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Room 738-G
200 Independence Avenue, SW
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RE: Draft Report of the 2005 Dietary Guidelines for Americans

The Center for Food and Nutrition Policy ("Center" or CFNP) at Virginia Tech—National Capital Region located in Alexandria is an independent, non-profit research and education organization that is dedicated to advancing rational, science-based food and nutrition policy. It is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United Nations (FAO). The Center uniquely operates like an independent "think-tank," while maintaining its academic affiliation with Virginia Tech, a major land-grant university. The research, education, outreach, and communications activities of the faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy process on food and nutrition issues.

Encompassed in the Center's activities on nutrition policy are its interests in policy and regulatory issues involving dietary guidance. The Center respectfully submits the following comments in response to the solicitation for written comments regarding the proposed 2005 Dietary Guidelines for Americans as published in the *Federal Register*.[1]

The comments contained herein urge the final guidelines to *1*) reflect the priorities or order of importance in producing desirable health outcomes; *2*) delete the section on the role of the environment as speculative rather than substantive; and *3*) re-draft certain segments of the carbohydrates chapter to accurately reflect the results of publications used to justify the recommendations of the DGAC.

<u>Executive Summary Should Reflect the Order of Priority of the Guidelines</u>
As it is currently written, the executive summary does not reflect the order of the dietary guidelines—"choose fats wisely for good health" and "choose carbohydrates wisely for good health" should follow the guideline, "increase daily intakes of fruits and vegetables, whole grains, and reduced-fat milk and milk products."

[1] Federal Register: Notice. August 27, 2004, Volume 69, Number 166, pages 52697-52698.

Presumably, the 2005 Dietary Guidelines for Americans Committee (DGAC) prioritized the guidelines based on the importance and likelihood of accruing positive health benefits, such as maintaining or achieving a healthy body weight. This appears to be the underlying key message for the first three and fully one-third of the guidelines.

- Consume a variety of foods within and among the basic food groups while staying within energy needs;
- Control calorie intake to manage body weight;
- Be physically active every day.

Assuming that most people will remember only a few messages, these three are the most important to a population that is increasingly overweight and obese.

Delete "The Role of the Environment in Implementing the Guidelines"
The task given to the DGAC was to review the "available science base to characterize elements of guidance for a healthful diet—dietary guidelines that, if followed, will reduce the risk of chronic disease while meeting nutrient requirements."[2]

Proposals such as those suggested by the DGAC regarding the role of the environment in implementing the guidelines should certainly be scrutinized rigorously. For example, the policy options proposed by in this section should be evaluated against several well-defined, objective criteria in the following areas: *1*) scientific validity, *2*) technical feasibility, *3*) value acceptability, *4*) cost, and *5*) risk reduction.

Unfortunately, certain statements made in this section are based on conjecture and untested hypotheses that are inappropriate for this scientific report. There is virtually no "science" to support the speculations made by the DGAC; therefore, this section should be deleted from the report. The DGAC opines that

> "because many of these factors are beyond the control of individuals (e.g., the size of portions served in food establishments and lack of information on calorie content at point of purchase), substantial changes to the environment are required to achieve a milieu that supports healthy behaviors"[3]

This language is not supported by the scientific evidence. While portion sizes served in food establishments have increased, the idea that patrons can not refuse to eat the entire offering or order a smaller portion is wrong and misguided. Patrons have many choices in restaurants including how much of a purchased food or meal they will consume at one sitting. Most restaurants already have some items with smaller portion sizes and/or "healthy" or "light" items designed specifically for consumers who want a lower-calorie option. Furthermore, the food and restaurant industries have proven very responsive to consumer demand in the past, most recently as exhibited by the wave of new products and menu items for individuals following "low-carb" diets. If consumer demand for smaller portion size options increases, the food and restaurant industries are likely to respond without any need for government intervention. In addition, CFNP is

[2] 2005 Dietary Guidelines Advisory Committee Report, Part B: Introduction, p. 12.
[3] 2005 Dietary Guidelines Advisory Committee Report, Part B: Introduction, p. 3.

not aware of any evidence that displaying calorie content at the point of purchase will have any effect on consumer purchases that will ultimately support healthy behaviors and better health outcomes.

Given persistent budgetary constraints, the federal government can ill-afford to promote the unsupported speculations that are proposed in this section. The Center therefore urges the Secretaries of Agriculture (USDA) and Health and Human Services (DHHS) to delete the section entitled "The role of the environment in implementing the guidelines" in Part B—Introduction.

Choose Carbohydrates Wisely for Good Health

The following comments pertain to Part D Science Base, Section 5 Carbohydrates. The Center agrees that the message to "choose carbohydrates wisely for good health" is scientifically sound advice. Yet the language of the Conclusion and the Rationale of the guideline suggesting that *added* sugars may uniquely contribute to certain undesirable health outcomes such as poorer nutrient intake, unhealthy body weight, and increased risk of dental caries, is overstated.

What is the relationship between intake of carbohydrates and dental health?

The DGAC draft report suggests a possible relationship between added sugars and dental health. Question 1 asked: "What is the relationship between intake of carbohydrates and dental health?" Enclosed is a recent paper published by Forshee and Storey examining the association between dental caries and soft drink consumption.[4] The study showed that for most age groups, soft drink consumption was not linked to an increase in dental caries. Our examination generally agrees with the findings of Heller and coworkers, but our interpretation of the policy implications of the results differs from theirs.[5]

The Center agrees that good dental hygiene, drinking fluoridated water, and using fluoridated dentifrices are the most effective ways to reduce dental caries. A secondary consideration is intake of fermentable carbohydrates that stick to the teeth and are not removed by brushing or rinsing the mouth. The Center therefore urges the draft report to reflect the priority of behaviors that will lead to better oral health by re-stating the final sentence in the conclusion to read:

> *"A combined approach of optimizing oral hygiene practices and reducing the frequency and duration of exposure to fermentable carbohydrate intake is the most effective way to reduce caries incidence."*

[4] Forshee RA, Storey ML. Evaluation of the association of demographics and beverage consumption with dental caries. *Food Chem Toxicol.* 2004; 42:1805-1816.

[5] Heller KE, Burt BA, Eklund SA. Sugared soda consumption and dental caries in the United States. *Journal of Dental Research* 2001; 80: 1949-1953.

Does intake of added sugars have a negative impact on achieving recommended nutrient intake?

The sentence in the Conclusion—"A reduced intake of added sugars (especially sugar-sweetened beverages) may be helpful in achieving recommended intakes of nutrients and in weight control"—overstates the evidence presented. The evidence in fact shows that focusing on added sugars intake as a way to control or lose weight or improve micronutrient intake is unlikely to have any effect on these outcomes.

The Center is pleased that the DGAC considered our research during its deliberations, however, we object to the manner in which our research is characterized in the draft report. For example, the draft report notes that most cross-sectional studies have found that "an increased intake of added sugars is associated with increased total energy intake" and the study by Storey et al, 2003[6] is cited as support for this statement. Our study in fact showed that less than 10% of children's BMI and less than 15% of adolescents' BMI could be explained by the parameters of our models. Of the variance that was explained by the models we developed, the largest predictors of BMI among children and adolescents were factors that can not be modified, such as age, gender, and race-ethnicity. Of the lifestyle factors that can be modified, sedentary behavior was far more predictive of BMI than was dietary intake; and within dietary intake, added sugars did not predict BMI. The conclusions we reached therefore do not support the statement made in the draft DGAC report.

The Center also objects to how another one of our studies is represented in the draft report. The DGAC asked the sub-question: "Does intake of added sugars have a negative impact on achieving recommended nutrient intake?" The sentence in the draft report—"each of these papers shows a decreased intake of at least one micronutrient with higher levels of added sugar intake"—is true on its face, but it misrepresents the intent and overall conclusion of at least the study conducted by the Center. While again the Center is pleased that the DGAC cited our study (Forshee and Storey, 2001),[7] we in fact showed that added sugars intake had an inconsistent association with micronutrient intake and that the association was always small. In addition, whether the association was positive or negative, it was probably small enough to be biologically insignificant.

The DGAC also relied heavily on the Institute of Medicine of the National Academies draft report—specifically Appendix J—that examined the relationship between added sugars intake and micronutrient intake. Unfortunately, the NAS report used a ratio variable (percent energy from added sugars [$\%E_{AS}$]) that introduced a statistical and mathematical complexity that certainly affected the results of the study. In a study to be published by Forshee and Storey and that was provided to the DGAC carbohydrate subcommittee, we found that the relationship between total energy intake and

[6] Storey ML, Forshee RA, Weaver AR, Sansalone WR. Demographic and lifestyle factors associated with BMI among children and adolescents. *International Journal of Food Science and Nutrition* 2003; 54: 491-503.

[7] Forshee RA, Storey ML. The role of added sugars in the diet quality of children and adolescents. *Journal of the American College of Nutrition* 2001; 20: 32-43.

micronutrient intake is far stronger than the one between energy from added sugars and micronutrients.[8]

Does intake of added sugars contribute to excess intake of energy?
This question is irrelevant because one could just as easily ask if intake of any macronutrient contributes to excess intake of energy. Of course, the answer is yes; intake of any macronutrient, including added sugars, can contribute to excess intake of energy. In addition, the first two sentences in this section should be deleted because the statements address a different scientific question of underreporting food intake.[9]

The language in the draft report alludes to "prospective studies" that suggest a positive association between consumption of sugar-sweetened beverages and weight gain. At least one DGAC member argued that prospective studies are more important than cross-sectional studies in providing evidence regarding relationships between health behaviors and health outcomes.

The Center agrees that prospective studies allow the testing of certain hypotheses that cannot be tested in cross-sectional studies. We therefore encourage the principal investigators of existing prospective studies to make the data widely available so that the scientific and policy communities can benefit from the work of many independent research teams. In order to better understand the importance of these studies, we critically reviewed five of the prospective studies cited by the DGAC [10, 11, 12, 13, 14] and one prospective study published since the release of the draft report.[15]

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[8] Forshee RA, Storey ML. Controversy and statistical issues in the use of nutrient density in assessing diet quality. *Journal of Nutrition* 2004; *in press.*

[9] "The analysis of dietary data on added sugars may underestimate intake because of the underreporting of food intake, which is more pervasive among obese adolescents and adults than among their lean counterparts (Johnson, 2000). It appears that foods high in added sugars are selectively underreported (Krebs-Smith et al., 2000)."

[10] Ludwig DS, Peterson KE, Gortmaker SL. Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. *The Lancet* 2001; 357: 505-508.

[11] Berkey CS, Rockett HR, Field AE, Gillman MW, Colditz GA. Sugar-added beverages and adolescent weight change. *Obesity Research* 2004; 12: 778-788.

[12] Newby PK, Peterson KE, Berkey CS, Leppert J, Willett WC, Colditz GA. Beverage consumption is not associated with changes in weight and body mass index among low-income preschool children in North Dakota. *J Am Diet Assoc*. 2004; 104: 1086-94.

[13] James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing the consumption of carbonated soft drinks: cluster randomised controlled trial. *British Medical Journal* 2004; 328:1237-1242.

[14] Schulze MB, Manson JE, Ludwig DS, Colditz GA, Stampfer MJ, Willett WC, Hu FB. Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. *Journal of the American Medical Association* 2004; 292: 927-934.

[15] Field AE, Austin SB, Gillman MW, Rosner B, Rockett HR, Colditz GA. Snack food intake does not predict weight change among children and adolescents. *Int J Obes Relat Metab Disord*. 2004; 28:1210-1216.

Each of these studies was conducted with the primary purpose of linking sweetened beverages with weight gain in children, adolescents, or adults. We believe the studies, as a body of evidence, show inconsistent results. The relationship between sugar-sweetened beverages and BMI ranges from not statistically significant to a weak relationship affecting a small percentage of the population. A critique of each study is shown below.

Ludwig et al., Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. *The Lancet* 2001; 357: 505-508.

This 19-month prospective observational study examined dietary habits and weight gain among 548 11-12 year old school children living in Massachusetts. Separate multivariate regression analyses were performed to estimate BMI and the probability of a child becoming overweight as a result of consuming calorie-containing carbonated soft drinks. At the end of the study, the authors found that only 6.8% of the study population of growing children, or 37 previously normal-weight, growing children, moved to the overweight category. At the same time, 35 (6.4% of the study population) previously overweight, growing children moved to the normal-weight category. Therefore, a net of two more children out of 548 (or 0.36% of the population) were classified as overweight at the end of the study.

The regression analysis in Table 2 reports a relation of 0.24 kg/m^2 increase in BMI for a one serving per day increase in sugar-sweetened drink consumption (controlling for other covariates). According to Table 1, baseline sugar-sweetened drink consumption was 1.22 servings per day and increased by 0.22 to 1.44 servings per day at followup. Therefore, the model predicts that for the average participant sugar-sweetened drink consumption contributed to a 0.05 kg/m^2 increase in BMI over 19 months. While statistically significant, it does not appear that sugar-sweetened drinks made a large contribution to BMI for the average child in this study.

Moreover, the authors did not report the coefficients of the other independent variables in the regression analyses. This prevents readers from determining the relative strength of the evidence upon which the authors made their conclusions regarding any possible unique contribution of soft drink consumption and weight gain among growing children.

Berkey et al., Sugar-added beverages and adolescent weight gain. *Obes Res* 2004; 12: 778-788.

This prospective, observational study (U.S. Growing Up Today Study) uses a powerful dataset, and the statistical modeling is generally good. However, the interpretation of the results does not appear to reflect the findings. Many of the reported p-values for the sweetened beverage variables were greater than (not statistically significant) or barely below 0.05. This is particularly surprising for such a large sample (>10,000 after exclusion criteria).

For example, in this sample of more than 10,000 boys and girls ages 9-14 years (y), the largest increase in BMI was 0.14 kg/m^2 for boys who increased their consumption of caloric beverages by more than two servings per day. This small increase in BMI was attributed to a very large increase in calorically sweetened beverages. On average, there was an increase of 0.03 kg/m^2 per serving/day for males, which was significant at $p = 0.04$. For females, there was a non-significant increase of 0.02 kg/m^2 per serving/day ($p = 0.096$).

Sugar-added beverages were defined as soda pop, sweetened iced tea, and non-carbonated fruit drinks. For boys, the average soda pop consumption in this study ranged form 0.34 (for 9 y) to 0.77 (for 14 y); iced tea ranged from 0.69 (for 9 y) to 0.20 (for 14 y), and non-carbonated fruit drinks ranged from 0.69 (for 9 y) to 0.78 (for 14 y). An increase of two servings per day is very large relative to the average consumer; indeed it is larger than the mean servings for the highest consuming age group. Even if we reduced consumption by more than the mean of the highest consumers, we would reduce average BMI by 0.14 kg/m^2 at most.

The coefficients and p-values for milk, sweetened beverages, and fruit juices are all very similar. Furthermore, the coefficients are much smaller and not statistically significant once total energy is introduced as a control variable. This suggests, as the authors report, that energy explains the relationships observed rather than any special property of sweetened beverages. Given the small magnitude of the reported relationships and the borderline p-values, the impact of sweetened beverages on BMI appears to be small.

The authors also collected data on physical activity and sedentary behavior. Although these variables were included in the analysis, the authors did not report the results. Other research has shown that these variables have a stronger relationship with BMI than does added sugars. Since the results for physical activity and sedentary behavior were not reported, there is no context or basis for comparison in the interpretation of the reported relationship between sugar-added beverages and BMI.

Despite these weak relationships and the lack of context, the authors still call for limiting the consumption of soft drinks and claim that this approach may prevent excessive weight gain. However, their results do not support the claim that limiting consumption of soft drinks may play a meaningful role in preventing weight gain. Based on these results, it is difficult to see how discouraging sweetened drink consumption could have a meaningful impact on average adolescent BMI.

James et al., Preventing childhood obesity by reducing the consumption of carbonated soft drinks: cluster randomised controlled trial. *BMJ* 2004; 328:1237-1242.
This cluster, randomized controlled trial was designed to discourage consumption of "fizzy" drinks among 7-11 year old British school children. The so-called "Ditch the Fizz" campaign told the children that reducing calorie-containing soft drink consumption would improve well-being and dental health.

The original published version of the paper noted that consumption of carbonated drinks decreased by 0.6 glasses per day. It was amended to show that consumption decreased by 0.6 servings over three days, or 0.2 servings per day. These results indicated that few children changed their dietary habits as a result of the campaign. The results also showed that consumption of carbonated drinks with sugar was unchanged in the control group and decreased by 0.3 of a (250ml) serving over a 3-day period in the intervention group. Neither change was statistically significant, and there was no statistically significant difference between the control and intervention groups.

Furthermore, the mean change in BMI was 0.8 kg/m^2 for the control group and 0.7 kg/m^2 for the intervention group. This difference was not statistically significant.

Newby *et al*. Beverage consumption is not associated with changes in weight and body mass index among low-income preschool children in North Dakota. *J Am Diet Assoc*. 2004; 104:1086-94.
Newby *et al.* analyzed data from a prospective cohort study of 1,345 children 2-5y who were participating in the North Dakota Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Their models found no statistically significant association between beverage consumption and change in either weight or BMI. Specifically with regard to soda consumption, the estimated coefficient in the multivariate adjusted model for weight was -0.00 ± 0.04 (p=.95) and for BMI was -0.01 ± 0.02 (p=.58). Moreover, zero was in the middle of the confidence interval and the estimate was negative, not positive, which was the hypothesis being tested.

As the authors note, average consumption of soda in this study is only a little over one ounce per day, but this is very close to the national average of 1.75 oz/day for children under 5y as reported by the CSFII 1994-96, 1998 Table Set 17, Table 15A.[16] This prospective study of a group of young, low-income children consuming nearly the national average of

[16] U.S. Department of Agriculture, Agricultural Research Service. 1999. Food and Nutrient Intakes by Children 1994-96, 1998. Online. ARS Food Surveys Research Group, available on the "Products" page at <http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm> [accessed September 23, 2004].

soda showed no association between soda consumption and either weight or BMI.

Schulze et al., Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. *JAMA* 2004; 292: 927-934.

This article addresses important nutrition, public health, and public policy issues using an extraordinarily rich and important dataset. Unfortunately, some of the commentary in the study does not accurately reflect the data presented.

This prospective cohort analysis used data from the Nurses' Health Study II. This non-representative sample of women had a full sample of 116,671 women, but the authors excluded nearly half of the respondents (n=51,603). It is important to note that the average weight increased in all sugar-sweetened beverage consumption categories during the four-year periods 1991-1995 and 1995-1999. Even the category that sharply reduced consumption of sugar-sweetened beverages had an average weight gain of 1.34 kg from 1991-1995.

Percent of Population Affected by Sugar-sweetened Beverage Consumption *1991-1995*

Consumption Category	Percentage of the Population	∆kg/4years	∆lb/year
Consistent ≤1/wk	75	3.21	1.8
Consistent ≥1/day	5	3.12	1.7
≤1/wk to ≥1/day	2	4.69	2.6
≥1/day to ≤1/wk	2	1.34	0.7
Other	16	3.04	1.7

Source: Adapted from data presented in Schulze *et al.*

As shown in the table above, 75% of the participants were already in the lowest category of sweetened beverage consumption, consistently drinking one or fewer soft drinks per week (Consistent ≤1/wk). Only 2% of the participants increased sweetened beverage consumption from ≤1/wk to ≥1/day, and these participants gained about 1.5 kg more than those in the lowest consumption category. Similarly, only 2% of the participants reduced their sweetened beverage from ≥1/day to ≤1/wk, and those

participants gained 1.9 kg less than participants in the lowest consumption category.

Percent of Population Affected by Sugar-sweetened Beverage Consumption
1995-1999

Consumption Category	Percentage of the Population[1]	∆kg/4years	∆lb/year
Consistent ≤1/wk	76	2.04	1.1
Consistent ≥1/day	5	2.21	1.2
≤1/wk to ≥1/day	1.5	4.20	2.3
≥1/day to ≤1/wk	2	0.15	0.1
Other	16	2.10	1.2

Source: Adapted from data presented in Schulze *et al.*
[1] Does not sum to 100 due to rounding.

Slightly more than 96% of the women in this study had the same average weight gain between 1995 and 1999. Three out of four women in this study already consumed soft drinks once a week or less and can not be expected to reduce their consumption much further. Of the four percent of women who went from one extreme category to another (i.e., dramatically decreased or increased consumption), their weight gain changed by about one pound per year compared with the 96% of the rest of the population. This association was somewhat smaller after controlling for total energy.

If less than a two kilogram change over a four-year period for less than four percent of the population is the best single opportunity we have to curb the obesity epidemic, then we have a serious challenge ahead for all of us, including the 96 percent of the population who are low or very modest consumers of sweetened beverages.

Field et al. Snack food intake does not predict weight change among children and adolescents. *Int J Obes Relat Metab Disord*. 2004;28:1210-1216.

Using the same prospective, observational study as Berkey *et al.* (U.S. Growing Up Today Study), Field *et al.* report no association between consumption of snack foods and annual change in BMI z-score among the nearly 15,000 girls and boys who were 9-14y in 1996. The estimated coefficients were negative, small, and not significant for both boys and

girls. Adding sugar-sweetened beverages to the snack food category "did not meaningfully change the results" (p. 1214).

Body of Evidence Does Not Support a Public Health Strategy Targeting Sweetened Beverages

Overall risk from any substance depends on the level of exposure and the degree to which the substance is considered a hazard. The table below illustrates that seven studies using a variety of designs show a very slight difference in BMI that is often not significant. "Hazard" estimates in this set of data range from not significant to about 0.20 (kg/m^2)/year per serving/day. It is therefore difficult to justify public health strategies that would focus on reducing sweetened beverages as a unique risk for obesity and Type 2 diabetes.

Summary of Findings from Selected Major Papers

Study	**Magnitude** ΔBMI/year/(serving/day)	**Significance**
Forshee & Storey[17] *(cross-sectional)*	0.11 (males) 0.26 (females)	Not Significant Not Significant
Ludwig *et al.* *(prospective)*	0.15 (0.24 over 19 months)	p=0.03
Berkey *et al.* *(prospective)*	0.03 (boys) 0.02 (girls)	p=0.04 p=0.096 Not Significant
James *et al.* *(intervention)*	0.1 difference between treatment and control	Not Significant
Newby *et al.* *(prospective)*	-0.01 (children)	Not Significant
Schulze *et al.* *(prospective)*	0.20 (women) (applies to 4% of participants)	p<0.05
Field *et al.* *(prospective)*	~0 (not directly reported)	Not Significant

Source: Compiled by CFNP from data presented in published studies.

Several approaches have been developed to evaluate the overall strength of a body of scientific evidence. One recent example is the U.S. Food and Drug Administration's Interim Evidence-based Ranking System for Scientific Data[18] that is part of the Interim

[17] Forshee RA, Anderson PA, Storey ML. The role of beverage consumption, physical activity, sedentary behavior, and demographics on body mass index of adolescents. *Int J Food Sci Nutr. In press*.

[18] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. Interim Evidence-based Ranking System for Scientific Data. July 2003. <http://www.cfsan.fda.gov/~dms/hclmgui4.html> last accessed September 21, 2004.

Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.[19] The guidance describes an approach to evaluate how strongly the totality of scientific evidence supports a claim in the form of "consuming more *X* reduces the risk of *Y,*" with its counterpart claim being, "consuming less *X* reduces the risk of *Y*." Based on the type and quality of the evidence, a proposed claim will be placed in one of four categories (First-level is the existing standard of Significant Scientific Agreement):

Scientific Ranking	FDA Category	Appropriate Qualifying Language
Second Level	B	... "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."

Source: FDA Interim Procedures for Qualified Health Claims

Using this approach, we believe that the claim "Consuming less sugar-sweetened beverages may reduce body mass index" would be a Third-level or Fourth-Level claim.

There are no large clinical trials testing this claim. One small randomized control trial (James *et al.*) showed no difference in the change in BMI between treatment and control groups. The evidence from prospective observational studies is inconsistent. The Newby *et al.* and Field *et al.* studies found no relationship between sugar-sweetened beverages and BMI. The Berkey *et al.* study found only a weak relationship between sugar-sweetened beverages and BMI, and that relationship disappeared after controlling for total energy. Ludwig *et al.* found a statistically significant relationship ($p=0.03$) that predicted an increase of 0.05 kg/m^2 over 19 months for the average respondent in their study. Schulze *et al.* found statistically significant differences of about one pound/year that affected the approximately four percent of the participants who went from one extreme consumption category to the opposite extreme category. The other ninety-six percent of the participants had indistinguishable weight gains regardless of their sugar-sweetened beverage consumption. The prospective studies therefore have not confirmed a relationship between calorically sweetened beverages and BMI and cross-sectional studies generally have not found a relationship between sugar-sweetened beverage consumption and BMI either.

[19] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. July 2003. <http://www.cfsan.fda.gov/~dms/hclmgui3.html> last accessed September 21, 2004.

Broad policies promoting the reduction of caloric-sweetened beverage consumption in order to decrease overweight/obesity in the U.S. population are not supported by the existing evidence.

Summary of Comments

In summary, the Center for Food and Nutrition Policy urges the following:

1) Prioritize the executive summary of the report to reflect the order of priority of the guidelines;

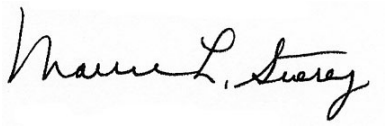
2) Delete the section on the role of the environment in implementing the guidelines as speculative and not supported by a science base;

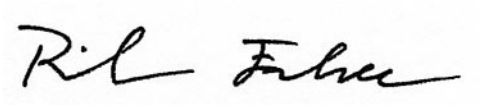
3) Re-write the sentence on dental health as shown in these comments, which reflect the priority and relative importance of the factors that contribute the most to dental caries.

4) Re-write the section on added sugars and micronutrient intake to reflect the inconsistency and size of the relationship;

5) Re-write the section on added sugars and weight gain to reflect the actual findings in the scientific literature; that is, the relationship is small, weak, or not statistically significant. Furthermore, only a small percentage of the population appears to be affected by excessive intake of added sugars and/or sweetened beverages.

Respectfully submitted,





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