Dietary Guidelines process, the WHO report or the WHO commissioned meta-analyses (Te Morenga, 2013) does not provide the level of scientific evidence or agreement upon which the 2015 DGAC can credibly base its grade of "**strong**" evidence to associate "added sugars" intake uniquely to obesity, other than a source of calories.

Additionally, the sole use of a WHO commissioned review as evidence that "added sugars" intake is a unique contributor to dental caries is even weaker. It also undermines decades of scientific evidence and professional advice that *all* fermentable carbohydrates can cause dental caries and that dental hygiene is the most important factor in reducing tooth decay.

The use of hypothesis-based dietary patterns studies to link or associate dietary components with serious disease outcomes or set intake recommendations is not a validated scientific methodology

To further emphasize concerns that sound scientific principals were undermined in an effort to make "bold and innovative" recommendations, we strongly question the scientific validity of using hypothesis-based dietary pattern studies to link dietary components to disease outcomes. The use of hypothesis-based research to infer, or even state, cause and effect relationships between dietary components and disease outcomes that are not yet established by more traditional, experimental science is not a validated scientific process.

The "hypothesis-based" methodologies used in these dietary pattern studies do not, and cannot, accurately isolate the positive or negative effects of individual components of the

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[48]American Dietetic Association, Position of the American Dietetic Association: Use of Nutritive and Nonnutritive Sweeteners, J Am Diet Assoc. Vol 4 Number 2, 255-274 Feb 2004

[49] 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 Epidemiol. 2014 Dec 19

dietary pattern. In this totally 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. Furthermore, examination of the science cited raises concerns that the conclusions drawn by the Committee do not accurately reflect what was represented in the actual scientific studies cited (again a theme in this process). As demonstrated in the table (pg. 21) of food pattern modeling, the majority of dietary pattern studies cited by the Committee did not include a total sugars or "added sugars" criteria. Yet, the Committee implies that there is a link or association between "added sugars" and serious disease outcomes.

The DGAC "**strong"** recommendation relating to the "The Relationship Between Dietary Patterns and Risk of Cardiovascular Disease" which states that low intakes of "added sugars" reduced risks of cardiovascular disease cited 20 studies identified as having assessed the association with ***individual food components*** of a dietary pattern score and ***CVD endpoint outcomes.*** Sixteen of those studies did not even include an "added sugars," sugars-sweetened food or sweetened beverage component in their scoring methodology.

Dietary guidance that links or associates any individual component of the diet with serious disease outcomes must be supported by a thorough systematic review of the full body of science (at the highest level of evidence available) to assure recommendations are based on a preponderance of scientific evidence. In some instances, the required scientific evidence for such conclusions does not yet exist. Therefore, the science used to support these conclusions is yet another example of why serious concerns are being raised in the 2015 DGAC process that biases and not scientific evidence are influencing recommendations.

There are unintended consequences of the 2015 DGAC recommendations to reduce "added sugars" intake to historically low levels

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 for intake

levels of many essential micronutrients.[50] [51] [52] [53] [54] [55] [56] 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 offer 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 (ie, 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."[57]

Further, a focus on reducing "added sugars" does not necessarily translate to reduced calories. Consumers who select foods based on a reduction in grams of sugars listed in the Nutrition Facts Panel are often being misled because "added sugars" are frequently replaced by carbohydrate bulking agents, such as glycerol or maltodextrins, 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.

Further, 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

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[50] Rennie KL et al "Association between added sugar intake and micronutrient intake: a systematic review" *British Journal of Nutrition* 2007; 97: 832-841

[51] World Health Organization & Food and Agric. Org. of the United Nations, FAO Food and Nutrition Paper 66, Carbohydrates In Human Nutrition: Report of a Joint FAO/WHO Consultation 36(1998)

[52] 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", *Journal of Adolescent Health* 2004; 34: 56-63

[53] 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" *J Am Diet Assoc*, 2008 Apr; 108(4):631-9

[54] RA Forshee, ML Storey, Controversy and statistical issues in the use of nutrient densities in assessing diet quality. *Journal of Nutrition*, 2004 134(10): 2733-2737

[55] SA Gibson, Dietary sugars intake and micronutrient adequacy: a systematic review of the evidence. *Nutrition Research Review*, 2007 20(2): 121-131

[56] Johnson RK et al Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. Circulation. 2009;120:1011-1020

[57] American Academy of Pediatrics. Policy Statement: Snacks, Sweetened Beverages, Added Sugars, and Schools. *Pediatrics.* 2015. 135;3.

European Union.[58] 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.

The 2015 DGAC "Added Sugars" policy recommendations went far beyond the Congressional mandate and DGAC Charter with no evidence-based support

The 2015 DGAC went far beyond the Congressional mandate and DGAC Charter in providing specific recommendations for federal policy and regulations. Public Law 101.445 specifically states,

> "Each such report shall contain *nutritional and dietary information and guidelines for the general public*, and shall be *promoted* by each Federal agency in carrying out any Federal *food, nutrition, or health program*."

We contend that the use of dietary guidance in Federal nutrition and nutrition education programs is far different from the use of dietary guidance as a basis for establishing Federal nutrition policy, rules and regulations. We have serious concerns the interpretation of the actual language in the statute governing the DGA process has been expanded beyond its original intent. The use of dietary guidance in the Dietary Guidelines for Americans (DGA) is now being used as the sole basis to support Federal rules and regulations. However, Section 301(b)(3) of Title III of the 1990 law states,

> "LIMITATION ON DEFINITION OF GUIDANCE- For purposes of this subsection, the term `dietary guidance for the general population' does not include any rule or regulation issued by a Federal agency."

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[58] M. Gibney et al., *Consumption of Sugars*, 62 Am. J. Clinical Nutrition 178S (Supp. 1995). This relationship was reflected in a more recent study that examined the impact of low fat interventions in school lunches—it was noted that "[a]s percent of calories from fat or saturated fat in lunches decreased, that from sugars increased." J.T. Dwyer et al., *Fat-Sugar See-Saw in School Lunches: Impact of a Low Fat Intervention*, 32 J. Adolescent Health 428 (Supp. 6 2003) R.P. Farris, *Nutrient Intake and Food Group Consumption of 10-Year-Olds by Sugar Intake Level: The Bogalusa Heart Study*, 17 J. Am. College Nutr. 579 (1998) ;J.O. Hill and A.M. Prentice, *Sugar and Body Weight Regulation*, 62 Am. J. Clin. Nutr. 262S (Supp. 1995).

This expansion of the intent and power of the DGA has far-reaching implications for stakeholders. This is most evident by the FDA almost sole use of "selective" dietary guidance in the 2010 DGA to support is proposal to require "added sugars" labeling on the NFP, which was supported by the 2015 DGAC in its policy recommendations.

This also raises serious concern for future regulations due to the fact the Departments will have the ability to select advisory panel members that support Government initiatives and regulatory agendas. These concerns are even more relevant due to FDA's recent pronouncement that the DGA is a "consensus" document in its Proposed Rule on changes to the NFP.

Therefore, we strongly object to the use of the 2015 DGAC "*Implications"* or Federal policy recommendations in the final DGAs, especially when the 2015 DGAC provided no scientific evidence to support the efficacy of its policy recommendations.

We have strong reservations about potential implications for future changes to regulations including labeling regulation should the scientific criteria for making regulations be based solely on a single U.S. Government generated report. Our reservations are even greater in light of our concerns regarding the quality of science and biases in this 2015 DGAC process.

USDA has undue influence on the DGAC processes relating to its role in food patterns modeling

Historically, the USDA Pyramid guidance, which are now USDA Food Patterns, were developed to reflect the recommendations of the Dietary Guidelines. However, in recent Dietary Guidelines processes, the USDA Food Patterns and food modeling are being used as ***the basis*** for recommendations and even for setting limits and intake recommendations. Such recommendations are the purview of the IOM.

Further, the mathematical construct of USDA food modeling to develop these Food Patterns is falsely being given the weight of science, even over peer-reviewed science and reports by authoritative scientific bodies; yet, this exercise lacks such rigor. USDA, as an agency that oversees the DGAC process, and as the agency that develops the food patterns and conducts food modeling, is in a position to unduly influence the DGAC process.
We ask the Secretaries to ensure all Dietary Guidelines recommendations are based solely on a thorough review of the scientific evidence. Only then should this science-based dietary guidance be used to construct USDA Food Patterns.

In conclusion,

As participants in the Dietary Guidelines process since its inception, the Association has legitimate concerns about the scientific integrity of the 2015 DGAC process. The 2015 DGAC has taken "added sugars" recommendations to unchartered territory, contradicting decades of science on sugar and current major reviews of the scientific literature on sugar intake. This raises serious concerns about the manner by which 2015 DGAC recommendations were derived.

To this point, despite the fact there has been considerable Government investment in the establishment of the NEL systematic review process, NEL reviews were not consistently used in the 2015 process to evaluate the scientific evidence, as was done for virtually all research questions in the 2010 process. The consistent use of NEL reviews across *all* research topics would have provided interested parties reasonable assurance that all subject areas were given the same consistent and unbiased consideration.

We emphasize that the 2015 DGAC did not undertake the rigorous scientific investigation necessary to conclude links or associations between "added sugars" and serious disease outcomes. Intake recommendations that lead the American public to believe any dietary component is a causal factor in a serious disease outcome should only be made based on significant scientific agreement due to a robust review of the entire body of scientific literature by experts in the field of investigation.

Dietary Guidelines for Americans are too important not to get them right. We have seen changing scientific agreement and dietary guidance on other dietary targets over the years, i.e. dietary cholesterol (eggs) and fats. This shifting dietary guidance that targets basic staples of the American diet has an economic impact on farmers, food and beverage manufactures and ultimately causes consumer confusion and apathy. Further, it has done little to improve the health of Americans.

We respectfully ask that the Secretaries maintain the integrity of the Dietary Guidelines process and to adhere to the Congressional mandate that clearly requires changes to Dietary Guidelines for Americans to be based solely on the preponderance of scientific information, which is not the case in the 2015 DGAC advisory report for "added sugars." Therefore, we ask that the Secretaries to maintain the 2010 Dietary Guidelines advice for "added sugars" until a thorough review of the scientific literature on "added sugars" intake is conducted by an authoritative scientific body, such as the Institute of Medicine.

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