UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Ensure the Safe Use of "Added Sugars"

Submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

February 13, 2013

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Contents

Dockets Management Division
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CITIZEN PETITION

The Center for Science in the Public Interest ("CSPI")[1] submits this Petition pursuant to 21 C.F.R. § 10.30 to request that the Food and Drug Administration ("FDA") take the action requested below.

I. Action Requested

CSPI requests that FDA take action as necessary to ensure the safe use of various caloric sweeteners (collectively, "added sugars") that are added to certain beverages[2] and other foods. These added sugars include sucrose and high-fructose corn syrup ("HFCS"), which are the main sugars added to foods and beverages, but also corn sugar, invert sugar, corn syrup, and others. Under FDA's regulatory scheme for foods, sucrose and HFCS, as well as corn sugar, invert sugar, and corn syrup, are currently denominated as "generally recognized as safe" ("GRAS"), and not as "food additives." *See* 21 C.F.R. § 184.1854 (GRAS status for sucrose); 21 C.F.R. § 184.1857 (GRAS status for corn sugar); 21 C.F.R. 184.1859 (GRAS status for invert sugar); 21 C.F.R. § 184.1865 (GRAS status for corn syrup); and 21 C.F.R. § 184.1866 (GRAS status for HFCS).[3]

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[1] CSPI is a nonprofit organization based in Washington, D.C. and is supported largely by about 850,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

[2] For purposes of this Petition, "beverages" includes carbonated and non-carbonated non-alcoholic drinks (including energy drinks, fruit drinks, and sports drinks) and flavored milks.

[3] While this Petition focuses on added sugars that are formally denominated GRAS, certain other added sweeteners—such as fruit juice, fruit juice ades, evaporated cane sugar, honey, and agave syrup—also contribute to many of the harms discussed below. This petition also urges FDA to consider the use of those added sweeteners in taking the actions requested herein to address the risks posed by GRAS and non-GRAS added sugars alike in both beverages and non-beverage foods.

Specifically, this Petition requests that:

1. FDA initiate a rule-making proceeding to ensure that the content of sucrose and HFCS in beverages is limited to safe levels consistent with authoritative recommendations. The lower levels could be achieved by, for example, amending FDA regulations to condition continued GRAS status for those ingredients on such content limits and could be implemented gradually over several years.

2. With respect to sucrose, HFCS, and other added sugars (GRAS or otherwise), FDA:

   - Revise the "Sugars" line on Nutrition Facts labels to address "added sugars";
   - Set targets for lower levels of added sugars in foods (apart from soft drinks and other beverages) that provide significant amounts of sugar to the general population or population sub-groups;
   - Conduct a public education campaign to encourage consumers to consume less added sugars; and
   - Work with the food industry and interested federal, state, and local agencies to encourage reduced use and consumption of added sugars—including by encouraging (1) limits on the sale of over-sized beverages containing added sugars in restaurants and from vending machines and (2) the development of means of reducing the use of added sugars.

II. Statement of Grounds

A. Summary

Excessive added sugars in the typical American diet has created a public health problem of crisis proportions.[4] As recognized nearly a decade ago by the then-Acting Commissioner of FDA, America suffers from an "epidemic of overweight and obesity," which in turn "increase[s] the risk for coronary heart disease, hypertension, type 2 diabetes, osteoarthritis, and certain cancers."[5] Numerous authorities, including the U.S. Departments of Agriculture and Health and Human Services, have concluded in recent years that over-consumption of added sugars contributes importantly to overweight and

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[4] CSPI has long been concerned about excessive added sugars in the typical American diet. Even before its 2005 Petition calling for warning notices on non-diet soft drinks (*see* Docket No. 2005P-0282), CSPI petitioned FDA to set a Daily Value for added sugars and add a line to the Nutrition Facts label indicating the number of grams of added sugars in a serving and the percentage of the Daily Value that that represents. *See* Docket No. 1999P-2630. FDA has never substantively responded to that Petition, just as it has not responded to CSPI's 2005 petition.

[5] Speech by Lester M. Crawford before the National Medical Association (August 4, 2004).

obesity and to the many obesity-related health problems and have advised consumers to reduce their consumption of those sugars.[6,7]

The data establishing the serious public health risks associated with large intakes of added sugars, particularly when consumed in beverages, are set forth in detail in this Petition, as well as in a Petition filed by CSPI in 2005 and updated in 2008, in which CSPI requested that FDA, either in a food additive regulation or, as a condition of continued GRAS status, adopt a series of rotating warning messages on the labels of soft drinks containing sucrose or HFCS. Docket No. 2005P-0282 (Attachments A [2005 petition] and B [2008 update] hereto). The FDA has not yet acted on that Petition, but it is clear that the actions that *have* been taken in certain circumstances—such as including sodium and sugars in Nutrition Facts labels—have not brought consumption down to safe levels. What *has* proven effective in protecting consumers is setting limits on the amounts of unhealthful ingredients in food (such as the amount of fat in ground beef and the amount of sulfites in wine). In other spheres, government has limited the amounts of harmful pollutants in air and water and required air bags in automobiles, child-resistant caps on medicine containers, and motor vehicles that are more fuel-efficient. Thus, and given the data that has emerged since 2008 showing to an even greater degree than previously the harms caused by excess consumption of added sugars, CSPI maintains that not only the actions sought by CSPI in 2005 and 2008, but also the additional measures sought here, are warranted.

Most of the evidence showing the harms caused by added sugars—including the data set forth in CSPI's 2005 Petition and 2008 Update, and in this Petition—emerged after FDA accorded GRAS status, 17-plus years ago, to the added sugars that are the subject of this Petition and therefore determined that those substances were entitled to more limited regulation by FDA than if they were considered "food additives." FDA regulations, however, clearly provide that the Agency may reconsider the GRAS status of any food ingredient based on "[n]ew information" (21 C.F.R. § 170.30) and may also impose specific uses of the ingredient as a condition of GRAS status to ensure its safe use. 21 C.F.R. § 170.30(j). Moreover, in 1982, when FDA first proposed a rule to accord GRAS status to several added sugars, the Agency *committed* that it would undertake a new safety determination if increased dietary consumption of these ingredients came to pass or if new scientific evidence were to reveal that the ingredients posed a potential hazard to public health. Both those possibilities occurred, with every year bringing forth new data showing the health risks of added sugars—especially in sweetened beverages, but more generally in all foods.

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[6] 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. http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf; accessed Dec. 22, 2012.

[7] USDA. Make better beverage choices. 2012. http://www.choosemyplate.gov/food-groups/downloads/TenTips/DGTipsheet19MakeBetterBeverageChoices.pdf; accessed September 13, 2012.

The data set forth below, on top of the data discussed in the 2005 CSPI Petition and 2008 Update, establish that limits on the use of sucrose and HFCS – *e.g.*, by conditioning those ingredients' GRAS status on such limits – are essential to the public health. Those data, the very data that FDA years ago promised would prompt a review of the GRAS status of added sugars, show that Americans are consuming added sugars generally, and especially those in sugar-sweetened drinks (principally sucrose and HFCS), at a level far in excess of recommended levels, and that current levels of consumption threaten individual and the public's health. FDA action modifying the GRAS status of added sugars in beverages and other foods is long overdue. Moreover, it is incumbent on the Agency to work with other agencies at the federal, state, and local levels, and with those who make and sell products containing added sugars, whether GRAS or otherwise, to reduce consumption of added sugars to safe levels.

GRAS status requires "a consensus among qualified experts about the safety of the substance for its intended use." 21 U.S.C. § 321(s) As demonstrated by the broad support for this Petition by leading experts in nutrition, cardiovascular disease, obesity, and epidemiology (as well as by recommendations from governmental and non-governmental health agencies), there is no consensus that added sugars as they are used today, without restrictions, are safe. (*See* Attachment 3.) Instead, the consensus is the opposite—that current levels of consumption of added sugars are harmful.

CSPI is aware that some companies offer beverages with less or no added sugars, but that has not averted the ongoing public health crisis. Fortunately, technological advances are making it easier to reformulate foods and beverages to lower added-sugar content while still delivering the taste that consumers seek. CSPI believes that an aggressive approach to this issue by the FDA would prompt affected companies to take full advantage of available technologies (and will stimulate new means of lowering sugar intake) to help consumers reduce their added-sugars intake to safe and recommended levels and thereby improve the public health.

B. Legal Background—FDA's Regulatory Scheme for Food

The regulatory scheme for food established under the Federal Food, Drug, and Cosmetic Act (FDCA) divides food ingredients into those that are "food additives" and those that are not. Under the FDCA, food additives may only be used if FDA has issued a regulation "prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a).

Under the FDCA, a substance added to food is not a "food additive" if it is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended

use." 21 U.S.C. § 321(s).[8] Foods that meet that requirement are characterized as "generally recognized as safe," or "GRAS."

A GRAS determination has two components. *First*, a GRAS product must be shown to be safe, which "means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). In determining safety, FDA considers:

> (1) The probable consumption of the substance and of any substance formed in or on food because of its use.
>
> (2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.
>
> (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

Id.

Second, GRAS status requires that the data and information that establishes safety be "generally available" and that there is "a basis to conclude that there is a consensus among qualified experts about the safety of the substance for its intended use."[9] *See also* Lars Noah and Richard Merrill, "Starting from Scratch: Reinventing the Food Additive Approval Process," 78 B.U. L.Rev. 329, 352 (1998) ("Noah & Merrill") ("It is generally agreed that GRAS requires a fairly high level of scientific consensus.")

The added sugars discussed in this Petition, including sucrose and HFCS, as well as corn sugar, invert sugar, and corn syrup, are currently accorded GRAS status, with no

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[8] A food substance is also not a food additive if it used in accordance with a sanction or approval granted prior to September 6, 1958. According to FDA's regulations, prior sanctions for certain added sugars at issue in this Petition either never existed or have been waived. *See* 21 C.F.R. § 184.1854(d) (sucrose); 21 C.F.R. § 184.1857(d) (corn sugar); 21 C.F.R. 184.1859(d) (invert sugar); and 21 C.F.R. § 1844.1865(d) (corn syrup). HFCS was not developed as a commercial product until the 1960s, and therefore no relevant prior sanction/approval exists for that product. To the extent that prior sanctions exist for the added sugars at issue here, FDA regulations provide that "[b]ased on scientific data or information that shows the use of a prior-sanctioned food ingredient may be injurious to health, . . . [FDA] will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient." 21 C.F.R. § 181.1(b).

[9] Letter from Mitchell A. Cheeseman, Ph.D., Acting Director Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, to City Brewing (Nov. 13, 2009), at 1. http://www.fda.gov/Food/FoodIngredientsPackaging/ucm190387.htm (last accessed Dec. 28, 2012).

limitations on their use other than compliance with good manufacturing practices. *See* p. 2, above. However, FDA regulations make clear that "[i]n the interest of the public health, such articles [of food] which have been considered in the past by [FDA] . . . to be generally recognized as safe for their intended use . . . or not to be food additives under the conditions of intended use, *must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.*" 21 C.F.R. § 170.6(c) (emphasis added). Accordingly, FDA's regulations state that "new information may *at any time* require reconsideration of the GRAS status of a food ingredient." 21 C.F.R. § 170.30(l) (emphasis added). Such reconsideration may take the form of FDA regulation of uses of that ingredient as a condition of continued GRAS status. *See* 21 C.F.R. § 170.30(j) (noting that a food may be affirmed as GRAS subject to "specific limitations" and that "[a]ny use of an ingredient not in full compliance with each such established limitation shall require a food additive regulation."); 21 C.F.R. § 1841(b)(2) ("If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food[s], the functional use[s] of the ingredient, and the level[s] of use."). *See also* Noah & Merrill, 78 B.U. L. Rev. at 358 ("GRAS substances are not exempt from all FDA controls. For instance, users must comply with any specific usage limitations in a GRAS affirmation regulation."); 47 Fed. Reg. 53917 (Nov. 30, 1982) (noting in connection with the GRAS status of corn sugar, corn syrup, and invert sugar that "when the safety of possible expanded consumption of a substance cannot be ascertained, FDA usually proposes to establish specific limitations on use of the substance in the food categories listed in [21 C.F.R. 170 § .3(n)]"); 47 Fed. Reg. 53923 (Nov. 30, 1982) (same statement in connection with GRAS status of sucrose).

Indeed, while CSPI does not request here that FDA revoke the GRAS status of any added sugars, but instead seeks the more limited step of conditional GRAS status, FDA *has* on several occasions rescinded its GRAS determinations in light of evidence showing that the GRAS product was in fact unsafe under the conditions of intended use. For example:

- In 1969, FDA banned the use of cyclamate salts, previously considered GRAS, because they were implicated in the formation of bladder tumors in rats. *See* 34 Fed. Reg. 17063 (Oct. 21, 1969);
- In 1985, FDA banned cinnamyl anthranilate, a flavoring agent previously considered GRAS, after studies linked it to liver cancer in mice. 50 Fed. Reg. 42932 (Oct. 23, 1985); Government Accountability Office (GAO), *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to be Generally Recognized as Safe (GRAS)* (Feb. 2010) (hereafter, "GAO Report"), at 22;
- In 1986, FDA prohibited the use of sulfites, considered GRAS since 1959, on fresh fruits and vegetables intended to be served raw because of potentially severe allergic reactions to people with sulfite sensitivities. GAO Report at 22.

See also 36 Fed. Reg. 12109 (June 25, 1971) (proposing to revoke saccharin's GRAS status and substitute a provisional food additive amendment).

Despite those authorities, however, and as recognized in a 2010 report by the GAO mentioned above, "FDA has not systematically reconsidered the safety of substances considered to be GRAS as new scientific information has come to light" and has not given careful review to numerous citizen petitions urging FDA to reconsider GRAS determinations based on new scientific findings. *See* GAO Report at 20–26. The GAO report notes that FDA last reconsidered systematically the safety of GRAS substances in the 1970s and 1980s (*id.* at 20)—well before the studies discussed in the 2005 CSPI Petition and 2008 Update and in this Petition that demonstrate the myriad health and safety issues associated with the current high level of use of added sugars.[10] As this Petition demonstrates, this new scientific evidence regarding added sugars and the threat they pose to the public health, particularly when used in beverages, compels the conclusion that these products' GRAS status must be revisited and, specifically, conditioned on specific limitations that are designed to protect the public health and ensure the products' safe use.

C. Factual Background—the History of GRAS Status for Added Sugars and FDA's Promise to Revisit the Issue in the Event of Increased Dietary Consumption or New Scientific Information

FDA action relating to the GRAS status of added sugars dates back at least 17 years, and in most cases beyond 25 years.

In 1976, a committee of the Federation of American Societies for Experimental Biology ("FASEB") assessed whether corn sugar, corn syrup, invert sugar, and sucrose should be accorded GRAS status. The FASEB committee concluded that at the then-current levels of consumption (and, implicitly, considering the current body of scientific evidence) the only health risk from these products was their contribution to dental cavities.[11,12] The

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[10] FDA's failure to respond to CSPI's 1999 and 2005 petitions regarding added sugars is but one example of this inaction.

[11] "Evaluation of the Health Aspects of Sucrose as a Food Ingredient," Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology (1976) ("FASEB Sucrose Report"), at 14; and "Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients," Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology (1976) ("FASEB Dextrose Report"), at 17.

[12] It has been reported that the FASEB committee was led by biochemist George W. Irving Jr., who had previously served two years as chairman of the scientific advisory board of the International Sugar Research Foundation. It has also been reported that industry documents show that another committee member, Samuel Fomon, had received sugar-industry funding for three of the five years prior to the sugar review. Taubes G, Couzens CK. Big Sugar's Sweet Little Lies. Mother Jones. Nov.–Dec. 2012. http://www.motherjones.com/environment/2012/10/sugar-industry-lies-campaign; accessed Dec. 22, 2012.

Committee also acknowledged, however, that it was "relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health."[13] The Committee added that because "biological testing is dynamic . . . [it] cannot anticipate the results of experiments not yet conducted or those tests that may be reconducted, using new technologies. *These conclusions will need to be reviewed as new or better information becomes available.*"[14] The FASEB reports noted in particular that the committee lacked the data to determine whether an increase in consumption of added sugars would constitute a dietary hazard.[15]

In 1982, FDA published proposed rules to accord GRAS treatment to (1) corn sugar, corn syrup, and invert sugar, and (2) sucrose, indicating that the Agency, following the FASEB Committee reports, did not view these products as posing a risk to the public health at the existing levels of consumption.[16] Critically, however, FDA recognized in its proposed rules that "the safety of possible expanded consumption [of these substances] cannot be ascertained."[17] FDA indicated that while normally it would address such uncertainty by imposing "specific limitations" on the use of the GRAS substance in food categories under 21 C.F.R. § 170.3(n), in each of these cases, it would instead "undertake a new safety evaluation if total dietary consumption increases significantly."[18] FDA further committed in its proposed rules that if average annual per capita consumption levels "increase significantly *or* should new scientific evidence reveal that [the relevant added sugars] pose a potential hazard to public health, a new safety evaluation *will* be undertaken."[19]

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[13] FASEB Sucrose Report at 2; FASEB Dextrose Report at 2.

[14] FASEB Sucrose Report at 2 (emphasis added); FASEB Dextrose Report at 2 (emphasis added).

[15] FASEB Sucrose Report at 17; FASEB Dextrose Report at 14. FASEB's reports also acknowledged that "[i]nforming the consumer of the sugar content of foods by appropriate labeling could lead to judicious use of sweetened food. Choices would be made easier with a greater selection of less-sugared foods in the market place." Some 15 years later, Nutrition Facts panels disclosed to consumers the total sugars content of foods, but did not disclose the added-sugars content and did not set a Daily Value for added sugars. FASEB Sucrose Report at 16; FASEB Dextrose Report at 14.

[16] 47 Fed. Reg. 53917 (Nov. 30, 1982)(covering corn sugar, corn syrup, and invert sugar); 47 Fed. Reg. 53923 (Nov. 30, 1982) (covering sucrose).

[17] 47 Fed. Reg. at 53920; 47 Fed. Reg. at 53926.

[18] 47 Fed. Reg. at 53920-21; 47 Fed. Reg. at 53926-27.

[19] 47 Fed. Reg. at 53921 (emphasis added); 47 Fed. Reg. at 53927 (emphasis added).

In 1983, FDA formed a Sugars Task Force to further assess the safety of dietary sugars.[20] The Task Force published its report in 1986, supporting the GRAS treatment of the products covered in FDA's 1982 proposed rule. And in 1988, FDA published final rules affirming that the uses of corn sugar, corn syrup, invert sugar and sucrose in food are GRAS. 53 Fed. Reg. 44862 (Nov. 7, 1988). Once again, however, FDA emphasized that its determinations were based on *present* levels of consumption (and implicitly, on the existing data on which the safety determination was necessarily based). *Id.* at 44865 ("there is no conclusive evidence that sugars consumption *at present levels* poses a health hazard to the general public, other than a contribution to dental caries.") [emphasis added].

With regard to the newly marketed HFCS, FDA initially granted GRAS status to that product in 1983 (48 Fed. Reg. 5716 (Feb. 8, 1983)), but conditioned that grant on the completion of the ongoing 1983 review by the Sugars Task Force. In 1988, after GRAS status was accorded to corn syrup, corn sugar, invert sugar, and sucrose (see above), FDA proposed to affirm the GRAS status of HFCS. 53 Fed. Reg. 44904 (November 7, 1988). FDA reiterated in the proposed rule that its conclusion "is predicated on the assumption that the consumption and availability of total sugars will remain at current levels" (and implicitly, on the existing data on which the safety determination was necessarily based). 53 Fed. Reg. at 44907. In 1996, FDA issued a final rule declaring HFCS to be GRAS. 61 Fed. Reg. 43447 (Aug. 23, 1996).

Consumption of caloric sweeteners, according to USDA estimates, increased from 86.2g/day in 1982, when the FDA first proposed that sucrose, corn syrup, corn sugar, and invert sugar be declared GRAS, to 95.3g/day when the rule was finalized in 1988. Consumption then rose by 16.2 percent to its peak of 110.7g/day in 1999. It has since declined to 96.4g/day in 2010, slightly more than in 1988, but still appreciably more than in 1982.

D. Discussion

The information on which FDA relied to grant essentially unrestricted GRAS status to added sugars is antiquated and obsolete, as FDA itself recognized it might become. There simply cannot be said to be the needed level of consensus that the added sugars currently denominated GRAS are in fact safe as they are used today. It is time for the Agency to honor its 30-year-old commitment to review the GRAS status of added sugars and to adjust such status accordingly (at least for sucrose and HFCS) as well as to undertake other actions to ensure the safe use of both GRAS and non-GRAS added sugars in the future.

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[20] It has been reported that Walter Glinsmann, the task force's lead administrator, would later become a consultant to the Corn Refiners Association, which represents producers of HFCS. Taubes G, Couzens CK. Big Sugar's Sweet Little Lies. Mother Jones. Nov.–Dec. 2012. http://www.motherjones.com/environment/2012/10/sugar-industry-lies-campaign; accessed Dec. 22, 2012.

Since the FDA's review of these products three decades ago, a mountain of evidence has emerged to demonstrate that added sugars, at the levels they are currently consumed by Americans *today*, are harmful to the public health. Part of this change is due to changes in behavior: Americans' consumption of added sugars is different—*i.e.*, greater, especially from beverages—than it was in the 1970s and early 1980s (though consumption has declined since its peak in the late 1990s to the levels consumed in the late 1980s). Even more importantly, scientists have a better understanding of the linkages between the consumption of added sugars and certain serious and widespread diseases and diet quality. In any event, the evidence is clear that when consumed at current levels, added sugars pose significant health risks. That is why the U.S. government and other authorities have recommended that people greatly reduce their intake of added sugars. The current body of evidence provides precisely the kinds of "current scientific information" (21 C.F.R. § 170.6) and "new scientific evidence" (47 Fed. Reg. at 53921, 47 Fed. Reg. at 53927) on which FDA's reconsideration of GRAS status should—and FDA promised would – be based.

1. Current levels of consumption of all sugars added to foods are well above recommended levels

a. Sugars consumption

The U.S. Department of Agriculture ("USDA") estimates that in 2011 average per-capita loss-adjusted availability, its closest estimate to actual population consumption, of caloric sweeteners (mostly sugar and HFCS) was **96.4g (22.9 teaspoons or 386 calories)** per day (**14.8 percent of 2,604 calories**).[21] Similarly, an analysis of National Health and Nutrition Examination Survey ("NHANES") 2007–2008 data concluded that the average American over the age of 2 consumes **77 grams (18.3 teaspoons or 308 calories)** of added sugars per day (**14.7 percent of 2,100 calories**).[22] The differences between the USDA and NHANES estimates is presumably due to their very different methodologies.

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[21] USDA. Food availability (per capita) data system. http://www.ers.usda.gov/data-products/food-availability-(per-capita)-data-system.aspx; accessed August 24, 2012. Note that USDA's figures, which assume that 41 percent of sugars produced are lost prior to consumption, are crude estimates, not hard science. *See* Strom S. Nation's sweet tooth shrinks. The New York Times. Oct. 27, 2012.

[22] Welsh JA, Sharma AJ, Grellinger L, et al. Consumption of added sugars is decreasing in the United States. Am J Clin Nutr. 2011;94:726–34. Note that Welsh et al. reported a 23 percent decrease in added-sugars consumption based on NHANES data from 1999–2000 to 2007–2008. That decline is inconsistent with the 9.8 percent decrease in sugar production and consumption, based on USDA's figures. As Welsh et al. noted, dietary-recall surveys, such as NHANES, tend to underestimate food intake, especially by obese individuals and of less-healthful foods. They recognized that public concerns about obesity grew over the period of their study and that that "could have resulted in a greater underestimate of total added-sugar intake in the latter years of our study." Also, average loss-adjusted availability and consumption figures do not reflect the fact that many people, particularly teenaged boys

An analysis by Marriott et al. of NHANES 2003–2006 data found that 12.5 percent of all participants (four years and older)—equivalent to 36.4 million people in the general population—overall consumed more than 25 percent of their calories in the form of added sugars.[23] Using data from NHANES 2007–2008, Welsh found a similar result: 6.25 percent of the study population (over the age of two)—equivalent to 19.0 million people in the general population—consumed more than 25 percent and up to 30 percent of their calories from added sugars; 3.3 percent of the population—10.0 million people—consumed greater than 30 percent and up to 35 percent of their calories from added sugars; and 4.6 percent of the population—14.0 million people—consumed greater than 35 percent of their calories from added sugars. Thus, a total of 14.2 percent of the study population—equivalent to 41.6 million people in the general population—consumed more than 25 percent of their calories from added sugars.[24]

Teens and young adults consume considerably more added sugars than the population average. Welsh et al. analyzed NHANES data from 1999–2004 and found that daily consumption of added sugars by 2,157 adolescents (aged 12–18) was 21.4 percent of total calories.[25] Furthermore, 32.4 percent of the adolescents—9.2 million people[26]—consumed at least 25 percent of their calories from added sugars, including 18.4 percent—equivalent to 5.2 million people—who consumed at least 30 percent of calories from added sugars.

Marriott et al.'s analysis of NHANES 2003–2006 data, which found that 12.5 percent of all participants consumed more than 25 percent of their calories from added sugars, additionally found that 14.4 percent of males 9–13, 17.0 percent of males 14–18, and 18.1 percent of males 19–30 consumed more than 25 percent of their calories from added

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and young men, consume far more calories and sugar than the average. See below in this Petition, at 12–13.

[23] Marriott BP, Olsho L, Hadden L, et al. Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES), 2003–2006. Crit Rev Food Sci Nutr. 2010;50:228–58. (This study was funded by the industry-sponsored International Life Sciences Institute.)

[24] Welsh JA. Pers. Comm. Jan. 10, 2013. Based on a population of 304.1 million people as of July 1, 2008. Based on Howden LM, Meyer JA. Age and sex composition in the United States: 2010 Census Brief. Age and Sex Composition: 2010. U. S. Census Bureau, May 2011. http://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf; accessed Jan. 17, 2013.

[25] Welsh JA, Sharma A, Cunningham SA, et al. Consumption of added sugars and indicators of cardiovascular disease risk among US adolescents. Circulation. 2011 (Jan 25);123(3):249–57.

[26] Based on Howden LM, Meyer JA. *Op. cit.*

sugars.[23] Likewise, 20.3 percent of females 14–18 and 19.3 percent of females 19–30 consumed more than 25 percent of their calories from added sugars. Among the approximately 48 million[27] people aged 19 to 30 in the United States, 4.2 percent of males and 4.9 percent of females—about two million people—consumed more than 35 percent of their calories from added sugars. Of the people who consumed more than 25 percent of their calories from added sugars, 60.2 percent of the added sugars came from regular soft drinks and fruit ades/drinks, far more than from any other food category.

In follow-up analyses for the 2007–2008 NHANES, Welsh found that adolescents 12–18—about 30.0 million people—consumed an average of 17.6 percent of their calories from added sugars, with 22.2 percent (about 6.7 million people[28]) consuming more than 25 percent of calories from added sugars; young adults aged 19–28 (about 42.9 million people) consumed an average of 15.9 percent of their total calories from added sugars, with 16.3 percent—7.0 million people—consuming more than 25 percent of their calories from added sugars.[29,22] Thus, even though consumption of added sugars has been decreasing in the past decade,[22] huge numbers of people are consuming far more added sugars than is healthful.[30]

Finally, USDA's loss-adjusted food-availability data estimate that boys 12–19 consume 57.0 percent more added sugars, but only 25.2 percent more calories, than the average American. Men 20–39 consume 44.9 percent more added sugars, but only 31.6 percent more calories, than the average American.[31,32] In short, large numbers of Americans, especially adolescents and young adults, consume large amounts of sugar.

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[27] Based on Howden LM, Meyer JA. *Op. cit.*

[28] Based on Howden LM, Meyer JA. *Op. cit.*

[29] Pers. Comm. Welsh JA. Dec. 25, 2012. Similarly, Welsh and colleagues, using 2007–2008 NHANES data, found that teens 12–17 consumed 17.3 percent of their calories from added sugars.

[30] The estimates by Marriott et al. and Welsh et al. cited above are not directly comparable because of methodological differences (*e.g.*, the former used two days of survey data, the latter only one). Also, added-sugars consumption has declined modestly since 1999–2004.

[31] USDA. Commodity Consumption by Population Characteristics. Table 6: Nuts and Sweeteners Availability. (1999–2002) http://www.ers.usda.gov/data-products/commodity-consumption-by-population-characteristics.aspx; accessed Nov. 10, 2012.

[32] Wright JD, Wang CY, Kennedy-Stephenson J, et al. Dietary intake of ten key nutrients for public health, United States: 1999–2000. Advance data from vital and health statistics; No. 334. Hyattsville, Maryland: National Center for Health Statistics. 2003. http://www.cdc.gov/nchs/data/ad/ad334.pdf; accessed Nov. 10, 2012.

b. SSB consumption

The 2010 Dietary Guidelines for Americans indicates that almost 50 percent of added sugars come from sugar-sweetened beverages (SSB), including soda pop, fruit drinks, energy drinks, sports drinks, and tea.[6] Sales of non-diet[33] carbonated soft drinks steadily rose from about 11 gallons (equivalent to 117 12 oz. cans) per capita in the mid-1950s[34] to 40.5 gallons (432 12 oz. cans) in 1998, the year of peak consumption.[35] Since then, sales slid back to 31.3 gallons (334 12 oz. cans) per capita in 2011.[36] A portion of that sales decline has been offset by increases in sports drinks, energy drinks, and teas.

Those sales figures from industry sources are averages, which inevitably hide information about heavy consumers and demographic sub-groups. The Centers for Disease Control and Prevention (CDC) found, on the basis of 2005–2008 NHANES data, that on a given day, half the U.S. population over two years old does not consume any SSB, another 25 percent consumes some sugar drinks but less than 200 calories' worth (about 16 oz.), another 25 percent consumes at least 200 calories' worth, including 5 percent who consume at least 567 calories' worth (45 oz. or almost four typical cans of soda) of SSB. CDC also found that adults with an income under 130 percent of the poverty income ratio (PIR) consumed twice their percentage of calories from SSB as people at or over 350 percent of the PIR. (The differences among people under 20 were smaller.) CDC also found that among adults, Mexican Americans and non-Hispanic blacks consumed about 60 percent more of their daily calories from SSB compared to non-Hispanic whites. (Again, the differences in people of different races under 20 were smaller.) Age also makes a big difference in SSB consumption. For instance, males between 12 and 39 years old consume 48 percent more calories from SSB than the average male, while boys 6–11 consume 20 percent fewer calories, men 40–59 consume 11 percent fewer calories, and men over 60 consume 61 percent fewer calories than the average. And gender makes a big difference: females 2 and older consume 42 percent fewer calories from SSB than males.[37]

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[33] Percentages of drinks that were non-caloric in 1998 and 2011 are estimates from Beverage Digest.

[34] National Soft Drink Association. Sales survey of the soft drink industry 1983.

[35] Beverage Digest. 1998 Top 10 soft drink companies and brands. http://www.beverage-digest.com/editorial/990212s.html; accessed Feb. 6, 2013.

[36] Beverage Digest. U.S. beverage results for 2011. http://beverage-digest.com/pdf/top-10_2012.pdf; accessed Feb. 6, 2013.

[37] Ogden CL, Kit BK, Carroll MD, et al. Consumption of sugar drinks in the United States, 2005–2008. NCHS data brief, no 71. Hyattsville, MD: National Center for Health Statistics. 2011.

c. Recommended consumption of added sugars

The current consumption levels of added sugars, partly due to SSB consumption, discussed above are significantly greater than the levels recommended by public health experts, including the U.S. Government.

- USDA offered perhaps the first governmental recommendation for added-sugar consumption in "Food Guide Pyramid," a 1993 brochure that recommended limiting daily consumption to 10 teaspoons (42 grams or 168 calories)—8.4 percent of total calories—for someone consuming a 2,000-calorie diet.[38] Thus, USDA recommended a level of consumption slightly over one-half of current *population-average* levels (8.4 percent of total calories versus 14 to 15 percent). USDA noted that complying with that 10 teaspoon recommendation would result in adherence to one of the seven dietary guidelines—"use sugars only in moderation"— that will help Americans "enjoy better health and reduce your chances of getting certain diseases.'"[39]
- In 2003, the World Health Organization recommended that people consume less than 10 percent of their total calories from "free" sugars, which includes added sugars and the sugars in fruit juices, honey, and syrups. Under that recommendation, a person consuming 10 percent of 2,000 calories in free sugars could consume up to 50g (11.9 teaspoons or 200 calories), of sugars per day.[40] (The British Food Standards Agency subsequently also recommended that people consume under 10 percent of their calories from "free sugars," which includes fruit juice.[41])
- Since 2003, experts have recommended even lower intakes of added sugar, leading to an even greater gulf between recommendations for a healthy diet and the reality of Americans' overconsumption of added sugars. Beginning in 2005, the Dietary Guidelines for Americans ("DGA"), identified the foods and calories needed to fulfill the nutrient requirements of people of both sexes and different

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[38] USDA. The Food Guide Pyramid Home and Garden Bulletin No, 252. (Aug. 1992)(rev'd Oct. 1996 at 17) The recommended sugar intakes cited here were interpolated from the information provided in the Bulletin (6 teaspoons for a 1,600-calorie diet, 12 teaspoons for a 2,200-calorie diet, and 18 teaspoons for a 2,800-calorie diet).

[39] *Id.* at 1.

[40] World Health Organization. Diet, Nutrition, and the Prevention of Chronic Diseases. WHO Technical Report Series 916. 2003. http://whqlibdoc.who.int/trs/who_trs_916.pdf; accessed April 1, 2012.

[41] Food Standards Agency. Rationale and discussion of the 15 g high sugars criterion within the FSA signposting scheme. http://www.food.gov.uk/multimedia/pdfs/paperexpert.pdf; accessed Dec. 23, 2012.

ages. By subtracting the calorie content of essential, nutritious foods from the recommended total daily calorie intake, the authors of the DGA calculated the number of extra, "discretionary" calories that could be expended on solid fats and added sugars (and alcohol). About half of those discretionary calories are then dedicated to added sugars to reach a recommendation on the amount of added-sugar consumption that is consistent with a healthy diet. The 2010 DGA, for example, recommends that a person consuming 2,000 calories per day should not consume more than 258 calories from solid fats and added sugar; dividing those calories equally between added sugars and solid fats indicates a limit of about 129 calories from sugars (32.3 grams or 7.7 teaspoons). That amounts to 6.5 percent of calories—or about 60 percent less than actual estimated *population-average* consumption levels.[42]

- Similarly, in 2009, the American Heart Association (AHA) recommended that most American women should consume no more than 100 calories (25g or 6.0 teaspoons of added sugars) per day and that most American men should consume no more than 150 calories (37.5g or 8.9 teaspoons) per day from added sugars.[43] That is equivalent to 5.6 percent to 6.8 percent of total calories (based on intakes of 1,800 calories for women and 2,200 for men).[44] The Heart Association's average recommended intake of 31g is one-third of what USDA estimates that Americans consume and two-fifths of what the 2007-2008 NHANES data found. The recommendation for all males and females combined, 6.2 percent of calories, is almost 60 percent lower than current consumption of 14.8 percent (average based on USDA and NHANES estimates).

Dietary intakes of added sugars by different gender/age (4 years and up) groups (from NHANES 2003–2006) can be compared to the intakes recommended by the DGA (see Appendix 1). In making those comparisons, we assumed a sedentary lifestyle, chose mid-points of estimated calorie needs, and allotted half of the "discretionary calories" to added sugars. Based on those assumptions, most gender/age groups consume three times the recommended levels of added sugars.

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[42] Dietary Guidelines for Americans, *op. cit.*, Appendix 7. http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/Appendices.pdf; accessed July 9, 2012.

[43] Johnson RK, Appel LJ, Brands M, et al. Dietary sugars intake and cardiovascular health." A Scientific Statement from the American Heart Association. Circulation. 2009;120:1011-20.

[44] The AHA provided examples of added-sugars allowances for people of several different ages and levels of physical activity. Thus, a sedentary woman 71 to 75 years old should consume no more than 3 teaspoons (3.0 percent of calories) of added sugars, while an active man, 21 to 25 years old, could consume as many as 18 teaspoons (9.6 percent of calories) of added sugars.

Taken together, the above data show that current consumption of added sugars is about 18–23 teaspoons per day, or about 15 percent of calories, for an average person over 2 years old, with much higher levels of consumption for many people. Health authorities recommend, depending on the demographic group, that no more than about 3–10 percent of calories come from added sugars. As noted above, for someone consuming 2,000 calories per day, the DGA suggests consuming no more than 7.7 teaspoons (32.3 grams or 6.5 percent of calories) of added sugars. For someone consuming 15 percent of their calories (current average consumption) from added sugars, achieving the recommended goal would require almost a 60 percent reduction in consumption.[45,46]

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[45] In 2002, the Institute of Medicine (IOM) published Dietary Reference Intakes [DRI] for energy, carbohydrate, and other nutrients. (Dietary Reference Intakes [DRI] for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids. National Academy of Sciences, Institute of Medicine; Food and Nutrition Board, Sept. 2002.) The advice for added sugars was based on nutrient dilution: how much sugar could one consume before experiencing reductions in intakes of essential nutrients. While the IOM report stated that "a maximal intake of 25 percent or less of energy from added sugars is suggested," IOM President Harvey Fineberg later qualified that statement in an April 15, 2003, letter to Secretary of Health and Human Services Tommy Thompson, noting:

> This language is not meant to convey a desirable or even acceptable standard intake. The report states that persons whose intake of added sugars is 25 percent or more of total calories are more likely to have poorer intakes of important essential nutrients. It does not address the issue that added sugar intakes at 25 percent or even well below it, may well have significant implications for caloric balance and weight control. Interpretations suggesting that a sugar intake of 25 percent of total calories is endorsed by the Institute's report are incorrect.

Also, as noted in the text above, tens of millions of people consume more than 25 percent of their calories from added sugars (with millions of those consuming more than 35 percent of their calories from added sugars), and, with data that the IOM committee did not have, each 5 percent increase in added sugars above the 0–5 percent group was associated with decreased nutrient intake.

[46] Consumption of sugary drinks and added sugars has declined moderately over the past decade (data from USDA's loss-adjusted food availability database; Beverage Digest; Beverage Marketing Corporation; and Welsh JA, Sharma AJ, Grellinger L, et al. *op. cit.*), but Americans still consume far more added sugars than is recommended and is safe. To dispute the link between soft-drinks and obesity, some soft-drink industry officials contend that consumption of soft-drinks has been declining while obesity rates have been rising. In fact, the decline in soft-drink consumption parallels an apparent leveling off of obesity rates, as discussed elsewhere in this petition.

The wide gap between the actual levels and recommended levels of consumption of added sugars *demands* the GRAS review that FDA promised in 1982, along with remedial actions to encourage healthier diets.

2. Current levels of consumption of added sugars can cause serious health problems.

Since 1982 considerably more evidence has emerged to show that added-sugar consumption at current levels not only detracts from a diet containing adequate levels of essential nutrients and dietary fiber, but can also cause a multitude of serious health problems. Some of those problems are on the rise in the United States, a development that parallels the increased consumption of added sugars.

a. Added sugars contribute to obesity and overweight.

Obesity is a major problem in the United States, with rates of overweight and obesity far higher now than in 1980. Obesity (Body Mass Index (BMI) ≥95th percentile of the BMI-for-age growth charts) rates in children 6–19 were almost level between 1963–1965 and 1976–1980, but then tripled.[47] Likewise, the prevalence of adult obesity (BMI ≥30 kg/m^2) was almost level between 1960–1962 and 1976–1980, but has since more than doubled.[48] The rates of extreme obesity (BMI>40 kg/m^2) in adults 20–74 rose six-fold between 1960–1962 and 2007–2008. While increases in obesity rates in children and adults may have moderated in the past decade,[48,49] about one-third of children and two-thirds of adults are overweight or obese.[50,49] The prevalence of obesity is particularly high

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[47] Ogden C, Carroll M. Centers for Disease Control and Prevention. Prevalence of obesity among children and adolescents: United States, trends 1963–1965 through 2007–2008. June 2010. http://www.cdc.gov/nchs/data/hestat/obesity_child_07_08/obesity_child_07_08.pdf; accessed Feb. 7, 2013.

[48] Ogden CL, Carroll MD. Centers for Disease Control and Prevention. Prevalence of overweight, obesity, and extreme obesity among adults: United States, trends 1960–1962 Through 2007–2008. June 2010. http://www.cdc.gov/nchs/data/hestat/obesity_adult_07_08/obesity_adult_07_08.pdf; accessed Feb. 7, 2013.

[49] Flegal ML, Carroll MD, Kit BK, et al. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999–2010. JAMA. 2012;307(5):491-7.

[50] Ogden CL, Carroll MD, Kit BK, et al. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999–2010. JAMA. 2012;307(5):483-90.

among Mexican American and non-Hispanic black children and women.[51,52] Currently, more than 80 percent of African American women are overweight or obese.[49]

Obesity is a risk factor for cardiovascular disease, hypertension, diabetes, cancer, and premature death.[6] Obesity costs America about $150 billion annually in higher medical costs[53] and $73 billion annually in reduced productivity.[54] Beyond those dollar costs are the significant effects of pervasive and powerful weight stigma that affects the lives of overweight individuals in education, healthcare, employment, and other settings.[55] All those costs are likely to increase greatly as the present generation of obese children advances to middle age.

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[51] Flegal ML, Carroll MD, Ogden CL, et al. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010;303:235–41.

[52] Ogden CL, Carroll MD, Curtin LR, et al. Prevalence of high body mass index in US children and adolescents, 2007–2008. JAMA. 2010;303:242–9.

[53] Finkelstein EA, Trogdon JG, Cohen JW, et al. Annual medical spending attributable to obesity: Payer- and service-specific estimates. *Health Affairs.* 2009;28(5):w822-31.

[54] Finkelstein EA, DiBonaventura MD, Burgess SM, et al. The costs of obesity in the workplace. J Occup Environ Med. 2010 Oct;52(10):971-6.

[55] Puhl RM, Heuer CA. The stigma of obesity: a review and update. Obesity (Silver Spring). 2009 May;17(5):941-64.

i. Cohort studies

A consistent and growing body of evidence indicates that consumption of sugar-sweetened beverages (SSBs) increases the risk of overweight, obesity, or weight gain in children and adults.[56,57,58,59, 60]

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[56] Sugar-sweetened beverages include non-diet carbonated soft drinks, fruit ades, fruit drinks, sports drinks, energy drinks, vitamin-fortified drinks, sweetened iced tea, and other beverages with added sugars.

[57] Hu FB, Malik VS. Sugar-sweetened beverages and risk of obesity and type 2 diabetes: epidemiologic evidence. Physiol Behav. 2010(Apr 26);100(1):47–54.

[58] Malik VS, Schulze MB, Hu FB. Intake of sugar-sweetened beverages and weight gain: a systematic review. Am J Clin Nutr. 2006;84:274–88.

[59] It is critical that any review exclude studies that adjust for total calorie intake, because consumption of SSBs appears to cause weight gain by increasing calorie intake. Studies that adjust for calorie intake are essentially comparing the BMI of SSB drinkers to SSB non-drinkers who consume an equal number of calories. Not surprisingly, when researchers adjust for total calorie intake, the association between SSB intake and weight or weight gain disappears. For example, a 2009 meta-analysis did not find a link between SSBs and weight in children. Forshee RA, Anderson PA, Storey ML. Sugar-sweetened beverages and body mass index in children and adolescents: a meta-analysis. Am J Clin Nutr. 2008;87:1662–71. (The authors of that report were employed by a research center that was partially funded by Coca-Cola Co. and PepsiCo, and one author was subsequently employed by the American Beverage Association. *Id.*) However, when other researchers re-analyzed the data including only studies with data that were not adjusted for weight, consumption of one 12 oz. serving of SSB per day was associated with an increase of 0.08 BMI units. Malik VS, Willett WC, Hu FB, et al. Sugar-sweetened beverages and BMI in children and adolescents: reanalyses of a meta-analysis. Am J Clin Nutr. 2009;89(1):438–9.

[60] Scientists (with ties to the food industry) have criticized some of the evidence linking SSBs to health. For example, a Coca-Cola-funded "systematic review" of the "quality of reviews on sugar-sweetened beverages and health outcomes" concluded that "the quality of reviews with positive conclusions and reviews without positive conclusions were, on average, equally poor." Weed DL, Althuis MD, Mink PJ. Quality of reviews on sugar-sweetened beverages and health outcomes: a systematic review. Am J Clin Nutr. 2011;94:1340–7. However, an accompanying editorial said that the industry-funded paper was severely flawed. For example, by lumping narrative reviews together with systematic reviews, the paper reached a "spurious conclusion" and "created a distorted view of the state of the literature on SSBs and health outcomes." Malik VS, Hu FB. Sugar-sweetened beverages and health: where does the evidence stand? Am J Clin Nutr. 2011;94:1161–2. Also, the editorial noted that an industry-supported meta-analysis (previous footnote) of

The evidence linking SSBs to weight gain led the 2010 Dietary Guidelines Advisory Committee to conclude that "strong evidence supports the conclusion that greater intake of sugar-sweetened beverages is associated with increased adiposity in children."[61] The committee's conclusion was based on a review by USDA's Nutrition Evidence Library of studies published between 2004 and 2009, including two randomized controlled trials and 17 longitudinal studies.[62] Furthermore, the Committee recommended that the "consumption of sugar-sweetened beverages in childhood should be discouraged (1) because of the positive association with increased adiposity; and (2) because of the need to replace empty calories with nutrient- rich energy for optimal growth and development."[63]

Similar results have been observed in cohorts of adults.

- When researchers tracked more than 50,000 healthy women for four years, they found that weight gain was greatest (about 10 pounds) among women who went from drinking no more than one SSB a week to at least one a day.[64]
- In the Black Women's Health Study, which tracked more than 40,000 healthy women for six years, those who went from drinking no more than one serving of SSB per week to at least one serving per day gained the most weight (15 pounds), while those who reduced their intake gained the least weight (9 pounds).[65]
- Among roughly 4,000 men and women in the Framingham Offspring Study, those who consumed at least one soft drink a day had a 35 percent higher risk of obesity over the next four years, compared to those who drank no soft drinks.[66]

SSBs and BMI in children and adolescents was one of the few reviews that Weed, et al. rated highly, yet it had "gross errors that fundamentally changed the findings."

[61] Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, at D1–23.

[62] Is intake of sugar-sweetened beverages associated with adiposity in children? http://www.nutritionevidencelibrary.com/evidence.cfm?evidence_summary_id=250363.

[63] *Id.* at D1-24.

[64] Schulze MB, Manson JE, Ludwig DS, et al. Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. JAMA. 2004;292:927–34.

[65] Palmer JR, Boggs DA, Krishnan S, et al. Sugar-sweetened beverages and incidence of type 2 diabetes mellitus in African American women. Arch Intern Med. 2008(Jul 28);168(14):1487–92.

[66] Dhingra R, Sullivan L, Jacques PF, et al. Soft drink consumption and risk of developing cardiometabolic risk factors and the metabolic syndrome in middle-aged adults in the community. Circulation. 2007(Jul 31);116(5):480–8.

- In the PREMIER study, people who reduced their intake of SSBs by one serving a day lost one pound after six months and 1.4 pounds after 18 months.[67] However, that study might have underestimated the impact of SSBs on weight because the main findings were adjusted for calorie intake.

A recent study of a different kind examined 32 gene variations linked to obesity in roughly 28,000 women and men who were not obese when the study started. For every 10 obesity-linked gene variations the participants had, the risk of becoming obese over the next 6 to 18 years was three times higher in those who consumed at least one sugary beverage a day than in those who drank less than one a month.[68]

In a meta-analysis of five cohort studies of children, those who consumed at least one SSB per day when the studies started had a 55 percent higher risk of becoming overweight than those who consumed little or no SSBs.[69] An editorial accompanying the meta-analysis concluded that "reducing the amount of sugar consumed in drinks deserves special attention because of the strength of the evidence and the ease with which excessive sugar is consumed in this form."[70]

ii. Clinical trials

The evidence from the above prospective cohort studies on sugary drinks and body weight is consistent with clinical trials lasting three weeks to 1½ years.

- In the longest and largest double-blind, randomized intervention trial done to date, Dutch researchers randomly assigned 641 normal-weight children aged 4 to 12 who typically drank sugary beverages to receive one 8 oz. can a day of a beverage sweetened with either sugar (104 calories, about the same as a cup of Coca-Cola) or artificial sweeteners (0 calories). After 1½ years, body weight, BMI, waist size, and fat mass increased more in the youngsters who got the

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[67] Chen L, Appel LJ, Loria C, et al. Reduction in consumption of sugar-sweetened beverages is associated with weight loss: the PREMIER trial. Am J Clin Nutr. 2009(May);89(5):1299–306.

[68] Qi Q, Chu AY, Kang JH, et al. Sugar-sweetened beverages and genetic risk of obesity. N Engl J Med. 2012(Oct 11);367(15):1387–96.

[69] Many of the studies had small sample sizes, which may have limited their power to detect a significant change in weight. However, when the results were combined in a meta-analysis, the overall effect was significant. 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. 345:e7492. doi: 10.1136/bmj.e7492.

[70] Willett W, Ludwig DS. Science souring on sugar. BMJ. 2013 Jan 15;346:e8077. doi: 10.1136/bmj.e8077.

sugary drinks. "Children in the United States consume on average almost three times as many calories from sugar-sweetened beverages as the amount provided in our trial," noted the authors.[71]

- Boston Children's Hospital scientists studied 224 overweight or obese 9th- or 10th-graders who regularly drank at least one 12 oz. serving of sugary beverages or fruit juice a day. Half got home deliveries of calorie-free beverages (water or diet drinks) plus phone calls and visits encouraging them to switch to calorie-free drinks. The other half (the control group) was given two $50 gift cards to a local supermarket. After one year, the gift-card recipients had gained more weight than those who got the calorie-free drinks.[72] A previous pilot trial assigned 103 adolescents aged 13 to 18 who regularly consumed SSBs to either receive home delivery of non-caloric beverages or to continue their usual beverage habits for 25 weeks. Among the participants in the highest BMI tertile, BMI decreased in the group that received the non-caloric beverages, leading to a significant difference in BMI change between groups.[73]
- Researchers randomly assigned 29 classes (644 children aged 7–11) in six British primary schools to get either advice on reducing consumption of "fizzy" drinks or to a control group. After one year, the percentage of overweight and obese children increased by 7.5 percent in the control group and decreased by 0.2 percent in the intervention group.[74]
- University of North Carolina researchers assigned 318 overweight or obese adults who reported consuming at least 280 calories of caloric beverages a day (including soda, juice, sports drinks, etc.) to one of three groups: one group was provided with water and encouragement to switch to non-caloric beverages; a second group was provided with diet drinks and the same encouragement; and a third group, the "attention control," was provided with equivalent advice on weight loss, weigh-ins, and feedback on their efforts to lose weight. Although weight loss was not significantly different among the three groups at six months, the participants assigned to non-caloric beverages were twice as likely to

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[71] de Ruyter JC, Olthof MR, Seidell JC, et al. A trial of sugar-free or sugar-sweetened beverages and body weight in children. N Engl J Med. 2012 Oct 11;367(15):1397–406.

[72] Ebbeling CB, Feldman HA, Chomitz VR, et al. A randomized trial of sugar-sweetened beverages and adolescent body weight. N Engl J Med. 2012 Oct 11;367(15):1407–16.

[73] Ebbeling CB, Feldman HA, Osganian SK, et al. Effects of decreasing sugar-sweetened beverage consumption on body weight in adolescents: a randomized, controlled pilot study. Pediatrics. 2006 Mar;117(3):673–80.

[74] James J, Thomas P, Cavan D, et al. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. BMJ. 2004(May 22);328(7450):1237.

achieve at least a 5 percent weight loss as those in the "attention control" group.[75,76]

Several smaller studies also randomly assigned people to consume either SSBs (containing sugar or HFCS) or diet beverages (typically sweetened with aspartame):

- Researchers gave 30 normal-weight adults four 10 oz. bottles of cola sweetened with either HFCS (which supplied 530 calories) or aspartame (0 calories) a day. A significant increase in weight and calorie intake (13 percent) occurred after three weeks on HFCS drinks, while weight decreased (significantly in males) and calories fell (by 7 percent) during three weeks on diet soda.[77]
- Researchers gave 41 overweight subjects daily supplements of beverages and foods made with either sucrose (152 grams a day) or artificial sweeteners. The participants were allowed to consume unlimited quantities of food in addition to the supplements. Roughly 70 percent of the sucrose came from drinks and 30 percent came from yogurt, marmalade, ice cream and stewed fruits. After 10 weeks, the sucrose group had increased its average intake by roughly 360 calories a day and gained 3.5 pounds, while the artificial-sweetener group lost 2.2 pounds.[78]
- In a similar study, researchers randomly assigned 23 overweight people to consume beverages, yogurts, marmalade, ice cream, and stewed fruits sweetened with either sucrose (2 g/kg body weight) or artificial sweeteners. After 10 weeks of daily consumption, the sucrose group had gained 3.1 pounds,

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[75] The two beverage replacement groups reduced their intake by two servings a day, while the control group members reduced their caloric beverage consumption by one serving a day. The study may have been underpowered to see a significant difference in weight loss, which averaged 5.5 pounds in the diet-beverage group, 4.5 pounds in the water group, and 3.9 pounds in the control group.

[76] Tate DF, Turner-McGrievy G, Lyons E, et al. Replacing caloric beverages with water or diet beverages for weight loss in adults: main results of the Choose Healthy Options Consciously Everyday (CHOICE) randomized clinical trial. Am J Clin Nutr. 2012;95:555–63.

[77] Tordoff MG, Alleva AM. Effect of drinking soda sweetened with aspartame or HFCS on food intake and body weight. Am J Clin Nutr. 1990;51(6):963–9.

[78] Raben A, Vasilaras TH, Møller AC, et al. Sucrose compared with artificial sweeteners: different effects on ad libitum food intake and body weight after 10 wk of supplementation in overweight subjects. Am J Clin Nutr. 2002;76:721–9.

while the artificial sweetener group had lost 3.3 pounds. According to dietary records, total calorie intake was 32 percent higher in the sucrose group.[79,80]

- A recent systematic review and meta-analysis of 30 randomized controlled trials examined the association between sugars and weight. Many of the studies specifically examined the role of SSBs. In trials of adults whose calories were not restricted, reducing the intake of sugars was associated with a significant weight loss (0.80 kg or 1.71 lbs), while increasing the intake of sugars was associated with a significant weight gain (0.75 kg or 1.65 lbs) over periods that ranged from two weeks to six months. The review provides "consistent evidence that increasing or decreasing intake of dietary sugars from current levels of intake is associated with corresponding changes in body weight in adults," according to the authors.[81]

Studies indicate that people who consume moderate to large amounts of added sugars (especially in liquids) are especially prone to gain weight because they do not compensate well for those liquid calories in subsequent meals. That is, calories from beverages can be less satiating than the same number of calories from foods. For example, when people were given 450 calories' worth of soft drinks to consume throughout each day for four weeks, they consumed more total calories per day than when they were given 450 calories' worth of jelly beans. They also gained a small but statistically significant amount of weight during the four weeks on the soft drinks.[82] Similarly, when researchers tested liquid versus solid forms of high-carbohydrate (watermelon vs. watermelon juice), high-

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[79] Raben A, Møller BK, Flint A, et al. Increased postprandial glycaemia, insulinemia, and lipidemia after 10 weeks' sucrose-rich diet compared to an artificially sweetened diet: a randomized controlled trial. Food Nutr. Res. 2011;55. doi: 10.3402/fnr.v55i0.5961.

[80] A recent systematic review (co-authored in part by scientists with unrestricted grants from Coca-Cola Co.) concluded that "fructose does not seem to cause weight gain when it is substituted for other carbohydrates in diets providing similar calories. Fructose at high doses that provided excess calories modestly increased body weight, an effect that may be due to the extra calories rather than the fructose." Sievenpiper JL, de Souza RJ, Mirrahimi A, et al. Effect of fructose on body weight in controlled feeding trials. A systematic review and meta-analysis. Ann Intern Med. 2012;156(4):291–304. This review may not be entirely relevant given that it excluded studies that used HFCS or sucrose—the major added sugars in the diet—and included studies in which fruit was a source of fructose. The review is also of little value because it side-steps a key question: whether sugary beverages or foods promote weight gain by leading people to consume excess calories.

[81] 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. 345:e7492. doi: 10.1136/bmj.e7492.

[82] DiMeglio DP, Mattes RD. Liquid versus solid carbohydrate: effects on food intake and body weight. Int J Obes. 2000;24:794–800.

protein (cheese vs. milk), and high-fat (coconut meat vs. coconut milk) foods on 120 lean and obese adults, daily calorie intakes were higher when subjects consumed the liquid forms of food.[83,84] Studies also found that fruit juice is less satiating than whole fruit or puree.[85,86] In addition, studies found that when people are given a caloric beverage shortly before or with a meal, they consume more total calories (from the beverage and meal) than when they consume a calorie-free drink, such as water, before or with a meal.[87,88] This evidence supports the results of longer-term studies indicating that liquid calories lead to increases in total calorie intake and weight.

Researchers suggest that differences in neural and humoral signals, chewing, gastric distention, GI transit, calorie extraction, and expectations may lead to higher calorie intakes when foods are consumed in liquid rather than solid form.[89,90] As the authors of one review concluded:

> [T]here is increasing evidence that liquid carbohydrates are less satiating and energy compensation at subsequent meals is incomplete and imprecise, which leads to increased energy intake.... Current recommendations call for restricted intake of beverages high in added sugars to reduce the risk of excessive weight gain and cardiometabolic disorders.[90]

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[83] Daily calorie intakes were 12 percent higher when people got watermelon juice instead of watermelon, 15 percent higher when people got milk instead of cheese, and 19 percent higher when people got coconut milk instead of coconut meat.

[84] Mourao DM, Bressan J, Campbell WW, et al. Effects of food form on appetite and energy intake in lean and obese young adults. International Journal of Obesity. 2007;31:1688–95.

[85] Haber GB, Heaton KW, Murphy D, et al. Depletion and disruption of dietary fibre; effects on satiety, plasma-glucose, and serum-insulin. Lancet. 1977;2:679–82.

[86] Bolton RP, Heaton KW, Burroughs LF. The role of dietary fiber in satiety, glucose, and insulin; studies with fruit and fruit juice. Am J Clin Nutr. 1981;34:211–7.

[87] DellaValle DM, Roe LS, Rolls BJ. Does the consumption of caloric and non-caloric beverages with a meal affect energy intake? Appetite. 2005;44:187–93.

[88] Flood JE, Roe LS, Rolls BJ. The Effect of increased beverage portion size on energy intake at a meal. J Am Diet Assoc. 2006;106:1984–90.

[89] Mattes RD. Beverages and positive energy balance: the menace is the medium. International Journal of Obesity. 2006;30:S60–5.

[90] Pan A, Hu FB. Effects of carbohydrates on satiety: differences between liquid and solid food. Curr Op Clinl Nutr Metab Care. 2011;14:385–90.

In a guide to reducing consumption of SSBs, the CDC has explained why its scientists believe that SSBs contribute to weight gain:

> Several mechanisms have been proposed to explain the association between SSB consumption and obesity. First, individuals may fail to compensate for the added calories consumed as liquid and may result in excess intakes of sugar and calories. Second, the rapid drop in blood sugar that follows the insulin response to consumption of foods high in sugar increases hunger and may thereby increase food consumption. The third possible mechanism is the inability of fructose (a sugar found in commonly used sweeteners) to stimulate hormones that help regulate satiety. Fourth, the inborn human desire for the sweet taste can override normal satiety signals.[91]

Another line of evidence also indicates that fructose, specifically, may promote over-eating more than other carbohydrates. A recent study compared the results of magnetic resonance imaging (MRI) when 20 normal-weight volunteers were given 75 grams (300 calories) of either fructose or glucose.[92] Glucose, but not fructose, reduced cerebral blood flow (i.e., brain activity) in key regions of the brain that regulate appetite and reward (hypothalamus, insula, and striatum). Furthermore, glucose resulted in increased ratings of fullness and satiety, while fructose did not. "These findings support the conceptual framework that when the human brain is exposed to fructose, neurobiological pathways involved in appetite regulation are modulated, thereby promoting increased food intake," noted an editorial accompanying the study.[93] The implications of this study, "as well as the mounting evidence from epidemiologic, metabolic feeding, and animal studies, are that the advances in food processing and economic forces leading to increased intake of added sugar and accompanying fructose in US society are indeed extending the supersizing concept to the population's collective waistlines."[93]

Furthermore, in a study of overweight and obese men and women aged 40 to 72, those who consumed 25 percent of their calories from fructose for 10 weeks had a reduction in energy expenditure (calorie burning) that was not seen in a similar group that

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[91] Centers for Disease Control and Prevention. The CDC guide to strategies for reducing the consumption of sugar-sweetened beverages. March 2010. http://www.cdph.ca.gov/SiteCollectionDocuments/StratstoReduce_Sugar_Sweetened_Bevs.pdf; accessed Dec. 23, 2012.

[92] Page KA, Chan O, Arora J, et al. Effects of fructose vs glucose on regional cerebral blood flow in brain regions involved with appetite and reward pathways. JAMA. 2013;309(1):63–70.

[93] Purnell JQ, Fair DA. Fructose ingestion and cerebral, metabolic, and satiety responses. JAMA. 2013;309(1):85–6.

consumed 25 percent of their calories from glucose.[94] (While 25 percent of calories from sugar might seem like an extraordinarily high level, as discussed earlier about 14 million Americans are consuming more than 35 percent of their calories from added sugars, about half of that from fructose, so there is no real safety margin in current levels of consumption.) "These changes suggest that sustained fructose consumption may contribute to an overall reduction in energy expenditure, which could increase the risk for weight gain if energy intake is not adjusted downward accordingly," the researchers wrote.

An editorial accompanying two of the largest clinical trials cited above[71,72] on SSBs concluded that the evidence is strong enough to warrant changes in policy:

> These randomized, controlled studies—in particular, the study by de Ruyter et al.—provide a strong impetus to develop recommendations and policy decisions to limit consumption of sugar-sweetened beverages, especially those served at low cost and in excessive portions, to attempt to reverse the increase in childhood obesity.... The time has come to take action and strongly support and implement the recommendations from the Institute of Medicine, the American Heart Association, the Obesity Society, and many other organizations to reduce the consumption of sugar-sweetened beverages in both children and adults.[95]

b. Added sugars contribute to cardiovascular disease, diabetes, and the metabolic syndrome.

More than 2,200 Americans die of cardiovascular disease (CVD) each day, an average of one death every 39 seconds. About 150,000 Americans killed by CVD in 2008 were younger than 65 years of age.[96] In 2008, 33 percent of deaths due to CVD occurred before the age of 75, which is well below the average life expectancy in 2010 of 78.7 years.[97] Coronary heart disease caused 405,309 deaths in 2008—roughly one of every six deaths. Each year, an estimated 785,000 Americans will have a new heart attack, and about 470,000 will have a recurrent attack. In addition, an estimated 195,000 "silent" first

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[94] Cox CL, Stanhope KL, Schwarz JM, et al. Consumption of fructose-sweetened beverages for 10 weeks reduces net fat oxidation and energy expenditure in overweight/obese men and women. Eur J Clin Nutr. 2012(Feb);66(2):201–8.

[95] Caprio S. Calories from soft drinks—do they matter? N Engl J Med. 2012;367:1462–3.

[96] Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics—2012 update. Circulation. 2012;125:188–97. All figures in this paragraph came from that report, except where otherwise noted.

[97] Murphy SL, Xu J, Kochanek KD. Deaths: Preliminary Data for 2010. National vital statistics reports. 2012(Jan. 11);60(4):2–51. http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_04.pdf; accessed Aug. 11, 2012.

myocardial infarctions occur each year. About every 25 seconds, an American will have a coronary event, and roughly every minute, someone will die of one. The costs of heart and artery surgeries (coronary artery bypass grafts, percutaneous coronary angioplasties, diagnostic cardiac catheterization, coronary arteriography) alone in 2010 amounted to $22.6 billion.[98] Each year, roughly 795, 000 people have a new or recurrent stroke. In 2008, stroke accounted for about one of every 18 deaths in the United States. On average, once every 40 seconds someone in the United States has a stroke.

Diabetes affects 25.8 million Americans, including seven million people who are undiagnosed. In 2010, among Americans aged 65 and older, 10.9 million, or nearly 27 percent, had diabetes. In addition, an estimated 35 percent of adults—79 million Americans—have prediabetes. People with diabetes have two to four times the risk of heart disease and stroke compared to people without diabetes. Diabetes is the leading cause of kidney failure, non-traumatic amputations, and new cases of blindness among adults. In 2007 diabetes was estimated to be responsible for $116 billion in direct costs and $58 billion in indirect costs (disability, time lost from work, and premature mortality) annually.[99]

The metabolic syndrome (or insulin resistance syndrome) increases the risk of diabetes and heart disease. The syndrome is defined as the presence of any three of the five following conditions:

- waist measurement of 40 inches or more for men and 35 inches or more for women
- triglyceride levels of 150 milligrams per deciliter (mg/dL) or above, or taking medication for elevated triglyceride levels
- HDL, or "good," cholesterol level below 40 mg/dL for men and below 50 mg/dL for women, or taking medication for low HDL levels
- blood pressure levels of 130/85 or above, or taking medication for elevated blood pressure
- fasting blood glucose levels of 100 mg/dL or above, or taking medication for elevated blood glucose.[100]

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[98] Healthcare Cost & Utilization Project (HCUP), Agency for Healthcare Quality and Research, US Dept. Health and Human Services. http://hcupnet.ahrq.gov; accessed Dec. 22, 2012.

[99] Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA. 2011. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

[100] Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and management of the metabolic syndrome: an American Heart Association/National Heart, Lung, and Blood Institute scientific statement. Circulation. 2005;112:2735–52.

An estimated 35 to 40 percent of American adults have the metabolic syndrome, depending on the criteria used.[101] Insulin resistance may be the underlying cause of the metabolic syndrome. When people are insulin resistant, their muscle, fat, and liver cells do not respond properly to insulin, so they need more insulin to help glucose enter cells. The pancreas tries to keep up with the increased demand for insulin by producing more. Eventually, the pancreas fails to keep up with the body's need for insulin. Excess glucose builds up in the bloodstream, leading to diabetes. People with the metabolic syndrome who do not become diabetic still have a higher risk of heart disease.

A growing body of evidence indicates that consumption of SSBs increases the risk of cardiovascular disease, type 2 diabetes, and the metabolic syndrome. In prospective or cross-sectional studies, consumption of SSBs is associated with those conditions and the consumption of caloric sweeteners, whether in food or beverages, is associated with higher triglycerides and lower levels of HDL ("good") cholesterol. Furthermore, in clinical studies, the consumption of sugars, especially fructose, is associated with increases in visceral and liver fat and in triglycerides, glucose, insulin, and small, dense LDL cholesterol levels.

i. Cohort and cross-sectional studies

Heart disease and stroke. Several studies have found associations between SSB consumption and heart disease and stroke[102]:

- In the Health Professionals Follow-Up Study of more than 42,000 men, those who consumed at least 3.7 SSBs per week had a 20 percent higher risk of coronary heart disease than those who consumed no SSBs. (Those calculations were made *after* adjustment for BMI.) SSB consumption was associated with higher levels of triglycerides and lower levels of HDL cholesterol.[103]
- In the Nurses' Health Study involving more than 88,000 healthy women who were tracked for 24 years, those who consumed at least two SSBs a day had a 35 percent higher risk of coronary heart disease than those who consumed less

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[101] Alberti KGMM, Eckel RH, Grundy SM, et al. Harmonizing the Metabolic Syndrome. A Joint Interim Statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. Circulation. 2009;20:640–5.

[102] Note that these studies estimate the increased risk associated with SSBs *above and beyond* their impact on weight gain (and, in some cases, diabetes and calorie intake).

[103] de Koning L, Malik VS, Kellogg MD, et al. Sweetened beverage consumption, incident coronary heart disease, and biomarkers of risk in men. Circulation. 2012(Apr 10);125(14):1735–41.

than one SSB per month.[104] After adjustment for BMI, diabetes, and total calories, those who consumed at least two SSBs a day had a 21 percent higher risk.[105]

- Among 84,085 healthy women who were followed for 28 years in the Nurses' Health Study and 43,371 healthy men who were followed for 22 years in the Health Professionals Follow-Up Study, the risk of stroke increased by 12 percent for each serving of SSB consumed per day (after adjustment for BMI).[106]

Type 2 diabetes. Numerous studies have linked SSB consumption with diabetes.

- In the Nurses' Health Study, which tracked more than 90,000 women for eight years, those who consumed at least one SSB per day had an 83 percent higher risk of being diagnosed with type 2 diabetes than those who consumed less than one SSB per month. When the data were adjusted for BMI, the risk was 39 percent higher among women who drank at least one SSB per day.[64]
- Similarly, in the Black Women's Health Study, which monitored more than 40,000 women for 10 years, those who consumed at least two SSBs per day had a 24 percent higher risk of type 2 diabetes than those who consumed less than one SSB per month.[65] (The results were no longer statistically significant after adjusting for BMI, indicating that SSBs increase the risk of diabetes largely because they increase calorie intake and BMI.)
- When researchers tracked 40,389 men in the Health Professionals Follow-Up Study for 20 years, those who consumed at least 4.5 servings of SSBs per week had a 24 percent higher risk of diabetes than those who consumed none, after adjustment for BMI and other factors.[107]
- Among 43,580 men and women in the Singapore Chinese Health Study, those who consumed at least two soft drinks a week had a 42 percent higher risk of

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[104] Fung TT, Malik V, Rexrode KM, et al. Sweetened beverage consumption and risk of coronary heart disease in women. Am J Clin Nutr. 2009;89:1037–42.

[105] As described below, SSBs may increase the risk of heart disease by raising LDL cholesterol and worsening components of the metabolic syndrome (elevated triglycerides, low HDL cholesterol, increased visceral fat, and elevated blood pressure). The impact of SSBs on these risk factors would explain why SSB intake is associated with an increased risk of heart disease even after adjustment for BMI.

[106] Bernstein AM, de Koning L, Flint AJ, et al. Soda consumption and the risk of stroke in men and women. Am J Clin Nutr. 2012 May;95(5):1190–9.

[107] de Koning L, Malik VS, Rimm EB, et al. Sugar-sweetened and artificially sweetened beverage consumption and risk of type 2 diabetes in men. Am J Clin Nutr. 2011;93(6):1321–7.

diabetes than those who rarely consumed soft drinks.[108] After adjustment for BMI and calorie intake, the risk was 34 percent higher among those who drank at least two soft drinks a day.

- In a meta-analysis of the above four studies and four additional studies involving more than 310,000 people in total, those who consumed at least one to two servings of SSBs per day had a 26 percent higher risk of type 2 diabetes than those who consumed less than one serving per month.[109]

Metabolic syndrome. Several studies have linked SSB consumption with the metabolic syndrome.

- In a study that was part of the Framingham Offspring Study, which followed roughly 6,000 people for 4 years, those who consumed at least one soft drink a day had a 44 percent higher risk of being diagnosed with the metabolic syndrome than those who consumed less than one soft drink a day.[66,110]
- In a meta-analysis of the study above and two other studies that included more than 19,000 people in total, the risk of metabolic syndrome was 20 percent higher among those who consumed at least one SSB a day than among those who consumed none.[109]

Prospective cohort and cross-sectional studies have also linked sugar-sweetened beverages to *individual components* of the metabolic syndrome:

Triglycerides

Studies have consistently found an association between SSB (or added sugar consumption) and triglyceride levels:

- The consumption of total caloric sweeteners, whether in foods or beverages, was positively associated with higher triglyceride levels among 6,113 adults and 2,157 adolescents in the National Health and Nutrition Examination Survey (NHANES) 1999–2006.[111]

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[108] Odegaard AO, Koh W, Arakawa K, et al. Soft drink and juice consumption and risk of physician-diagnosed incident type 2 diabetes; the Singapore Chinese Health Study. Am J Epidemiol. 2010;171:701–8.

[109] Malik VS, Popkin BM, Bray GA, et al. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. Diabetes Care. 2010(Nov);33(11):2477–83.

[110] Although this analysis combined diet and sugar-sweetened soft drinks, the study authors suggest that most of the effect was due to regular soft drink consumption.

[111] Welsh JA, Sharma A, Abramson JL, et al. Caloric sweetener consumption and dyslipidemia among US adults. JAMA. 2010;303(15):1490–7.

- In the Framingham Offspring Study, which followed 6,154 adults for 4 years, those who consumed at least one soft drink a day had a 25 percent higher incidence of high triglyceride levels (≥1.7 mmol/L or on treatment) than those who consumed less than one soft drink a day.[66]
- When researchers tracked 2,627 adults who participated in the CARDIA (Coronary Artery Risk Development in Young Adults) study for 20 years, the risk of high triglycerides (150 mg/dL or higher) increased by 6 percent with each increase from one quartile of SSB intake to the next.[112]

HDL ("Good") Cholesterol

Studies have found an inverse relationship between SSB consumption and HDL cholesterol.

- The consumption of caloric sweeteners, whether in food or beverages, was associated with lower levels of HDL cholesterol among 6,113 adults and 2,157 adolescents participating in the NHANES.[111,25]
- Among participants in the Framingham Offspring Study, daily soft-drink consumers had a 32 percent higher risk of low levels of HDL cholesterol (<1.03 mmol/L for men or <1.3 mmol/L for women or on treatment) than those who consumed less than one soft drink a day.[66]

Hypertension

Several studies have found associations between SSB consumption and hypertension:

- In the Nurses' Health Studies I and II, women who consumed at least four glasses or cans of sugared colas per day had a 44 percent and 28 percent higher risk of incident hypertension, respectively, than infrequent consumers.[113]
- In the Framingham Offspring Study, people who consumed at least one soft drink per day had a non-significant 18 percent higher incidence of hypertension (≥135/85 mm Hg or on treatment) than those who consumed less than one a day.

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[112] Duffey KJ, Gordon-Larsen P, Steffen LM, et al. Drinking caloric beverages increases the risk of adverse cardiometabolic outcomes in the Coronary Artery Risk Development in Young Adults (CARDIA) Study. Am J Clin Nutr. 2010(Oct);92(4):954–9.

[113] Winkelmayer WC, Stampfer MJ, Willett WC, Curhan GC. Habitual caffeine intake and the risk of hypertension in women. JAMA. 2005;294: 2330–5.

- Among 2,639 adults who participated in the CARDIA study for 20 years, the risk of hypertension increased by 6 percent with each increase from one quartile of SSB intake to the next.[112]

Those findings are supported by a cross-sectional analysis of NHANES data that found a positive association between SSB intake and blood pressure in adolescents.[114]

Visceral fat

Excessive visceral, or deep abdominal, fat is associated with type 2 diabetes, heart disease, and the metabolic syndrome.[115] Recent studies have found that SSB or fructose consumption is associated with higher levels of visceral fat:

- In a cross-sectional study of 791 men and women aged 18 to 70, greater frequency of SSB was associated with increased visceral fat and waist circumference.[116]
- In a cross-sectional study of 559 adolescents aged 14 to 18, fructose from beverages and foods was associated with higher levels of visceral adipose fat.[117]
- Among 2,444 adults who participated in the CARDIA study for 20 years, the risk of a high waist circumference (over 40 inches for men or 35 inches for women) increased by 9 percent with each increase from one quartile of SSB intake to the next.[112]

ii. Clinical studies

Recent clinical studies have documented harmful effects of added sugars on risk factors for heart disease, diabetes, and the metabolic syndrome. Those risk factors include elevated levels of postprandial triglycerides, glucose, insulin, visceral fat, liver fat, and

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[114] Nguyen S, Choi HK, Lustig RH, et al. Sugar-sweetened beverages, serum uric acid, and blood pressure in adolescents. J Pediatr. 2009;154:807–13.

[115] Montague CT, O'Rahilly. Causes and consequences of visceral adiposity. Diabetes. 2000;49:883–8.

[116] Odegaard AO, Choh AC, Czerwinski SA, et al. Sugar-sweetened and diet beverages in relation to visceral adipose tissue. Obesity. (2011) doi:10.1038/oby.2011.277

[117] Pollock NK, Bundy V, Kanto W, et al. Greater fructose consumption is associated with cardiometabolic risk markers and visceral adiposity in adolescents. J Nutr. 2012;142:251–7.

small, dense LDL ("bad") cholesterol. Growing evidence suggests that high levels of visceral, liver, and skeletal muscle fat trigger insulin resistance.[118,119] For example:

- When University of California researchers gave 32 overweight or obese middle-aged men and women 25 percent of their calories from beverages sweetened with either fructose or glucose for 10 weeks, those consuming fructose had higher levels of visceral fat and postprandial triglycerides and higher fasting levels of glucose, insulin, LDL cholesterol, and small, dense LDL cholesterol.[120] (That level of fructose consumption is only about 50 percent more than the 35 percent of calories from added sugars that some 14 million people are consuming [*see* page 12]. That represents a virtual absence of a safety factor to ensure that people are not harmed by added sugars.)
- When some of those same California researchers gave 48 men and women (aged 18 to 40) 25 percent of their calories from beverages sweetened with HFCS, fructose, or glucose for 2 weeks, those consuming either HFCS or fructose (but not glucose) had higher 24-hour triglyceride levels and higher fasting LDL levels.[121] (Self-reported intake data, which often underestimates consumption, indicate that 12.5 percent of the U.S. population (age 4 and over)—about 36 million people—consumes at least 25 percent of their calories from added sugars, with roughly half of that being fructose (*see* discussion on pages 12).)[23] A recent analysis of NHANES data found that roughly one out of three adolescents consumed at least 25 percent of their calories from added sugars, and nearly one out of five consumed at least 30 percent of their calories from added sugars (*see* discussion on page 12).[25] Thus, there may be *no* safety factor in consumption levels of added sugars, notwithstanding the conventional use of safety factors in setting safe levels of consumption of GRAS ingredients and food additives (*see* page 6).)
- When Danish scientists randomly assigned 47 overweight subjects to consume 1 liter a day of one of four test drinks (sucrose-sweetened cola, isocaloric semi-

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[118] Fabbrini E, Magkos F, Mohammed BS, et al. Intrahepatic fat, not visceral fat, is linked with metabolic complications of obesity. Proc Nat Acad Sci. 209;106(36):15430–5.

[119] Peterson KF, Dufour S, Befroy D, et al. Reversal of nonalcoholic hepatic steatosis, hepatic insulin resistance, and hyperglycemia by moderate weight reduction in patients with type 2 diabetes. Diabetes. 2005;54:603–8.

[120] Stanhope K, Schwarz JM, Keim NL, et al. Consuming fructose-sweetened, not glucose-sweetened, beverages increases visceral adiposity and lipids and decreases insulin sensitivity in overweight/obese humans. J Clin Invest. 2009;119(5):1322–34.

[121] Stanhope K, Bremer AA, Medici V, et al. Consumption of fructose and high fructose corn syrup increase postprandial triglycerides, LDL-cholesterol, and apolipoprotein-B in young men and women. J Clin Endocrinol Metab. 2011;96:E1596–605.

skim milk, aspartame-sweetened diet cola, or water) for six months, those consuming regular cola had a significant increase in visceral fat, liver fat, skeletal muscle fat, and blood triglycerides. Many people consume 1 liter per day of sugary beverages (about 400 calories, or about 20 percent of total caloric intake, with about half those calories coming from fructose) plus added sugars from other sources. The authors conclude that "daily intake of SSSDs [regular cola] for 6 mo[nths] increases ectopic fat accumulation and lipids compared with milk, diet cola, and water. Thus, daily intake of SSSDs is likely to enhance the risk of cardiovascular and metabolic diseases." [122] (These findings, too, indicate that there is no safety factor for the millions of people who obtain more than 10 percent of their calories from fructose.)

- Swiss researchers randomly assigned 29 healthy, normal-weight men aged 20 to 50 to avoid fructose-containing foods or to consume beverages containing one of the following: 40 grams of fructose, 80 grams of fructose, 40 grams of glucose, 80 grams of glucose, or 80 grams of sucrose per day. (Those doses are similar to one or two 12 oz. cans of Coca-Cola, which contain 39 grams of HFCS.) After 3 weeks, waist-to-hip ratio rose significantly and a smaller (more atherogenic) class of LDL was found in those consuming beverages containing 80 grams of fructose or 80 grams of sucrose. Leptin, which increases satiety, increased only in those consuming glucose. Note that those changes occurred after only 3 weeks in men who consumed either 6.5 or 13 percent of their calories from added sugars. The authors conclude that "this study clearly shows that consumption of SSBs, even in moderate amounts, has adverse effects on lipid and glucose metabolism as well as on the inflammatory status of healthy young men."[123] (This is yet another study that indicates an absence of a safety factor the consumption of added sugars and that current levels of consumption are harmful.)
- When Danish researchers gave 23 overweight men and women diets sweetened with either sucrose (2 g/kg body weight) or artificial sweeteners for 10 weeks, those who consumed sucrose had higher levels of postprandial glucose, insulin, and triglycerides than those who got artificial sweeteners. For the typical 80-kg subject in this study, the sucrose accounted for 23 percent of calories. The sucrose group gained 3.1 pounds while the artificial sweetener group lost 3.3 pounds during the study. After adjusting for changes in body weight and total calories consumed, levels of postprandial insulin were still higher in the sucrose group. (Beverages accounted for 80 percent of the sucrose.) The

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[122] Maersk M, Belza A, Stødkilde-Jørgensen H, et al. Sucrose-sweetened beverages increase fat storage in the liver, muscle, and visceral fat depot: a 6-mo randomized intervention study. Am J Clin Nutr. 2012(Feb);95(2):283–9.

[123] Aeberli I, Gerber PA, Hochuli M, et al. Low to moderate sugar-sweetened beverage consumption impairs glucose and lipid metabolism and promotes inflammation in healthy young men: a randomized controlled trial. Am J Clin Nutr. 2011;94:479–85.

> authors noted that "a sucrose-rich diet consumed for 10 weeks resulted in significant elevations of postprandial glycaemia, insulinemia, and lipidemia compared to a diet rich in artificial sweeteners in slightly overweight healthy subjects."[106]

Those and other studies represent the growing body of evidence that the fructose component of HFCS and sucrose—the major sweeteners in the American diet—promotes diabetes and heart disease by increasing the risk of several features of the metabolic syndrome. As the authors of one meta-analysis noted:

> fructose is preferentially metabolized to lipid in the liver, leading to increased hepatic de novo lipogenesis, the development of high triglycerides, low HDL cholesterol, small, dense LDL, atherogenic dyslipidemia, and insulin resistance. Recent evidence has also shown that fructose consumption may promote accumulation of visceral adiposity or ectopic fat deposition, two key features of a dysmetabolic state increasing risk of type 2 diabetes and cardiovascular disease, despite no difference in weight gain between glucose and fructose conditions.[109]

Furthermore, the deleterious effects of fructose occur within weeks and at doses that millions of Americans now consume. The University of California researchers whose research is cited above concluded:

> Importantly, the current results provide evidence that sugar consumption at this level increases risk factors for cardiovascular disease within 2 wk in young adults, thus providing direct experimental support for the epidemiological evidence linking sugar consumption with dyslipidemia and cardiovascular disease. The results contradict the conclusions from recent reviews that sugar intakes as high as 25–50 percent of energy have no adverse long-term effects with respect to components of the metabolic syndrome and that fructose consumption up to 140 g/d does not result in a biologically relevant increase of fasting or postprandial [triglycerides] in healthy, normal-weight or overweight or obese humans.[121]

Moreover, people who frequently consume SSBs are generally not consuming enough of other foods and nutrients that could lower blood pressure, LDL cholesterol, and triglycerides. The DASH (Dietary Approaches to Stop Hypertension) and OmniHeart (Optimal Macronutrient Intake Trial to Prevent Heart Disease) trials fed people diets that were rich in potassium (4,700 mg/day), calcium (1,200 mg/day), magnesium (500

mg/day), and fiber (more than 30 g/day).[124,125,126] The diets were low in saturated fat (5 percent of calories), cholesterol (less than 150 mg/day), and sodium (2,300 mg/day). Furthermore, the diets were rich in fruits and vegetables (9 to 11 servings per day), with minimum intakes of low-fat dairy foods (1 to 2 servings/ day), legumes or nuts (1 to 3 servings/day), and fish (1 serving/day). To reach the food and nutrient targets, the diets had room for only 0.7 to 4.6 servings of "desserts and sweets" a day.[127] In the OmniHeart study, the diets with 1.7 or 2.5 servings of "desserts and sweets" per day led to more favorable 10-year coronary heart disease risk (based on blood pressure, triglycerides, HDL, and LDL levels) than the diet with 4.6 servings of "desserts and sweets." A "serving" was 1 teaspoon of sugar, and includes any sugars added to breakfast cereals, yogurts, and coffee, not just to SSBs, sweet baked goods, candy, or other foods that people think of as desserts. Therefore, in the OmniHeart trial, the highest sugar intake on a typical 2,100-calorie diet was about half the amount in a 12 oz. soft drink. These studies demonstrate that diets that contain sufficient foods and nutrients to lower risk factors optimally for heart disease and stroke have room for only low levels of SSBs (or other added sugars).

c. Sugars increase the risk of gout.

Gout is a painful inflammatory arthritis that is triggered by the crystallization of uric acid in the joints. Evidence suggests that gout is associated with the metabolic syndrome, heart attacks, and type 2 diabetes. The prevalence and incidence of gout have increased in

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[124] All nutrient and food targets apply to a 2,100-calorie diet. Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. N Engl J Med. 1997 Apr 17;336(16):1117–24.

[125] Appel LJ, Sacks FM, Carey VJ, et al. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. JAMA. 2005(Nov 16);294(19):2455–64.

[126] Swain JF, McCarron PB, Hamilton EF, et al. Characteristics of the diet patterns tested in the Optimal-Macronutrient Intake Trial to Prevent Heart Disease (OmniHeart): Options for a heart-healthy diet. J Am Diet Assoc. 2008(Feb);108(2):257–65.

[127] In the OmniHeart trial, the "unsaturated fat" diet (which contained 1.7 servings of "desserts and sweets" per day) and the "protein" diet (2.5 servings of "desserts and sweets" per day) led to more favorable 10-year coronary heart disease risk (based on blood pressure, triglycerides, HDL, and LDL levels) than the "carbohydrate diet" (4.6 servings of "desserts and sweets.") The "combination" diet that led to the lowest blood pressure levels in the original DASH study had only 0.7 servings of "snacks and sweets" a day.

the past few decades, in tandem with an increase in the consumption of soft drinks and fructose.[128]

It is well established that consuming fructose raises uric acid levels, which can lead to gout. In humans, high doses (200g or more a day) of fructose increase blood levels of uric acid.[129] Furthermore, when researchers gave middle-aged and older overweight or obese subjects diets with 25 percent of calories from beverages sweetened with either fructose or glucose for 10 weeks, only fructose led to increases in uric acid levels.[130,131]

Although those clinical studies used unusually high doses of fructose, they are supported by evidence from lengthy cohort studies that tracked the reported consumption of more-realistic levels of fructose and the incidence of gout:

- In a study that followed more than 46,000 men for 12 years, the risk of gout was 45 percent higher in men who consumed at least one serving of a sugar-sweetened soft drink a day than in those who consumed less than one a day. The risk of gout was 85 percent higher in men who consumed at least two servings a day.[132]

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[128] Zhu Y, Pandya BJ, Choi HK. Prevalence of gout and hyperuricemia in the US general population: the National Health and Nutrition Examination Survey 2007-2008. Arthritis Rheum. 2011(Oct);63(10):3136–41.

[129] Perez-Pozo SE, Schold J, Nakagawa T, et al. Excessive fructose intake induces the features of metabolic syndrome in healthy adult men: role of uric acid in the hypertensive response. Int J Obes (Lond) 2010, 34:454–61.

[130] Cox CL, Stanhope KL, Schwarz JM, et al. Consumption of fructose- but not glucose-sweetened beverages for 10 weeks increases circulating concentrations of uric acid, retinol binding protein-4, and gamma-glutamyl transferase activity in overweight/obese humans. Nutr Metab (Lond). 2012 (Jul 24);9(1):68.

[131] This study contradicts the findings of an earlier industry-funded meta-analysis that reported an increase in uric acid levels only in studies that fed high doses of fructose at levels above caloric needs, and not in studies that exchanged equal quantities of fructose for other carbohydrates. However, the authors note that their conclusions regarding studies that compare isocaloric intakes of fructose vs. other carbohydrates "are limited by the short follow-up of the majority of trials and poor quality of one-half of the trials included in the meta-analysis." Wang DD, Sievenpiper JL, de Souza RJ, et al. The effects of fructose intake on serum uric acid vary among controlled dietary trials. J. Nutr. 2012;142:916–23.

[132] Choi HK, Curhan G. Soft drinks, fructose consumption, and the risk of gout in men: prospective cohort study. BMJ. 2008(Feb 9);336(7639):309–12.

- In a study of nearly 79,000 women who were monitored for 22 years, those who consumed at least one serving of sugar-sweetened soda a day had a 74 percent higher risk of gout that those who consumed less than one serving a month. The risk of gout was 140 percent higher for women who consumed at least two sugar-sweetened sodas a day.[133]

d. Added sugars contribute to dental caries.

Most Americans have dental caries, or tooth decay. Based on the 1999–2004 National Health and Nutrition Examination Survey (NHANES), 21 percent of children aged 6 to 11, 59 percent of adolescents, and 92 percent of adults 20 and older have caries in their permanent teeth.[134]

Caries are caused by the demineralization of tooth enamel by organic acids produced from the fermentation of dietary sugars and other carbohydrates by lactic acid bacteria in the mouth. Sucrose is considered the most cariogenic dietary carbohydrate because it is fermentable and because bacteria can also use sucrose to generate sticky extracellular polymers called glucans that promote bacterial attachment to tooth surfaces. The Surgeon General's Report on "Oral Health in America" classified frequent sugar intake as a "high" risk factor for the development of caries in children, adolescents, and adults.[135]

The cariogenicity of sugars in food is influenced by the physical consistency of the food and the frequency of its consumption.[135] Sugary foods that stick to the teeth provide a prolonged retention of substrate that can lead to extended periods of acid production and demineralization and, thus, increase the risk of caries.[136]

While sugary beverages have limited contact time or adherence to tooth surfaces, the pattern of fluid intake can affect the cariogenicity of the beverages. Holding a sugar-containing beverage in the oral cavity for a prolonged period of time or constantly sipping such a beverage increases the risk of caries.[136] Exposing tooth enamel to a sugar solution

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[133] Choi HK, Willett W, Curhan G. Fructose-rich beverages and risk of gout in women. JAMA. 2010;304(20):2270–8.

[134] National Institute of Dental and Craniofacial Research. Dental caries (tooth decay). http://www.nidcr.nih.gov/DataStatistics/FindDataByTopic/DentalCaries/; accessed Jan. 4, 2012.

[135] U.S. Department of Health and Human Services. *Oral Health in America: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000. http://www.surgeongeneral.gov/library/reports/oralhealth/; accessed Dec. 22, 2012.

[136] Touger-Decker R, van Loveren C. Sugars and dental caries. Am J Clin Nutr. 2003(Oct);78(4):881S–92S.

for 30 seconds at a time four or more times a day for five days caused net demineralization of the enamel, if the subjects used a non-fluoride toothpaste. When the subjects used fluoride-containing toothpaste, net demineralization of the enamel was observed with seven to ten exposures a day of the sugar solution.[137]

e. Diets high in added sugars are lower in nutrient levels

One major concern about sugar-rich foods is that they might replace more-healthful foods in the diet. The previously mentioned study by Marriott et al. found an inverse association between the consumption of added sugars and the consumption of a variety of essential vitamins and minerals.[23] It found that:

> For all nutrients our data showed that median intakes exhibited a monotonically decreasing pattern (with lower median intake levels with each 5 percent increase in added sugars intake category), and the median nutrient intake in the highest added sugars category (>35 percent of energy) with all life stage groups combined, were 40 percent or more less than the median intakes for the 0 to 5 percent added sugars category. (See Figure 1.)

3. FDA should address the problem of over-consumption of added sugars through a variety of regulatory and non-regulatory steps.

The above evidence demonstrates that many Americans, particularly adolescents and young adults, consume added sugars (often in the form of beverages) in amounts that are well in excess of what the Dietary Guidelines for Americans and other authoritative reports recommend and that contribute to serious health problems. FDA's regulations—and the Agency's own *promise* to review the GRAS status of added sugars if presented with precisely this kind of new evidence—compel the Agency to act. The FDA should use its regulatory authority, as well as its ability to encourage voluntary changes by industry and consumers, to address this critical issue.

a. Regulation of sucrose and HFCS in beverages

Beverages constitute the greatest health risk from added sugars: They provide almost half of all added sugars in the American diet; carbonated and non-carbonated soft drinks typically provide no nutrients other than sugars; beverages are more conducive to weight gain and obesity than foods; and more than half the added sugars in beverages[138] is

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[137] Duggal MS, Toumba KJ, Amaechi BT, et al. Enamel demineralization in situ with various frequencies of carbohydrate consumption with and without fluoride toothpaste. J Dent Res. 2001 Aug;80(8):1721–4.

[138] Five of the six top-selling non-diet carbonated soft drinks are made with a type of HFCS that is 55 percent fructose. Beverage Digest sweetener cost calculator. http://www.beverage-digest.com/cgi-bin/hfcs.cgi; accessed Dec. 22, 2012. Beverage

fructose, which may cause greater harm (such as through lipogenesis) than the glucose in dextrose and corn syrup. Also, the added-sugar content in beverages is particularly easy to reduce without impairing taste. Thus, we request that FDA focus its attention principally on reducing the amount of added sugars—mainly HFCS and sucrose—in beverages. As discussed above, the agency has the authority to condition continued GRAS status on measures to ensure the safe use of these ingredients (21 C.F.R. § 170.3(n)). We therefore request that FDA consider as one approach amending the GRAS regulations for sucrose and HFCS to condition the safe use of those ingredients on limits on the amounts of those ingredients, in combination, in non-alcoholic beverages.[139]

Under this approach, FDA should consider limiting, perhaps over several years, sucrose and HFCS to levels that various health entities have recommended, in several contexts, to be safe and consistent with the public health. For example:

- The FDA's definition of "low-calorie" is 40 calories (10g of sugar) or fewer per serving (12 oz. is the most popular size of single-serving containers).[140]
- New York City's food standards for vending machines require most beverages to contain no more than 25 calories (about 6g of sugars) per 8 ounces (about 9g per 12 oz.).[141]
- The Harvard School of Public Health recommends that people consume beverages with no more than 12g (48 calories) per 12 oz. (or 8g or 32 calories

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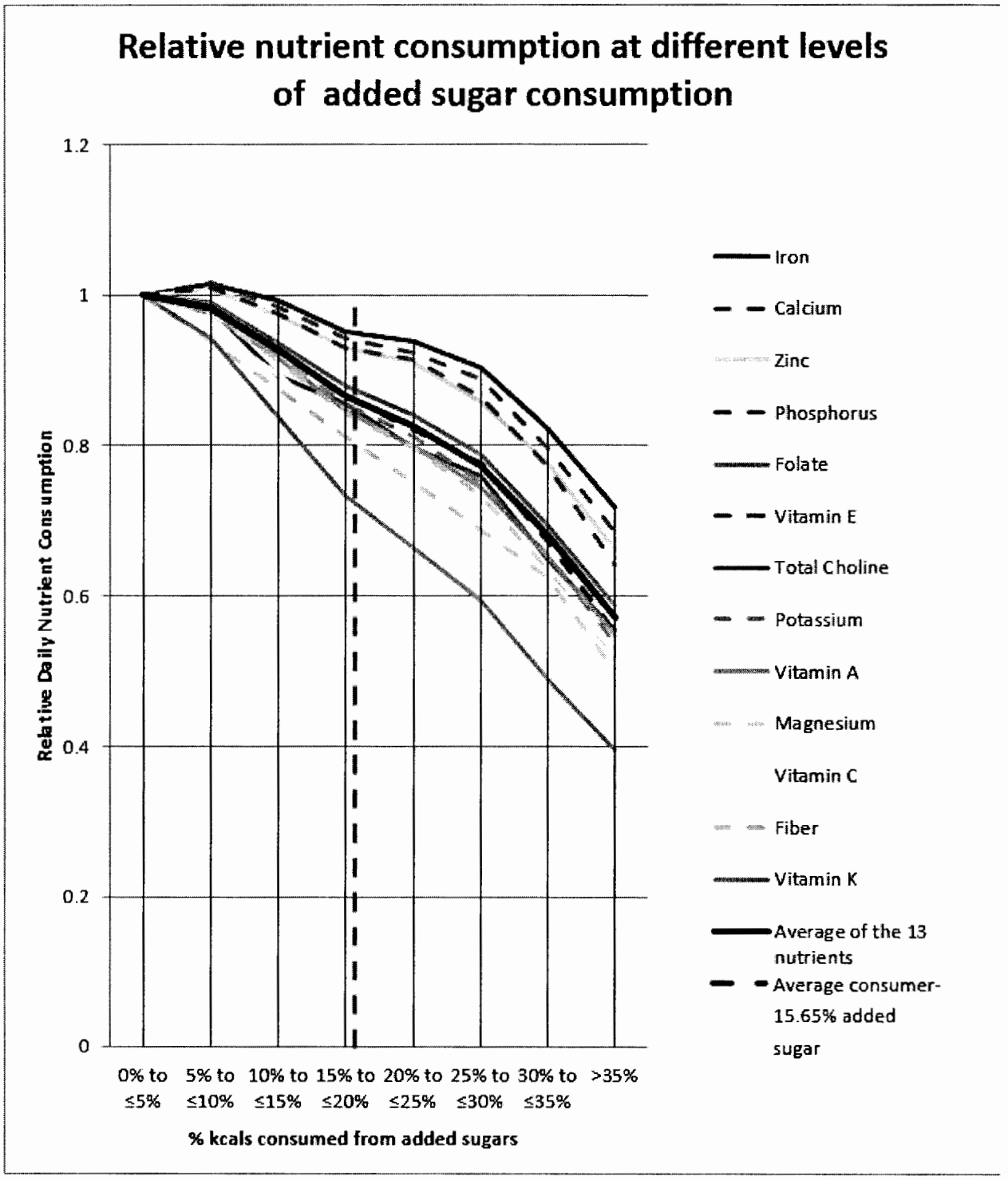
Digest Top-10 CSD results for 2010. http://beverage-digest.com/pdf/top-10_2011.pdf; accessed Dec. 22, 2012.

[139] Another means for FDA to reduce added sugars in beverages may be to use "standards of identity," by which FDA (and USDA for meat and poultry products) defines a given food product and the ingredients that must or may be used in the manufacture of that product. *See* 21 C.F.R. §§ 130–169. Standards of identity sometimes include limits on artificial sweeteners. *See* 21 C.F.R. § 150.60 (limiting use of "saccharine ingredients" for fruit preserves and jams). They may also be used more generally to limit the amounts of harmful substances in foods or to prevent consumer fraud. *See* 9 C.F.R. § 319.180(a) (limiting fat content of hot dogs); similar limits on added sugars could be appropriate standards of identity for non-alcoholic drinks.

[140] U.S. FDA. Make your calories count - use the nutrition facts label for healthy weight management: glossary. http://www.accessdata.fda.gov/videos/CFSAN/HWM/hwmgloss.cfm; accessed Jan. 17, 2013.

[141] New York City food standards for beverage vending machines. http://www.nyc.gov/html/doh/downloads/pdf/cardio/beverage-vend-machines-standards.pdf; accessed Dec. 29, 2012.

Figure 1. Relationship of sugar intake to added-sugar consumption. (Based on Marriott et al. 2010. Ref. 23)



per 8 oz.), and has urged industry to produce such beverages (though it still advises that such beverages be consumed only as occasional treats).[142]

- The Healthy and Sustainable Food Guidelines issued by the General Services Administration and U.S. Department of Health and Human Services recommends "At least 50 percent of available beverage choices (other than 100 percent juice and unsweetened milk) must contain ≤40 kcalories/serving." (10g of sugar, regardless of serving size)[143]
- King County's (Seattle) Health Vending Guidelines defines "Healthier" (not "Healthiest") beverages as containing up to 10 calories per 8 ounces (about 4g of sugar per 12 oz.).[144]

Fortunately, developments in beverage formulations, changing tastes, and new technologies should make it increasingly easy to reformulate soft drinks in ways that preserve taste and reduce the added-sugars content:

- Products made without non-caloric sweeteners, such as Honest Tea Lori's Lemon Tea, with 45 calories per 12 ounces; Snapple Earl Grey Black Tea, with 50 calories per 12 ounces; Sport Owater, with about 50 calories per 12 ounces; Zico Pineapple or Mango Coconut Water, with about 40–50 calories per 12 ounces; and Izze esque drinks, with about 50 calories per 12 ounces, are more consistent with safe levels (and do not contain any high-potency sweeteners).
- Products made with artificial non-caloric sweeteners, such as Dr Pepper 10, with only about 3g of sugar (12 calories) in a 12 oz. can, thanks to a mixture of HFCS, aspartame, and acesulfame potassium (according to Dr Pepper Snapple Group, that product provides "a fully satisfying flavor and low calories."[145] The products are selling so well that the company is coming out with five more

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[142] The Nutrition Source. How sweet is it? Harvard School of Public Health. http://www.hsph.harvard.edu/nutritionsource/healthy-drinks/how-sweet-is-it/index.html; accessed Dec. 1, 2012.

[143] Centers for Disease Control and Prevention. Health and sustainability guidelines for federal concessions and vending operations. http://www.cdc.gov/chronicdisease/pdf/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf; accessed Dec. 29, 2012.

[144] King County Healthy vending guidelines. http://www.kingcounty.gov/healthservices/health/nutrition.aspx; accessed Dec. 29, 2012.

[145] Dr Pepper Snapple Group. Dr Pepper Snapple dials the flavor up to "ten" with five new low-calorie sodas. Dec. 20, 2012. http://news.drpeppersnapple.com/press-release/dr-pepper-snapple-dials-flavor-ten-five-new-low-calorie-sodas; accessed Jan. 1, 2013.

brands, such as Sunkist 10 and 7Up 10, that are similarly sweetened. [146]); Pepsi Next, with 60 calories per 12 ounces—60 percent less than regular Pepsi—thanks to the use of several artificial sweeteners and HFCS[147]; Giant Foods supermarkets' Guaranteed Value soft drinks, which are sweetened with a mixture of HFCS, aspartame, and acesulfame potassium and have 9g of sugars (36 calories) per 12 oz.[148]

- Products are being made with rebiana (from stevia), such as Coca-Cola Co.'s Sprite Select and Fanta Select, which are sweetened with a mixture of sugar, erythritol, and stevia leaf extract and have 50 percent and 55 percent, respectively, fewer calories than those products' regular counterparts.

In addition, ingredients manufacturers have developed substances—hydrocolloids such as gums and proteins—that replace the texture or "mouth feel" normally provided by sugars.[149]

A new means of reducing sugar levels in beverages and other foods is to use ingredients called "sweetness enhancers." Those are substances that sensitize sweetness receptors on the tongue so as to enable a given amount of sweetener to taste sweeter. Using sweetness enhancers, as they are developed, could allow reductions (at least 50 percent less according to one company[150]) in the sugar content of products. PepsiCo's chief

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[146] Tanner S. Review: Sunkist ten. http://www.bevreview.com/2012/01/25/sunkist-ten/; accessed Jan. 17, 2013.

[147] Hsu T. Coca-Cola to test mid-calorie Sprite and Fanta. Los Angeles Times. May 14, 2012. http://www.latimes.com/business/money/la-fi-mo-coca-cola-midcalorie-20120514,0,1336082.story; accessed Jan. 17, 2013.

[148] Giant Foods. http://www.peapod.com/site_frameset.jhtml?NUM1=1352598159002; accessed Nov. 10, 2012.

[149] Pszczola DE. What makes a winning ingredient. Food Tech. 2012;66(8).

[150] Senomyx, Inc. Current flavor programs. http://senomyx.com/flavor_programs/appTech.htm; accessed June 9, 2012. PepsiCo, which has a goal of reducing added sugars by an average of 25 percent in key beverage brands by 2020 (http://www.pepsico.com/Download/PepsiCoCorporateFactSheet.pdf; accessed Dec. 29, 2012), is working with Senomyx to develop and commercialize sweet enhancers and natural high-potency sweeteners so as to be able to market "lower-calorie, great tasting PepsiCo beverages." http://www.pepsico.com/PressRelease/PepsiCo-and-Senomyx-Enter-Into-Collaboration-to-Discover-Develop-and-Commerciali08172010.html; accessed Dec. 29, 2012.

scientific officer has said that sweetness enhancers "will allow us to improve the nutritional profile of our products without sacrificing taste."[151]

The variety of products and technologies discussed here indicates the practicality of FDA's taking regulatory action to make sweetened beverages safe for consumption by people of all ages.[152] A mandatory limit on added sugars would serve to accelerate efforts to reduce levels of added sugars and possibly also accustom consumers to less-sweet products.

We note that Harold Honickman, the chairman of a large soft-drink bottling company in the mid-Atlantic region, recently said that within two years:

> ...you will see Pepsi and Coke and Dr Pepper coming up with a whole variety of no-calorie sweeteners....I honestly think that you will find "regular" Pepsi, "regular" Coke with new kinds of sweeteners. They will be better-tasting drinks than we have today.[153]

If that's really the case, the soft-drink industry shouldn't mind supporting this Petition, which would provide a level-playing field for all companies.

b. Voluntary efforts to ensure the safe use of all added sugars in beverages and other foods

While the large amounts of added sugars consumed in beverages pose the greatest health risk, breakfast cereals, cake, candy, cookies, frozen desserts, and other foods, in the aggregate, provide more than half the added sugars (in the form of sucrose, HFCS, corn syrup, dextrose, invert sugar, and other GRAS and non-GRAS added sugars) that Americans consume. The use of added sugars in non-beverage products has been less studied than in beverages and has not yet been demonstrated to be as conducive to weight gain and obesity as sugars in beverages, but those sugars still pose risks. With a few exceptions

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[151] PepsiCo press release. PepsiCo and Senomyx enter into collaboration to discover, develop and commercialize new sweet flavor ingredients. http://www.pepsico.com/PressRelease/PepsiCo-and-Senomyx-Enter-Into-Collaboration-to-Discover-Develop-and-Commerciali08172010.html; accessed Jan. 17, 2013.

[152] For many years the beverage industry has been developing products that are lower in sugar than conventional soft drinks. That is helpful, but full-calorie beverages still dominate the marketplace, and companies likely will continue to try to maximize sales of all their products. Thus, action by the FDA is necessary to make sugary drinks safe for the general public, as this Petition calls for.

[153] Sapatkin D. How health campaigns are shaking up the soda industry. Philadelphia Inquirer. Oct. 19, 2012. http://articles.philly.com/2012-10-20/news/34585360_1_soda-and-obesity-high-fructose-corn-syrup-liquid-calories/3; accessed Dec. 29, 2012.

(such as heavily fortified breakfast cereals), most sugar-rich foods are relatively low in nutrient density and reduce overall dietary quality, which is an important reason why the Dietary Guidelines and American Heart Association base their recommendations for consumption of added sugars on nutritional adequacy. Added sugars also may add calories to foods and contribute to obesity, and the added fructose (from sucrose and HFCS) in foods may have adverse metabolic effects. And sugars in many foods contribute to dental caries.

Thus, while FDA should take regulatory action to address HFCS and sucrose as they are used in beverages, we recommend that FDA, working with other relevant local, state, and federal agencies as well as with nonprofit organizations and the food industry, initiate a broader campaign aimed at reducing the general use and consumption of added sugars in foods and helping accustom people to eating foods that are less sweet and to eating fewer sweets. Again, technological developments should help companies reduce added sugars. We recommend the following steps as part of this effort:

- FDA should revise the "Sugars" line on Nutrition Facts labels by replacing "Sugars" with "Added Sugars,"[154] specifying a DV (Daily Value) for added sugars, and requiring a percent DV on the added-sugars line;
- FDA should set voluntary targets for lowering levels of added sugars in many breakfast cereals, baked goods, candy, frozen desserts, and other foods that provide substantial amounts of sugar to the general population.[155] Those targets could be based on such factors as (a) the sugar content of the lowest-sugar brands within a category; (b) new technical means of reducing the sugar content (without excessively increasing the content of saturated or trans fat, sodium, or refined flour); and (c) the need for sugar's preservative and textural effects. Opportunities to modestly reduce sugar levels in certain foods are evident on supermarket shelves, where different brands of the same product have different levels of sugar but about the same taste. See examples in Table 1 (the numbers are not exact, because of rounding on labels and because the Petitioner does not have product recipes).

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[154] On juices and other beverages containing real fruit juice (as opposed to "stripped" juices that are used as sweeteners and equivalent to sugar), the Nutrition Facts Panel should state "Added Sugars (including from fruit juice)."

[155] See Dietary Guidelines for Americans, 2010, *op. cit.,* Figure 3-6, p. 27. http://health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf; accessed April 1, 2012.

Table 1. Brand differences in sugar (including natural and added) content.

Food	g sugar/serving	percent difference
Newman's Own Tomato and Basil Bombolina, ½ cup (125g)	9	
Muir Glen Tomato Basil Pasta Sauce, ½ cup (125g)	4	-56 percent
Lucerne Low Fat Chocolate Milk, (8 oz.)	32	
Trumoo Chocolate 1% Lowfat Milk, (8 oz.)	18	-44 percent
Sweet Baby Ray's Barbecue Sauce, Original, 2 Tablespoons (37g)	16	
Kraft Barbecue Sauce, Original, 2 Tablespoons (35g)	10	-38 percent
Entenmann's Pop'ems Glazed Donut Holes, 4 donut holes (52g)	19	
Krispy Kreme Glazed Cake Donut Holes, 4 donut holes (51g)	12	-37 percent
Breyer's Chocolate Ice Cream, ½ cup (66g)	16	
Safeway Select, Chocolate Ice Cream, ½ cup (67g)	12	-25 percent
Open Nature (Safeway house brand), Cinnamon Rolls, 1 roll (99g)	26	
Pillsbury Grands Flaky Supreme Cinnabon, Cinnamon Rolls, 1 roll (99g)	20	-23 percent
Dole Mandarin Oranges in Light Syrup, ½ cup (122g)	20	
Wegman's Whole Segments Mandarin Oranges in Light Syrup, ½ cup (138g)	16	-20 percent

- FDA should encourage reductions in added sugars by publicly announcing the targets, meeting with companies and trade associations, and tracking and applauding progress in reaching those targets. The food industry should be advised that the consequences of not acting voluntarily could be FDA regulation.
- FDA, in collaboration with the CDC, state and local governments, consumer groups, industry (both product manufacturers and product sellers including grocery stores, vending machine owners, and restaurants), and the media, should undertake a campaign to advocate for voluntary industry programs to reduce consumption of added sugars. The FDA could urge companies to adopt such voluntary steps as:

- Limiting the size of non-diet soft drinks sold in certain forms and locations—*e.g.,* limiting the size of soft drinks sold in vending machines to 12 oz. and limiting restaurant sales of soft drinks to no larger than 16 oz.[156,157]
- Reducing the standard size of beverage cans from 12 oz. to 11 oz. (a 7 percent reduction), which is companies' standard size in many countries, or to 10 or eight oz.
- Marketing smaller single-serving packages of pastries and other foods high in added sugars;
- Using less sugar in cereals, baked goods, and other products, such as by placing sugar on the surface of breakfast cereals and certain other solid foods rather than throughout the product[158] or using safe, natural or synthetic high-potency sweeteners (such as sucralose, stevia-based ingredients, and others), sweetness enhancers, sugar alcohols, and other ingredients instead of added sugars;[159]

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[156] New York City's Board of Health recently enacted a law banning certain sales of soft drinks on containers larger than 16 ounces. New York City Department of Health and Mental Hygiene. http://www.nyc.gov/html/doh/downloads/pdf/boh/max_size_sugary_drinks_briefing.pdf; accessed Dec. 22, 2012.

[157] McDonald's largest soft drink was 7 oz. in the 1950s and 16 oz. in the 1970s compared to the current 32 oz. Young LR, Nestle M. Portion sizes and obesity: responses of fast-food companies. J Pub Health Policy. 2007;28:238–48. http://portionteller.com/pdf/jphpJune07.pdf.); currently, the largest soft drinks sold by McDonald's restaurants in Denmark, Austria, and Germany are 500 ml or 16.9 ounces (*see* McDonald's websites for those countries).

[158] Kummer C. Can technology save breakfast? Smithsonian magazine. June 2012. http://www.smithsonianmag.com/science-nature/Can-Technology-Save-Breakfast.html; accessed August 20, 2012.

[159] The FDA (and many foreign governments) consider those ingredients to be safe. Also, an American Medical Association review considered whether diet soft drinks promote sweet cravings, but concluded that the evidence is inconclusive. 2012 Annual Meeting. Reports of the council on science and public health. http://www.ama-assn.org/assets/meeting/2012a/a12-csaph-reports.pdf#page=35; accessed Dec. 31, 2012. Some researchers, though, believe that "high-quality, long-term clinical trials are needed to investigate the effects of artificially sweetened beverages compared to sugar-sweetened and nonsweetened, calorie-free fluids, such as water. In the interim, water is a healthy calorie-free substitute that reduces energy intake and may improve weight control and management." Pan A, Hu FB. *Op. cit.* CSPI has questioned the safety of aspartame, acesulfame-potassium, and saccharin and urged the FDA to support sensitive, lifetime feeding studies of those chemicals in rodents or revoke their approvals. However, CSPI believes that the certain harm caused by the 15 teaspoons of sugars in a 20 oz. drink outweighs the speculative harm from artificial sweeteners.

- Shifting marketing resources toward lower-sugar, healthier products, thereby potentially shifting consumption toward healthier alternatives.

Some companies have already begun taking affirmative steps to address the public health crisis caused by added sugars. For example, Walmart, the nation's largest supermarket chain, has told suppliers of dairy items, sauces, and fruit drinks that it expects them to reduce sugar levels by 10 percent by 2015.[160] Also, breakfast cereal companies have cut the sugar content in some of their products, with General Mills reformulating products advertised to children from 11–15 grams per serving to 10 or less (at least three are down to 9 grams).[161] Post, another manufacturer of breakfast cereals, reduced the sugar content of Alpha-Bits from 10 to 6 grams per serving.[162] Much more, however, needs to be done.

FDA could use commercial databases to monitor progress or ask major marketers of sugary foods and beverages to report their progress to the agency.

FDA, again in conjunction with the CDC, should mount a major campaign to encourage consumers to choose foods and beverages with little or no sugar foods (as Philadelphia, New York City, and Seattle have done). Such education campaigns should include encouraging people to opt for unsweetened beverages, not just beverages sweetened with high-potency sweeteners. Those two agencies also should encourage local and state health departments to limit serving sizes at restaurants (as New York City has done); not allow sugary drinks to be sold on government property, including schools and parks (as Boston has done); and get sugary drinks out of day-care settings. Education campaigns should reassure consumers that consuming modest amounts of added sugars is safe, but that current levels of consumption are harmful.

The table in Appendix 2 offers one example of how small and large restrictions of levels of added sugars, coupled with modest changes in consumer behavior, could lead to major reductions in added-sugars consumption. With average U.S. consumption of added

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[160] Walmart Corp. Walmart launches major initiative to make food healthier and healthier food more affordable. Jan. 20, 2011. http://www.walmartstores.com/pressroom/news/10514.aspx.

[161] Scott-Thomas C. General Mills says health has become "a primary driver of innovation." FoodNavigator-USA.com. http://www.foodnavigator-usa.com/Market/General-Mills-says-health-has-become-a-primary-driver-of-innovation/?utm_source=newsletter_daily&utm_medium=email&utm_campaign=Newsletter percent2BDaily&c=gLinbDewezao4eslcdg0Aw percent3D percent3D; accessed Aug. 24, 2012.

[162] Bachman K. Pebbles Boulders, Alpha Bits now safer for children. Adweek. Oct. 23, 2012; http://www.adweek.com/news/advertising-branding/pebbles-boulders-alpha-bits-now-safer-children-144707 accessed Nov. 5, 2012.

sugars estimated to be 87g per day (the average of estimates from USDA's loss-adjusted food-availability database and NHANES data), it would take a reduction of 51g to decrease consumption to 36g (8.6 teaspoons) per day, about the maximum intake recommended by the American Heart Association for men. A 70 percent reduction in the added-sugars content of beverages would reduce average intake by 30.2g per day, or three-fifths of the desired reduction. Modest 10 to 25 percent reductions, accomplished with reformulations and reduced portion sizes, of added sugars in certain other food categories, plus voluntary 17 percent reductions (different food choices and smaller portions) by consumers, would bring consumption of added sugars to healthful levels for the average person.

III. Conclusion

For the foregoing reasons, FDA should take the action requested in this Petition.

IV. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

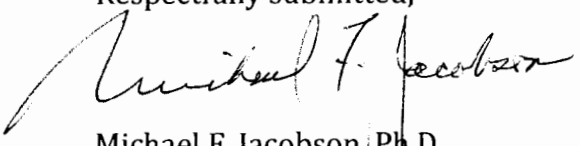
V. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner. *See* 21 C.F.R. 10.30(b).

VI. Certification

The undersigned certifies that, to their best knowledge and belief, this Petition includes all information and views on which the Petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the Petition.

Respectfully submitted,



Michael F. Jacobson, Ph.D.
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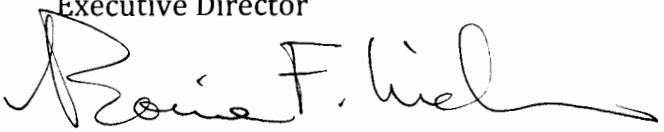

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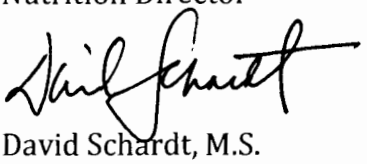

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Table: U.S. added sugar consumption compared to recommendation for added sugar intake in 2010 Dietary Guidelines of America

		Added sugar intake, NHANES 2003-2006*		Dietary Guidelines for Americans 2010 - Recommendations						Intakes vs. DGA Recommendations (not population weighted)		
Gender	Age	Estimated added sugar intake, g	Estimated added sugar intake, tsp	DGA estimated calorie needs, kcal**	DGA estimated calorie needs, kcal** (mid-point)	Maximum SoFAS limit, kcal***	Added sugars (1/2 of SoFAS), kcal****	Estimated recommendation for added sugar intake, g	Percent of calories from added sugars	Estimated recommendation for added sugar intake, tsp	Estimated actual+ added sugar intake, tsp	Multiple of intake over recommended intake
Child (female and male)	2-3	--	--	1000-1200	1100	129	64.5	16.1	5.9%	3.8	--	--
Child (female and male)	4-8	92.2	22.0	1200-1400	1300	121	60.5	15.1	4.7%	3.6	22.0	6.1
Female												
	9-13	87.2	20.8	1400-1600	1500	121	60.5	15.1	4.0%	3.6	20.8	5.8
	14-18	81.7	19.5	1800	1800	161	80.5	20.1	4.5%	4.8	19.5	4.1
	19-30	76.3	18.2	1800-2000	1900	210	104.8	26.2	5.5%	6.2	18.2	2.9
	31-50	69.2	16.5	1800	1800	161	80.5	20.1	4.5%	4.8	16.5	3.4
	51-70	58.0	13.8	1600	1600	121	60.5	15.1	3.8%	3.6	13.8	3.8
Male												
	9-13	103.4	24.6	1600-2000	1800	190	94.8	23.7	5.3%	5.6	24.6	4.4
	14-18	115.2	27.4	2000-2400	2200	294	147.0	36.8	6.7%	8.8	27.4	3.1
	19-30	117.7	28.0	2400-2600	2500	346	173.0	43.3	6.9%	10.3	28.0	2.7
	31-50	106.3	25.3	2200-2400	2300	298	149.0	37.3	6.5%	8.9	25.3	2.9
	51-70	78.2	18.6	2000-2200	2100	262	131.0	32.8	6.2%	7.8	18.6	2.4
							Averages (9-70 yrs)>>	27.0	5.4%	6.4	21.3	3.3

*--NHANES, 2003-3006 data source: Marriott BP,Olsho L, Hadden L, and Connor P (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, 50:228-258

--Estimated added sugar intakes are for 51-70 y.o., while recommended intakes for added sugar values are for 51+ y.o.

**Estimated calorie needs retrieved from Table 2-3 of the 2010 DGA policy document found at http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf; range only considers calorie needs for the sedentary physical activity level

***Maximum SoFAS limits calculated based on the kcal reommendations set forth for the respective calorie levels shown in Appendix 7 (see condensed version below) of http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/Appendices.pdf; if a range was provided, an average of the recommendation for the respective range

****These figures are based on the assumption that 50% of the SoFAS recommendation is from added sugars

+ Dietary intake surveys typically underestimate actual consumption.

Appendix 2. Example of Options for Reducing Added Sugars

Food*	% of sugar in category* (NHANES 2005-06)	Consumption Estimates: USDA (LAFA**) 96.4g (2010) g/day	NHANES 77g (2007-08) g/day§	Average of USDA & NHANES g/day	Reduction %	Reduction g/day
Sugar-sweetened bev.	49.7	47.9	38.3	43.1	70%	30.2
Grain-based desserts	12.9	12.4	9.9	11.2	15%	1.7
Dairy desserts	6.5	6.3	5.0	5.6	10%	0.6
Candy	6.1	5.9	4.7	5.3	25%	1.3
RTE cereals	3.8	3.7	2.9	3.3	20%	0.7
Sugars and honey	3.5	3.4	2.7	3.0	10%	0.3
Yeast breads	2.1	2.0	1.6	1.8	10%	0.2
All other categories	15.4	14.8	11.9	13.4	15%	2.0
Totals	**100**	**96.4**	**77**	**86.7**		
Voluntary consumer changes (food choices, serving sizes)					17%	14.7
			GOAL g/day (8.6 tsp/day)	36g	Reductions> *Goal: 51g reduction*	**51.6**

* Dietary Guidelines for Americans 2010, Fig. 3-6

** LAFA = loss-adjusted food availability (USDA "guesstimate")

§ Welsh JA, et al. Am J Clin Nutr. 2011. Sep;94(3):726-34. May underestimate consumption because of underreporting.

Reductions may be achieved through using less sugar; replacing sugar with starch, gums, or other ingredients; high-potency sweeteners (sucralose, rebiana, etc.); sweetness enhancers; smaller portions; etc.

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