October 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket FDA-2012-N-1210 RIN 0910-AF22

Dear Madam or Sir,

The North American Branch of the International Life Sciences Institute (ILSI North America) appreciates the opportunity to share ILSI supported scientific research published in peer-reviewed journals and/or presented by experts in nutrition, dietary assessment and epidemiology. Evidence submitted herein provides sound science and reasoning in response to the Food and Drug Administration's (FDA) proposed revisions to the Nutrition and Supplement Facts Labels: Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions that were published in the July 27, 2015 Federal Register (Docket No. FDA-2012-N-1210 RIN 0910-AF22).

ILSI North America is a public, non-profit organization that actively collaborates with government and academia to identify and resolve scientific issues important to public health. The organization carries out its mission by sponsoring relevant research, professional education programs and workshops, seminars and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the wellbeing of the general public. ILSI North America programs are supported primarily by industry member companies.

ILSI North America's Technical Committee on Carbohydrates submits these comments in response to the supplemental rule stating intent "to establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars [and] proposing to require the declaration of the percent Daily Value (DV) for added sugars on the label…" In doing so, FDA stated:

> *Based on our review of the evidence presented in the 2015 DGAC report (see link to individual studies reviewed by the 2015 DGAC—(http://www.nel.gov/—then click on "Dietary Patterns and Health Outcomes Systematic Review Report."), we find that the evidence further supports FDA's proposal to require an added sugars declaration in the Nutrition and Supplement Facts labels. 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. There is also evidence to support a reference amount for added sugars, i.e., limiting added sugars intake to no more than 10 percent of total daily caloric intake.*

Information submitted below by ILSI North America is consistent with the USDA Nutrition Evidence Library (NEL) review for the 2015 DGAC on the question: "What Is the Relationship Between Added Sugars and Risk of Cardiovascular Disease." – (http://www.nel.gov/conclusion.cfm?conclusion_statement_id=250454&full_review=true). According to this NEL evidence review noted in FDA's rationale, evidence is "moderate" (not strong) and furthermore, does not quantify a specific level of added sugar. It appears that FDA relied on the DGAC 2015 diet pattern modeling work and not the actual scientific evidence review of CVD for the 10% of total energy intake, despite previously stating: "We do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine Dietary Reference Values (DRVs)." [Federal Register Vol 79, No 41 Food and Drug Administration, 2014, p.11895 - http://www.gpo.gov/fdsys/pkg/FR-2014-03-03/html/2014-04387.htm] This lack of a quantified level is consistent with evidence reviews by several experts on a wide range of health outcomes, as noted below.

ILSI North America Comments

ILSI North America sponsored work suggests the lack of *strong evidence* base for a dietary recommendation to limit added sugars to no more than 10% of calories, and thus no *scientific* basis for establishing a Daily Value for added sugars.

1) Excerpts below are relevant from comments submitted by ILSI North America on March 31, 2014 to the World Health Organization on the WHO Draft Guideline: "Sugars Intake for Adults and Children."

> *ILSI is not a standards-setting organization, but it has considerable experience in examining available data and is active in efforts to enhance the quality of research design and interpretation (Webb et al. 2013). Given that national governments worldwide are stretched to meet the health care needs of their populations, it seems important to provide guidance in which there is considerable confidence to avoid wasting valuable resources on implementing actions that will not result in effective outcomes.*
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> *The WHO guidance is based on two evidence-based reviews related to dental caries and obesity/overweight. The new, conditional recommendation to further reduce free sugars intake to 5 percent of total calories appears to be based solely on data from several studies that are more than 50 years old. Even so, the findings of the evidence-based review are described by the review authors as of "very low quality" (Moynihan and Kelly 2014).*
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> *<u>ILSI reviews of literature regarding sugars and dental caries</u>*
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> *ILSI North America reviewed the data related to dental caries as recently as September 2002 and the findings were published in 2003 (Touger-Decker and van Loveren 2003). An earlier review was conducted in 1994 and published in 1995 (König K and Navia JM 1995). This second, earlier review addresses the issue of dental caries during wartime. The data cited by the WHO review were collected following World War II in Japan, where there were undoubtedly many confounding factors, e.g., undernutrition and lack of dental care. The authors of the 1994 ILSI review state: "Although sugar consumption rose rapidly after World War II and has been ~ 45 kg*

per capita during the past 40 y, the number of caries-free schoolchildren aged 7-15 y had risen to 65% b 1989 and the DMFT index for 12 y-old children had decreased to 1.0." The data cited come from Büttner 1991.

ILSI Europe published a concise monograph on this topic as well (van Loveren 2009). This monograph reviews studies showing that frequency of consumption of fermentable carbohydrates is a driver of dental caries along with oral hygiene, exposure to fluoride, and salivary flow and composition. The monograph cites studies showing a decline in dental caries in children from Germany and The Netherlands from the 1960s to 2005.

ILSI contributions to the understanding of the impact of added sugars consumption on Body Mass Index (BMI)

ILSI North America supported a re-analysis of "Appendix J: Association of Added Sugars Intake and Intake of Other Nutrients" published by the Institute of Medicine in 2002. Marriott et al. 2010 combined the 2003-2006 National Health and Nutrition Examination Survey (NHANES) data (15,189 respondents, ages 4 years and older, with the U.S. Department of Agriculture My Pyramid Equivalents Database to estimate individual added sugars intake as a percentage of total energy. Respondents were then classified into 8 added sugars percent energy intake categories. Table 1 in this paper shows that the majority of individuals had an estimated intake of >5 to <20 percent of energy from added sugars, with mean daily total energy intake of 2062 kcal to 2183 kcal. Controlling for total energy intake in their analysis, this represented an estimated range of 45 to 92 mean gram-equivalents of added sugar intake daily. There were no appreciable differences between male and female respondents across the 8 categories.

The BMI for the same nationally representative sample from the United States (US) was higher for individuals with low or high intakes of added sugars, thus there does not appear to be a linear relationship between BMI and intake of added sugars for this population. Those with low added sugars intake (< 5 percent of energy) had a similar BMI to those with high added sugars intake (> 35 percent of energy): 28.9 compared to 28.1, respectively. Of persons who were overweight or obese, the highest proportions reported consuming between 5 and 15 percent of their energy from added sugars. With each 5 percent increase in added sugars intake above 15 percent added sugars intake, a lower prevalence of overweight and obese individuals was found, until the highest category of sugars intake was reached (>35 percent).

ILSI Europe published a concise monograph, Ziesenitz et al. 2012, that reviews the available data and found that sustained overconsumption of energy, irrespective of the energy sources, leads to weight gain. The most effective means of weight loss is to reduce energy intake and increase physical activity.

2) The following excerpt is relevant from ILSI North America Comments on the FDA Proposed Revisions to the Nutrition Facts labels [Docket No. FDA-2012-N-1210 RIN 0910-AF22].

ILSI North America-sponsored work is consistent with the FDA's [original] decision not to propose a [Daily Reference Value] DRV for added sugars, given insufficient scientific

evidence. The ILSI Sugars workshop paper by Murphy and Johnson (2003) reviewed the DRIs for carbohydrates and stated the following:

"The panel extensively reviewed the literature examining potential adverse effects of overconsumption of sugars. This included the available data on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia. The panel concluded that there was insufficient evidence to set a tolerable upper intake level (UL) for sugars. A UL for sugars was not set because of the limitation in the UL definition that requires a specific endpoint for an adverse effect from excessive nutrient intake."

In addition, as cited by Hess et al. (2012), a European Food Safety Authority panel concluded that there are insufficient data to set an upper limit for (added) sugar intake. The basis for this conclusion was a review of the effects of sugar intake on the nutrient density of the diet, body weight, dental caries, and risk factors for cardiovascular disease and type 2 diabetes mellitus.

In conclusion

Scientific evidence is lacking with respect to quantifying a level of sugar or added sugar relative to health outcomes, as noted by several experts in scientific publications cited herein. This is consistent with the lack of a quantified level of sugar in the DGAC 2015 scientific evidence review on added sugars and CVD cited by the FDA in the supplemental proposed rule.

Respectfully submitted,

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